



# ICHOM

International Consortium for  
Health Outcomes Measurement

## DIABETES DATA COLLECTION REFERENCE GUIDE

Version 5.0.1  
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DIABETES

Measuring  
results  
that matter





We are thrilled that you are interested in measuring outcomes for adult patients with type 1 and type 2 diabetes. It is our hope that this Reference Guide will facilitate the process of implementing this Set of Patient-Centered Outcome Measures and ensure collection of comparable data for global benchmarking and learning.

© 2023 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 Sets of Patient-Centered Outcome Measures.

# Introducing ICHOM and the Reference Guide

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

Each 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 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 these 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 [info@ichom.org](mailto:info@ichom.org)

## ICHOM Cardiometabolic Family of Sets - Updates

As ICHOM strives to keep our Sets up to date with clinical advancements, implementation requirements, and relevant to patient interests, we have begun an initiative to review and update all our Sets routinely every three years.

The Cardiometabolic Family of Sets represents the first group of Sets to be revised and updated as a group simultaneously. This marks an important milestone in ICHOM's journey to promote value-based healthcare from an evidence-based and patient-centered perspective. For this process, we have worked with a Steering Committee, a group of experts from the original Working Groups involved in the development of these Sets, implementers from around the world, and patient representatives, to make necessary changes to the Sets in order to ensure that they are clinically up to date and harmonized in line with ICHOM standards.

These changes include:

- Set specific updates (specific updates to Sets individually, based on feedback and in order to keep in line with clinical advancements)
- Cross-Set updates (updates made across all Cardiometabolic Sets, with the aim to harmonize standardized variables throughout different Sets in order to facilitate simultaneous implementation)

A full list of changes specific to the Diabetes Set can be seen in the Appendix.

## Working Group Members for Diabetes in Adults

The following individuals dedicated both time and expertise to develop the ICHOM Set for Diabetes in Adults in partnership with ICHOM, under the leadership of Fabrizio Carinci and Massimo Massi-Benedetti, ICHOM 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.

Australia	Germany	Cristina García Ulloa	Daniel Barthelmes
Tim Benson	Andreas Schmitt	Sergio Hernández	United Arab Emirates
Rob Haig		Jiménez	Jihan Dennaoui
Belize	India	Portugal	Saf Naqvi
Sharon Fraser	Anil Bhansali	João Raposo	
Cameroon	Israel	Singapore	United Kingdom
Jean Claude Mbanya	Ronit Calderon-Margalit	Hwee-Lin Wee	Katharine Barnard
Canada	Italy	Slovenia	Paul Buchanan
Maria Santana	Fabrizio Carinci	Jana Klavs	United States
Denmark	Massimo Massi-Benedetti	Jelka Zaletel	Anne Peters
Søren Eik Skovlund	Malaysia	South Africa	Mark Peyrot
	Mark Prabhaharan	Naomi Levitt	William Polonsky
	Mexico	Switzerland	Andrew Pumerantz

## Steering Committee Members who contributed to the update of the Cardiometabolic Family of Sets

The following individuals dedicated both time and expertise to update the ICHOM CardioMetabolic Family of Sets. The work was supported by ICHOM Project Managers Paula Blancarte Jaber and Spencer Connell, ICHOM Director of Outcomes Research Zofia Das-Gupta, and ICHOM Research Associate Isabel Miller.

Elena Arbelo	Tom Lumbers	Mark Peyrot	Jana Nano
Menno Huisman	Cristina García Ulloa	Magdalena Walbaum	Kevin Veen
Andreas Bollman	Andrew Pumerantz	Erik (F.A.) Klok	Cindy de Jong
Benjamin Steinberg	Sergio Hernández	Albertino Damasceno	Tim Benson
John Beltrame	Søren Skovlund	Camila de Menezes Succi	

## Supporting Organizations

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



مركز إمبريال كوليدج لندن للسكري  
IMPERIAL COLLEGE LONDON DIABETES CENTRE

A Mubadala Company



The Cardiometabolic Family Set Updates would not have been possible without the support of the following sponsor:



Thank you.

## Scope of Diabetes Set of Patient-Centered Outcome Measures

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

Conditions	Type 1 Diabetes   Type 2 Diabetes
Populations	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 Set of Patient-Centered Outcome Measures for Diabetes

## Case-Mix Variables

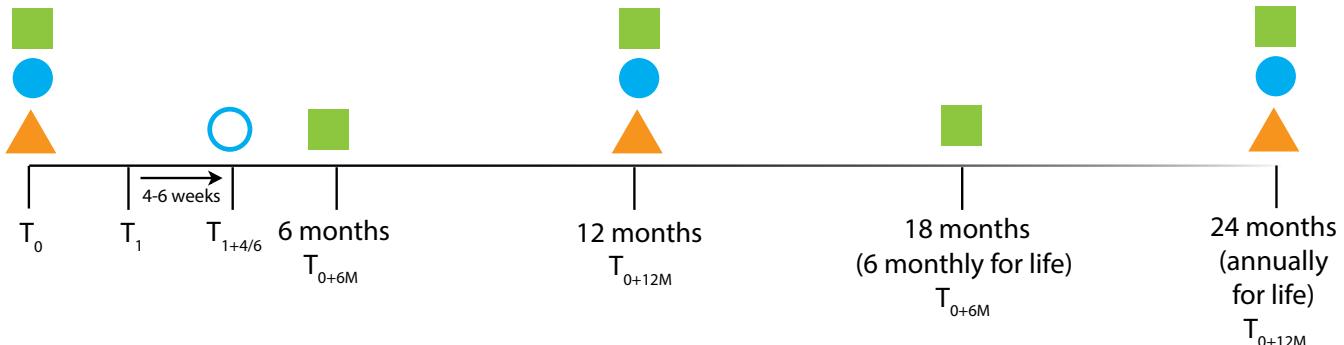
Patient Population	Measure	Timing	Reporting Source
<b>Demographic Factors</b>			
All patients	Sex		Clinical
	Year of Birth	Baseline	
	Gender		
	Ethnicity/Race		
	Education Level	Baseline and every 5 years	Patient-reported
<b>Diagnosis Profile</b>			
All patients	Diabetes Type	Baseline	
	Year of Diagnosis		Clinical
	Immunization Status		
	Comorbidities	Baseline and annually	
<b>Lifestyle and Social Factors</b>			
All patients	Smoking status		
	Alcohol Consumption	Baseline and annually	Patient-reported
	Physical Activity		
	Living Arrangements		
<b>Treatment Factors</b>			
All patients	Non-Pharmacological Treatment		
	Pharmacological Treatment		Clinical
	Cardiovascular Procedural Treatments	Baseline and annually	
	Treatment Adherence		
	Access to Healthcare		Patient-reported

## Outcomes

Patient Population	Measure	Timing	Reporting Source
<b>Diabetes Control</b>			
All patients	Glycemic Control	Baseline and every 6 months	Clinical
	Intermediate Outcomes	Baseline and annually	
<b>Acute Events</b>			
All patients	Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic Syndrome	Baseline and every 6 months	
	Hypoglycemia		Clinical
	Acute Cardiovascular Events (Stroke and Myocardial Infarction)	Baseline and annually	
	Lower Limb Amputation		
<b>Chronic Complications</b>			
All patients	Vision		
	Autonomic Neuropathy		
	Peripheral Neuropathy		
	Charcot's Foot		
	Lower Limb Ulcers		
	Peripheral Artery Disease		
	Ischemic Heart Disease		
	Chronic Heart Failure		
	Chronic Kidney Disease and Dialysis	Baseline and annually	Clinical
	Cerebrovascular Disease		
	Periodontal health		
	Sexual Dysfunction		
Persons on injectable insulin or non-insulin injectable therapies	Lipodystrophy		
<b>Health Services</b>			
All patients	Hospitalization	Annually	Clinical
	Emergency Room Utilization		
	Financial Barriers to Care	Baseline and annually	Patient-reported
<b>Survival</b>			
All patients	Vital Status	Annually	Clinical
<b>Patient-Reported Outcomes</b>			
All patients	Health-related Quality of Life		
	Psychological Wellbeing		
	Diabetes Distress	Baseline and annually	Patient-reported
	Depression		
	Obstructive Sleep Apnea		

# Follow-Up Algorithm

The following timeline illustrates when the Set variables should be collected from patients, clinicians, and administrative sources.



$T_0$  = Baseline entry into Set

$T_{0+6M}$  = 6 month review

$T_{0+12M}$  = 12 month review

$T_1$  = Initiation of a new therapy and/or significant change in treatment method.

$T_{1+4/6}$  = Review after clinical incident at 4-6 weeks

The following questionnaires should be administered at the indicated time points:

Patient-Reported Outcome Measures (PROMs) (Green Square)

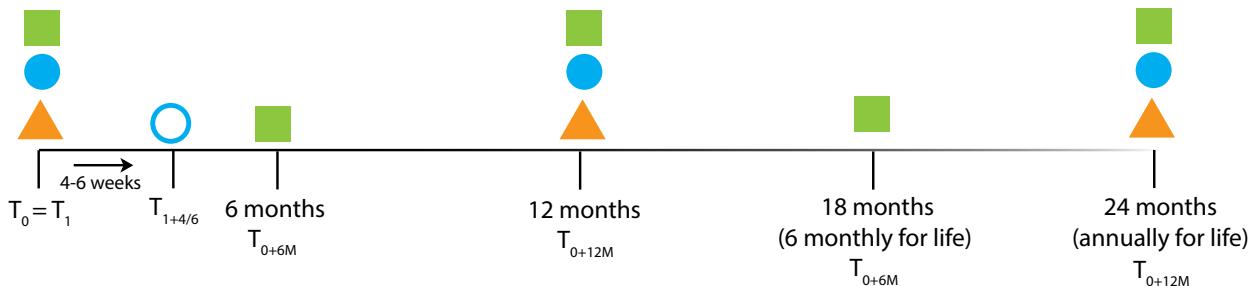
Clinical-Reported Outcome Measures (CROMS) (Blue Circle)

CROMs: Blood pressure, Blood Glucose, Medication side effects and adverse events (Orange Circle)

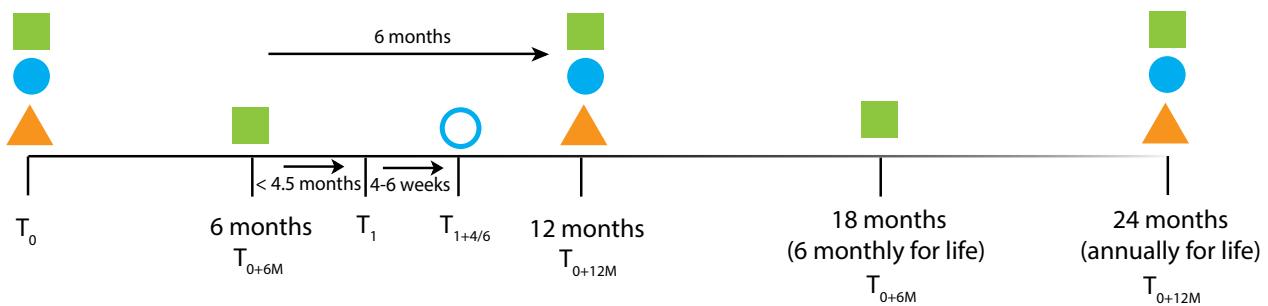
Case-Mix Variables (Orange Triangle)

The timeline is not reset in the case of hospitalization or medical emergency

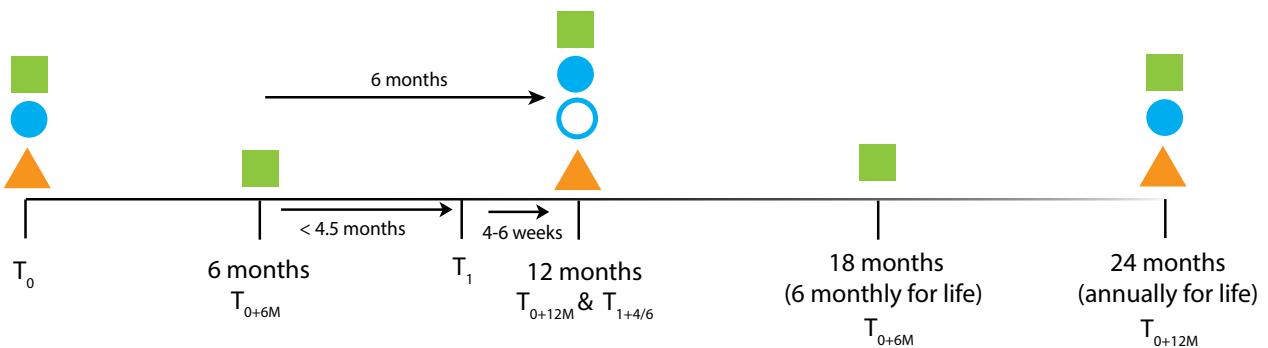
## Example 1: Newly diagnosed with initiation of new therapy



**Example 3a: Clinical incident at less than 4-5 months after routine review time-point**



**Example 3b: Clinical incident at more than 4-5 months after routine review time-point**



# Collecting Patient-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
PROMIS GH-10 v1.2	<p>Free access. PROMIS measures are copyrighted. All English and Spanish version of PROMIS are publicly available for use in one's individual research, clinical practice, educational assessment, or other application without licensing or royalty fees. Commercial users must seek permission to use, reproduce, or distribute measures. Integration into proprietary technology requires written permission. Please read the PROMIS Terms and Conditions of Use for more information. <a href="https://www.healthmeasures.net/images/PROMIS/Terms_of_Use_HM_approved_1-12-17 - Updated Copyright Notices.pdf">https://www.healthmeasures.net/images/PROMIS/Terms_of_Use_HM_approved_1-12-17 - Updated Copyright Notices.pdf</a></p>	The scoring guide for the PROMIS Global Health is available at: <a href="https://bit.ly/2Fm7Y2n">https://bit.ly/2Fm7Y2n</a>
EQ-5D-3L	<p><u>Use of the EQ-5D-3L requires a license.</u>  <u>It may be found at </u><a href="https://registration.euroqol.org/?_gl=1*1o6eln5*_up*MQ..*ga*MTUzNjk2OTE1NS4xNjcyODUzNTU0*"><u>https://registration.euroqol.org/?_gl=1*1o6eln5*_up*MQ..*ga*MTUzNjk2OTE1NS4xNjcyODUzNTU0*</u></a></p>	See link at left
WHO Disability Assessment Schedule (WHODAS v2.0)	<p><u>A license is needed to use the WHODAS 2.0 in systems for data capturing or electronic records, available at </u><a href="https://www.who.int/about/policies/publishing/permissions"><u>https://www.who.int/about/policies/publishing/permissions</u></a></p>	See link at left
VR-12	<p><u>Requires permission for use. Access can be requested at: </u><a href="https://www.bu.edu/sph/about/departments/health-law-policy-and-management/research/vr-36-vr-12-and-vr-6d/request-access/"><u>https://www.bu.edu/sph/about/departments/health-law-policy-and-management/research/vr-36-vr-12-and-vr-6d/request-access/</u></a></p>	See link at left
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>
Patient Health Questionnaire (PHQ-2)	<p>The PHQ-2 is free to use, and a license is not needed. It may be found at: <a href="https://doi.org/10.1097/01.mlr.0000093487.78664.3c">https://doi.org/10.1097/01.mlr.0000093487.78664.3c</a></p>	See link at left.

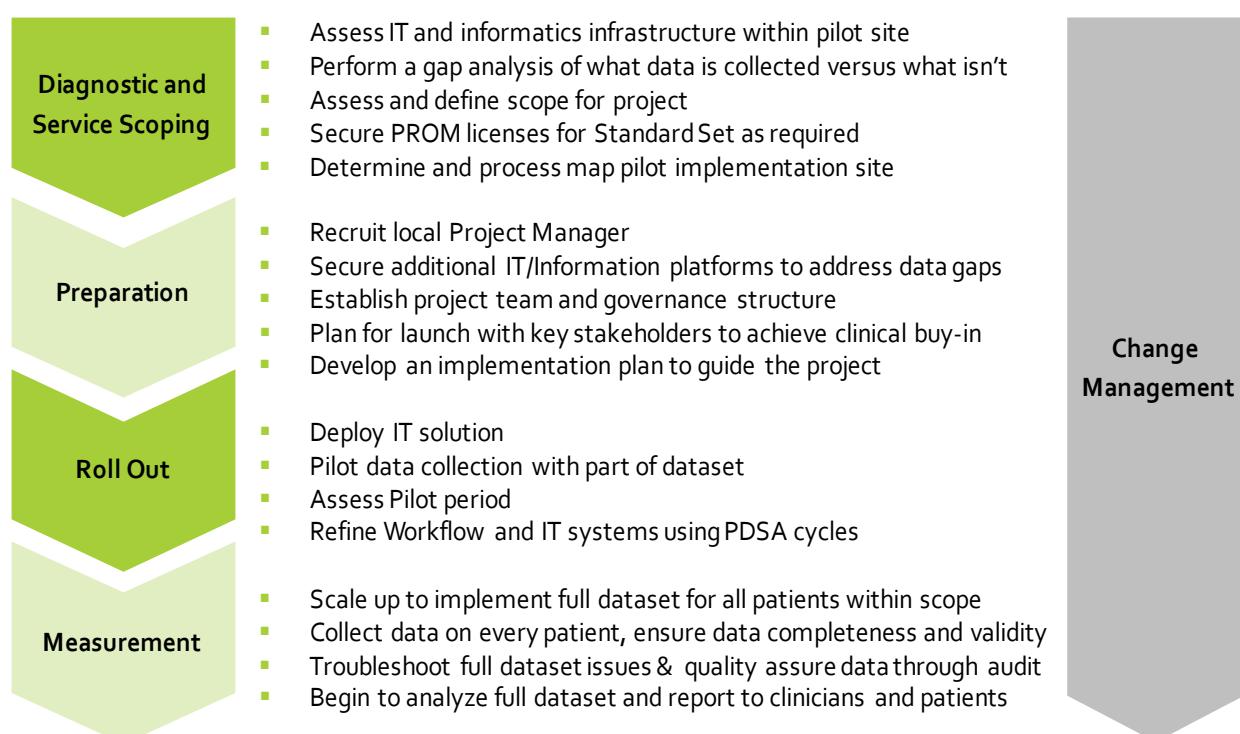
Problem Areas in Diabetes Questionnaire (PAID-5)	<p>The PAID, authored by Joslin Diabetes Center (<a href="http://www.joslin.org">http://www.joslin.org</a>), is the copyright of Joslin Diabetes Center (Copyright ©2000, Joslin Diabetes Center). The PAID, provided under license from Joslin Diabetes Center may not be copied, distributed or used in any way without the prior written consent of Joslin Diabetes Center. Please contact <a href="mailto:licenses@joslin.harvard.edu">licenses@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: <a href="mailto:licenses@joslin.harvard.edu">licenses@joslin.harvard.edu</a></p>
STOP-Bang Questionnaire (SBQ) for Sleep Apnea	<p><u><a href="#">The STOP-Bang Questionnaire (SBQ) is free to use, but you should register with the authors prior to use. Please fill out the form here: <a href="http://www.stopbang.ca/about/contactus.php">http://www.stopbang.ca/about/contactus.php</a></a></u></p>	<p>OSA - Low Risk : Yes to 0 - 2 questions  OSA - Intermediate Risk : Yes to 3 - 4 questions  OSA - High Risk : Yes to 5 - 8 questions or Yes to 2 or more of 4 STOP questions + male gender  or Yes to 2 or more of 4 STOP questions + BMI &gt; 35kg/m<sup>2</sup>  or Yes to 2 or more of 4 STOP questions + neck circumference 16 inches / 40cm</p> <p>See Link at Left for more information</p>

## The Growing ICHOM Community

There is a growing community of healthcare providers implementing the Set. 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. All materials can be downloaded for free from ICHOM Connect, for further information or to enquire about implementation support offered by ICHOM Partners, please contact us: info@ichom.org.

### **Implementation framework:**

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



### **Implementation Study:**

We are keen to find out if you have implemented or are implementing our Sets. Please fill in this survey: [bit.ly/InitialImp](http://bit.ly/InitialImp) or contact info@ichom.org for more information.

## 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, if permitted by its license, 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.



# Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Diabetes 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. **For technical use an Excel version of this data dictionary is also available for download on ICHOM Connect. Excel data dictionary is the most up-to-date version and it is the recommended document to plan data collection.**

Please timestamp all variables. Some 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

<b>Variable ID:</b>	Patient ID
<b>Variable:</b>	Indicate the patient's medical record number
<b>Definition:</b>	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
<b>Supporting Definition:</b>	
<b>Displayed Value</b>	All patients
<b>Inclusion Criteria:</b>	On all forms
<b>Timing:</b>	Administrative or clinical
<b>Reporting Source:</b>	Numerical
<b>Type:</b>	N/A
<b>Value Domain:</b>	According to institution
<b>Response Options:</b>	

## Demographic Factors

<b>Variable ID:</b>	Sex
<b>Variable:</b>	Sex
<b>Definition:</b>	The patient's sex at birth
<b>Supporting Definition:</b>	For statistical purposes, the following category codes, labels and definitions are preferred:

CODE 1 Male: Persons who have male or predominantly masculine biological characteristics, or male sex assigned at birth.

CODE 2 Female: Persons who have female or predominantly feminine biological characteristics, or female sex assigned at birth.

CODE 3 Other: Persons who have mixed or non-binary biological characteristics (if known), or a non-binary sex assigned at birth

The value meaning of 'Other' has been assigned to Code 3 for this value domain, which replaces 'Intersex or indeterminate' for the superseded value domain Sex code N. Terms such as 'indeterminate,' 'intersex', 'non-binary', and 'unspecified' are variously used to describe the 'Other' category of sex. The label 'Other' is used because a more descriptive term has not been widely agreed within the general community.

Sex refers to the chromosomal, gonadal and anatomical characteristics associated with biological sex. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.

<b>Displayed Value</b>	Please indicate your sex at birth.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer

<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Male 2 = Female 3 = Other 999 = Undisclosed
<b>Variable ID:</b>	Gender_CVD
<b>Variable:</b>	Gender identity
<b>Definition:</b>	The patient's gender identity
<b>Supporting Definition:</b>	This measure should be recorded if appropriate and legal based on local standards in the particular geographic region, and should be self-reported by the patient. This is an optional question but ICHOM encourages that this information is collected. This data will help to support combating health disparities based on gender identity but all patient data regarding gender identity will be kept confidential. The patient's response will then be coded based on LOINC's standards. All patients may choose not to answer as well.
<b>Displayed Value</b>	Do you think of yourself as ... ?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	1 = Boy/Man 2 = Girl/Woman 3 = Non-Binary 4 = Trans man/Transgender Man/FTM 5 = Trans woman/Transgender woman/MTF 6 = None of these describe me 999 = Prefer not to answer
<b>Variable ID:</b>	YearOfBirth
<b>Variable:</b>	Year of Birth
<b>Definition:</b>	Year of birth
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	In what year were you born?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	date
<b>Response Options:</b>	YYYY
<b>Variable ID:</b>	Ethnicity
<b>Variable:</b>	Ethnicity
<b>Definition:</b>	The cultural ethnicity of the person that they most closely identify with
<b>Supporting Definition:</b>	This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. This is an optional question but ICHOM encourages that this information is collected and is as racially and ethnically inclusive as possible. This data will help to support combating health disparities based on ethnicity but all patient data regarding race and ethnicity will be kept confidential. The patient's response will then be coded based on LOINC's standards. All patients may choose not to answer as well.
<b>Displayed Value</b>	Please indicate the ethnicity that you identify with
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	Please report your ethnicity based on your geographic region's local standards
<b>Variable ID:</b>	Race
<b>Variable:</b>	Race
<b>Definition:</b>	The biological race of the person
<b>Supporting Definition:</b>	This measure should be recorded based on local standards in the particular geographic region and should be self-reported by the patient. This is an optional question but ICHOM encourages that this information is collected and is as racially and ethnically inclusive as

possible. This data will help to support combating health disparities based on race but all patient data regarding race and ethnicity will be kept confidential. The patient's response will then be coded based on LOINC's standards. All patients may choose not to answer as well.

**Displayed Value** Please indicate the biological race that you identify with.

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** code

**Response Options:** Please report your race based on your geographic region's local standards.

**Variable ID:** EducationLevel

**Variable:** Level of education

**Definition:** Highest level of education completed based on local standard definitions of education levels

**Supporting Definition:** This measure may vary based on local standards for education levels so please consult the International Standard Classification to select what level most closely relates to your education experience. Please follow this link here:  
<http://uis.unesco.org/sites/default/files/documents/international-standard-classification-of-education-isced-2011-en.pdf>

**Displayed Value** Please indicate your highest level of schooling.

**Inclusion Criteria:** All patients

**Timing:** Baseline

Every 5 years

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** code

**Response Options:** 0= None

1= Primary

2= Secondary

3= Tertiary

## Diagnosis Profile

**Variable ID:** DiabetesMellitusType

**Variable:** Diabetes mellitus subtype

**Definition:** The type of diabetes mellitus, i.e. Type 1 or Type 2

**Supporting Definition:** "Unknown" indicates whether Type 1 or Type 2 diabetes is unknown and not another type of diabetes (i.e. gestational, mody, etc.)

**Displayed Value** None

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Reporting Source:** Clinical

**Type:** Single answer

**Value Domain:** code

**Response Options:** 0 = No diabetes

1 = Diabetes mellitus type 1

2 = Diabetes mellitus type 2

999 = 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.

**Displayed Value** None

**Inclusion Criteria:** All patients

**Timing:** Baseline

**Reporting Source:** Clinical

**Type:** Numerical

**Value Domain:** date

**Response Options:** Year of Diagnosis

<b>Variable ID:</b>	PROMs_Admin_Use
<b>Variable:</b>	PROMs Use
<b>Definition:</b>	Are PROMs being used in routine care?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Are PROMs being used in routine care?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1= Yes 999= Unknown
<b>Variable ID:</b>	PROMS_Admin_Mode
<b>Variable:</b>	PROMs Mode of Data Collection
<b>Definition:</b>	Please select the mode of delivery for PROMs
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please select the mode of delivery for PROMs
<b>Inclusion Criteria:</b>	if answer "o = Yes" to PROMs_Admin_Use
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	1= Telephone 2= Telephone Application (App) 3= Computer-based 4= Paper and Pencil 888 = Other

## Baseline health status

<b>Variable ID:</b>	CVComorbidities
<b>Variable:</b>	Cardiovascular Comorbidities
<b>Definition:</b>	Indicate which comorbidities the patient is living with. Select all that apply.
<b>Supporting Definition:</b>	Include ALL conditions that apply at every annual follow-up.
<b>Displayed Value</b>	Indicate which comorbidities the patient is living with. Select all that apply.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = no other diseases 1 = Heart Disease (Angina, heart attack, or HF) 2 = High Blood Pressure 3 = Atrial Fibrillation or Flutter 4 = Chronic Pulmonary Disease (Asthma, Chronic Bronchitis, COPD, Emphysema) 5 = Diabetes 6 = Peripheral Artery Disease 7 = Myocardial Infarction 8 = Obesity 9 = Stroke 10 = Ulcer or stomach disease 11 = Renal Insufficiency 12 = Liver Disease 13 = Anemia or other blood disease 14 = Cancer/Other Cancer in last 5 years 15 = AIDS/Immunodeficiency 16 = Presence/History of Depression

17 = Anxiety or Neuroses  
 18 = Presence/History of Psychotic Mental Illness (e.g., Schizophrenia)  
 19 = Substance Abuse  
 20 = Osteoarthritis, degenerative arthritis  
 21 = Rheumatoid Arthritis  
 22 = Periodontal Disease  
 888 = Other Medical Problems

<b>Variable ID:</b>	TSH
<b>Variable:</b>	Thyroid-stimulating hormone in person with type 1 diabetes
<b>Definition:</b>	Please provide the person with diabetes' most recent thyroid stimulating hormone levels from the past 12 months
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	For people with type 1 diabetes, if thyroid disease is present
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical value of TSH in mIU/L ooo if not available
<b>Variable ID:</b>	Immun_Status
<b>Variable:</b>	Immunization Status
<b>Definition:</b>	Which vaccinations, if any, has the patient received in accordance with local public health guidelines? Select All that Apply
<b>Supporting Definition:</b>	ADA 2022 recommendations: <a href="https://diabetesjournals.org/clinical/article/40/1/10/139035/Standards-of-Medical-Care-in-Diabetes-2022">https://diabetesjournals.org/clinical/article/40/1/10/139035/Standards-of-Medical-Care-in-Diabetes-2022</a>
<b>Displayed Value</b>	Which vaccinations, if any, has the patient received in accordance with local public health guidelines? Select All that Apply
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No Vaccinations (regardless of reason) 1 = COVID-19 (Initial and Booster) 2 = Annual Influenza 3 = Pneumococcal 4 = Tetanus

## Lifestyle and Social Factors

<b>Variable ID:</b>	SmokingStatus
<b>Variable:</b>	Smoking status
<b>Definition:</b>	A person's current and past smoking behavior
<b>Supporting Definition:</b>	Daily smoker: A person who smokes daily  Weekly smoker: A person who smokes at least weekly but not daily  Former smoker: A person who does not smoke at all now, but has smoked at least 100 cigarettes or a similar amount of other tobacco products in his/her lifetime  Never-smoker: A person who does not smoke now and has smoked fewer than 100 cigarettes or similar amount of other tobacco products in his/her lifetime
<b>Displayed Value</b>	Please indicate your smoking behavior. More detailed definitions are as follows:  Daily smoker: A person who smokes daily Weekly smoker: A person who smokes at least weekly but not daily Former smoker: A person who does not smoke at all now, but has smoked at least 100 cigarettes or a similar amount of other tobacco products in his/her lifetime

	Never-smoker: A person who does not smoke now and has smoked fewer than 100 cigarettes or similar amount of other tobacco products in his/her lifetime
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = Current every day smoker 1 = Current weekly smoker 2 = Former smoker 3 = Never smoker 4 = Others 999 = Unknown if ever smoked
<b>Variable ID:</b>	ALCFREQ1
<b>Variable:</b>	Alcohol Frequency
<b>Definition:</b>	How many days per week does the patient consume alcoholic drinks or beverages?
<b>Supporting Definition:</b>	Please provide an estimated average frequency over the past year.
<b>Displayed Value</b>	How many days per week do you consume alcoholic drinks or beverages? Please provide an estimated average frequency over the past year.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Every day/7 days per week 1= 5 to 6 days per week 2= 3 to 4 days per week 3= 1 to 2 days per week 4= 1 to 3 days per month 5= Never
<b>Variable ID:</b>	AlcoholPerOccasion
<b>Variable:</b>	Alcohol Amount per drinking occasion
<b>Definition:</b>	On average, how many units of alcohol does the patient consume per occasion of drinking alcoholic drinks or beverages?
<b>Supporting Definition:</b>	Average number of drinks consumed per occasion of drinking alcohol over the last year, in whole numbers. Standard drink is defined as 10 grams of pure alcohol. This corresponds to: one can or bottle of beer (375ml or 12 oz at 3.5% alcohol by volume) - A small glass of wine (100ml or 3.4 oz at 13% alcohol by volume) - A shot of whiskey or other spirit (30ml or 1.0 oz at 40% alcohol by volume)
<b>Displayed Value</b>	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. A standard drink is defined as 10 grams of pure alcohol. This corresponds to: one can or bottle of beer (375ml or 12 oz at 3.5% alcohol by volume) - A small glass of wine (100ml or 3.4 oz at 13% alcohol by volume) - A shot of whiskey or other spirit (30ml or 1.0 oz at 40% alcohol by volume)
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Average number of units consumed in whole numbers
<b>Variable ID:</b>	PHYSACT
<b>Variable:</b>	Physical Activity
<b>Definition:</b>	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.

<b>Supporting Definition:</b>	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 ( <a href="http://www.who.int/dietphysicalactivity/publications/recommendations18_64yearsold/en/">http://www.who.int/dietphysicalactivity/publications/recommendations18_64yearsold/en/</a> ).
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	PHYSFUNC
<b>Variable:</b>	Physical Functioning
<b>Definition:</b>	Disability/functional status
<b>Supporting Definition:</b>	Do you have a physical disability that is preventing you from being more active?
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "0= No" to PHYSACT
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	LivingArrangements
<b>Variable:</b>	Living arrangements
<b>Definition:</b>	The living arrangements of the person
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = Lives alone 1 = Lives with others 2 = Lives in supported home 3 = Homeless

## Treatment factors

<b>Variable ID:</b>	CVDNonPharmTx
<b>Variable:</b>	Cardiovascular Non-Pharmacological Treatment
<b>Definition:</b>	Please indicate which of the following non-pharmacological treatments the patient is receiving.
<b>Supporting Definition:</b>	Lifestyle modifications includes physical activity and other behavioural changes, e.g. smoking cessation.
<b>Displayed Value</b>	Please indicate which of the following non-pharmacological treatments the patient is receiving.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical

<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	1= Disease Education 2= Comorbidity Education 3= Vaccination Education 4= Dietary Advice 5= Lifestyle modifications
<b>Variable ID:</b>	CVDPharmaTx
<b>Variable:</b>	Cardiovascular Pharmacological Treatment
<b>Definition:</b>	Please indicate if the patient is currently receiving any pharmacological treatment?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate if the patient is currently receiving any pharmacological treatment?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1= Yes 999= Unknown
<b>Variable ID:</b>	CVDPharmaTx_Drug
<b>Variable:</b>	Cardiovascular Pharmacological Treatment Drug
<b>Definition:</b>	Please indicate which of the following pharmacological treatments the patient is receiving.
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate which of the following pharmacological treatments the patient is receiving.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	1= Insulin therapy 2= Statins (e.g. atorvastatin, rosuvastatin, etc.) 3= SGLT2 Inhibitors 4= Metformin 5= Sulfonylurea 6= GLP1 Agonists 7= Antiplatelet agents (e.g. ASA, Clopidogrel, Prasugrel, Ticagrelor, etc.) 8= Novel oral anticoagulant (NOAC) (e.g. rivaroxaban, dabigatran, etc.) 9= Isosorbide Dinitrate 10= Angiotensin Receptor Blocker/Neprilysin Inhibitor Combination 11= Beta-blockers (e.g. metoprolol, bisoprolol, propranolol, etc.) 12= Vitamin K Antagonists (e.g. warfarin) 13= Mineralocorticoid Receptor Antagonists (e.g spironolactone) 14= Angiotensin II Receptor Antagonist (e.g. losartan, irbesartan, candesartan, etc.) 15= ACE Inhibitors (e.g. enalapril, captopril, etc.) 16= Loop diuretics (e.g. furosemide) 888= Other

<b>Variable ID:</b>	CVDProcedTx
<b>Variable:</b>	Cardiovascular Procedural Treatment
<b>Definition:</b>	Please indicate if the patient has previously undergone cardiac procedure.
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate if the patient has previously undergone cardiac procedure.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0= None 1=CABG 2=Valve surgery 3=Any cardiac surgery 4=prior percutaneous coronary procedure 5=prior percutaneous valve procedure 6= Another percutaneous intervention (e.g. catheter ablation)
<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>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<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>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Integer response between 1 and 10 0 = not rated
<b>Variable ID:</b>	ADHESUGA
<b>Variable:</b>	Treatment Adherence
<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
<b>Supporting Definition:</b>	This scale was developed by the Diabetes Working Group and has not yet been validated
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients

<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Integer response between 1 and 10 0 = not rated
<b>Variable ID:</b>	ADHEMEDI
<b>Variable:</b>	Treatment Adherence
<b>Definition:</b>	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
<b>Supporting Definition:</b>	This scale was developed by the Diabetes Working Group and has not yet been validated
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Integer response between 1 and 10 0 = not rated

## 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:**  
**Displayed Value** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
 Every 6 months  
**Reporting Source:** Clinical  
**Type:** Numerical  
**Value Domain:** quantity  
**Response Options:** Numerical value of HbA1c

---

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

**Supporting Definition:**  
**Displayed Value** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
 Every 6 months  
**Reporting Source:** Clinical  
**Type:** Single answer  
**Value Domain:** code  
**Response Options:** o= mmol/mol  
 1= %

---

**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:**  
**Displayed Value** None  
**Inclusion Criteria:** Only persons with diabetes on continuous glucose monitoring  
**Timing:** Baseline  
 Every 6 months  
**Reporting Source:** Clinical  
**Type:** Numerical  
**Value Domain:** quantity  
**Response Options:** Numerical value of time in range

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**Variable ID:** SystolicBloodPressure  
**Variable:** Systolic blood pressure  
**Definition:** Systolic reading of blood pressure, as measured by the indicated device type, in mmHg

**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

**Displayed Value** None  
**Inclusion Criteria:** All patients  
**Timing:** Baseline  
 Every 6 Months  
 Annually  
 6-week Follow-up  
**Reporting Source:** Clinical  
**Type:** Numerical

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<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical systolic BP in mmHG
<b>Variable ID:</b>	DIABP
<b>Variable:</b>	Diastolic blood pressure
<b>Definition:</b>	Diastolic reading of blood pressure, as measured by the indicated device type, in mmHg
<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>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Every 6 Months Annually 6-week Follow-up
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	string
<b>Response Options:</b>	Numerical diastolic BP in mmHg
<b>Variable ID:</b>	BloodGlucose
<b>Variable:</b>	Blood Glucose
<b>Definition:</b>	Provide the patient's blood glucose value at the point of follow-up for a new intervention
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	6-week Follow-up
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	Quantity
<b>Response Options:</b>	Value of Blood Glucose
<b>Variable ID:</b>	BloodGlucose_Unit
<b>Variable:</b>	Blood Glucose Unit of Measure
<b>Definition:</b>	Please select the unit of measure for blood glucose
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	6-week Follow-up
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = mg/dL 1 = mmol/L
<b>Variable ID:</b>	MEDEFFECTS
<b>Variable:</b>	Medication side effects and adverse events
<b>Definition:</b>	Has the patient experienced any adverse events or unwanted side effects of medication?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Every 6 Months Annually 6-week Follow-up
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	MEDEFFECTSSPEC
<b>Variable:</b>	Type of medication side effects
<b>Definition:</b>	If yes, please specify by selecting all that apply
<b>Supporting Definition:</b>	Hypotension and clinical manifestations of hypotension

<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1= Yes" to MEDEFFECTS
<b>Timing:</b>	Every 6 Months Annually 6-week Follow-up
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Falls 2 = Acute kidney injury 3 = Peripheral oedema 4 = Fatigue or unusual tiredness 5 = Electrolyte abnormalities 6 = Hypokalaemia 7 = Cough 8 = Erectile dysfunction 9 = Urinary frequency 10 = Other
<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>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<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>	Please indicate unit of measure for Total Cholesterol
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= mg/dL 1= 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>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<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>	Please indicate unit of measure for LDL Cholesterol
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients

<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= mg/dL 1= 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>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<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>	Please indicate unit of measure for HDL Cholesterol
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= mg/dL 1= 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>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical value of blood triglyceride concentration
<b>Variable ID:</b>	LIPTRYUNI
<b>Variable:</b>	Units of Triglycerides
<b>Definition:</b>	Please indicate unit of measure for Triglycerides
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= mg/dL 1= mmol/L
<b>Variable ID:</b>	WeightValue
<b>Variable:</b>	Body weight
<b>Definition:</b>	The body weight of a person, measured in the indicated units

<b>Supporting Definition:</b>	The collection of anthropometric measurements, particularly in those who are overweight or obese or who are concerned about their weight, should be performed with great sensitivity and without drawing attention to an individual's weight.
<b>Displayed Value</b>	Please indicate your body weight.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical value of weight
<b>Variable ID:</b>	WeightUnit
<b>Variable:</b>	Body weight units
<b>Definition:</b>	Units of body weight
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate what units of measurement (kilograms or pounds) that you recorded your weight in.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = kilograms 2 = lbs
<b>Variable ID:</b>	HeightValue_DIA
<b>Variable:</b>	Body height
<b>Definition:</b>	The height of a person, measured in the indicated units
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate your body height.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical value of height
<b>Variable ID:</b>	HeightUnit
<b>Variable:</b>	Body height units
<b>Definition:</b>	Units of body height
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	Please indicate what units of measurement (centimeters or inches) that you recorded your height in.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = centimeters 2 = inches
<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. - 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]
<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]
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline

<b>Reporting Source:</b>	Annually
<b>Type:</b>	Clinical
<b>Value Domain:</b>	Numerical quantity
<b>Response Options:</b>	Numerical value of waist circumference in centimeters

**Acute Events**

<b>Variable ID:</b>	DKAHHS
<b>Variable:</b>	Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic Syndrome
<b>Definition:</b>	Indicate if the person with diabetes experienced Diabetic Ketoacidosis or Hyperosmolar Hyperglycemic Syndrome in the past 6 months.
<b>Supporting Definition:</b>	Diabetic ketoacidosis includes euglycemic and hyperglycemic ketoacidosis.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Every 6 months
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Yes, experienced DKA 1= Yes, experienced HHS 2= Yes, experienced both 3= No 999= Unknown
<b>Variable ID:</b>	HYPOL3
<b>Variable:</b>	Hypoglycemia - Level 3
<b>Definition:</b>	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)?
<b>Supporting Definition:</b>	Level 3 hypoglycemia is defined as a hypoglycemic event needing assistance
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Every 6 months
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= 0 1= 1 2= 2 3= more than 2 999= Unknown
<b>Variable ID:</b>	HYPOL2
<b>Variable:</b>	Hypoglycemia - Level 2
<b>Definition:</b>	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?
<b>Supporting Definition:</b>	Level 2 hypoglycemia is defined as a measurable glucose concentration <54 mg/dL (3.0 mmol/L) that needs immediate action
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Every 6 months
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numeric Response
<b>Variable ID:</b>	HYPOL2AWAR
<b>Variable:</b>	Hypoglycemia - Level 2
<b>Definition:</b>	Loss of awareness of hypoglycemia
<b>Supporting Definition:</b>	Did any of these hypoglycemic episodes occur without symptoms?

<b>Supporting Definition:</b>	Level 2 hypoglycemia is defined as a measurable glucose concentration <54 mg/dL (3.0 mmol/L) that needs immediate action
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered 1 or more to HYPOL2
<b>Timing:</b>	Baseline Every 6 months
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<hr/>	
<b>Variable ID:</b>	MyocardialInfarction
<b>Variable:</b>	Myocardial infarction
<b>Definition:</b>	Indicate whether the patient has a documented history of myocardial infarction.
<b>Supporting Definition:</b>	Item is phrased as a patient reported measure. However, if the patient is unable to answer, this information can be abstracted from the medical records.
<b>Displayed Value</b>	Have you ever been told by your doctor that you've had a heart attack or myocardial infarction?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<hr/>	
<b>Variable ID:</b>	CVTIA
<b>Variable:</b>	Cerebrovascular Disease - Acute events
<b>Definition:</b>	Has the person with diabetes ever experienced an acute cerebrovascular event? This includes stroke or transient ischemic attacks
<b>Supporting Definition:</b>	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."
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<hr/>	
<b>Variable ID:</b>	LLAMP
<b>Variable:</b>	Lower Limb Amputation
<b>Definition:</b>	Has the person with diabetes had a lower limb amputation?
<b>Supporting Definition:</b>	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?"
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown

<b>Variable ID:</b>	LLAMPLEV
<b>Variable:</b>	Lower Limb Amputation Level
<b>Definition:</b>	If yes to amputation, at what level is the amputation?
<b>Supporting Definition:</b>	If more than one procedure in the past 12 months, state the most severe level.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1= Yes" to LLAMP
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Distal to the ankle joint 1= Below knee 2= Above knee 999= Unknown

## Chronic Complications

<b>Variable ID:</b>	VISIMP
<b>Variable:</b>	Visual Outcomes - Visual Impairment
<b>Definition:</b>	Does the person with diabetes experience visual impairment?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown

<b>Variable ID:</b>	VISIMPACU
<b>Variable:</b>	Visual Outcomes - Visual Impairment
<b>Definition:</b>	Visual Acuity
<b>Supporting Definition:</b>	If yes - what is the visual acuity?
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	None
<b>Timing:</b>	If answered "1= Yes" to VISIMP
<b>Reporting Source:</b>	Baseline Annually
<b>Type:</b>	Clinical
<b>Value Domain:</b>	Numerical
<b>Response Options:</b>	Quantity

<b>Variable ID:</b>	VISIMPACUMET
<b>Variable:</b>	Visual Outcomes - Visual Impairment
<b>Definition:</b>	Visual Acuity Measurement Method
<b>Supporting Definition:</b>	Method of measurement (Snellen vs logMAR)
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	None
<b>Timing:</b>	All patients
<b>Reporting Source:</b>	Baseline Annually
<b>Type:</b>	Clinical
<b>Value Domain:</b>	Single answer
<b>Response Options:</b>	code

<b>Variable ID:</b>	VISTHREAT
<b>Variable:</b>	Visual Outcomes - Diabetes-related Sight Threatening Conditions
<b>Definition:</b>	Has the person with diabetes been diagnosed with any of the listed sight-threatening conditions? (select all that apply)
<b>Supporting Definition:</b>	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?"
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Non-proliferative diabetic retinopathy 1= Proliferative diabetic retinopathy 2= Unspecified diabetic retinopathy 3= Macular edema 4= Other 5= No sight threatening conditions 999= Unknown
<b>Variable ID:</b>	AUTNEU
<b>Variable:</b>	Autonomic Neuropathy
<b>Definition:</b>	Is there evidence of diabetic autonomic neuropathy?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	PERINEUCLI
<b>Variable:</b>	Peripheral Neuropathy - Clinician Diagnosis
<b>Definition:</b>	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.
<b>Supporting Definition:</b>	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."
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	PERINEUPAT
<b>Variable:</b>	Peripheral Neuropathy - Symptoms experienced by person with diabetes
<b>Definition:</b>	What symptoms are you experiencing due to your peripheral neuropathy (nerve damage to your lower or upper limbs)?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline

<b>Reporting Source:</b>	Annually Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Numbness 1= Pain 2= Paresthesia 3= Asymptomatic/ No symptoms 999= Unknown
<b>Variable ID:</b>	CHARCF
<b>Variable:</b>	Charcot's Foot
<b>Definition:</b>	Is there evidence of Charcot's foot?
<b>Supporting Definition:</b>	At annual follow-up, do not re-present this question if responded "yes" to "Is there evidence of Charcot's foot?"
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	LLULC
<b>Variable:</b>	Lower Limb Ulcers
<b>Definition:</b>	Active lower limb ulcer present?
<b>Supporting Definition:</b>	Did the person with diabetes have an active lower limb ulcer in the past 12 months?
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	LLULCSTAG
<b>Variable:</b>	Lower Limb Ulcers
<b>Definition:</b>	Staging
<b>Supporting Definition:</b>	If Yes, provide the most severe stage diagnosed using the University of Texas wound classification system
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1= Yes" to LLULC
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Stage A: No infection or ischemia 1= Stage B: Infection present 2= Stage C: Ischemia present 3= Stage D: Infection and ischemia present 999= Stage Unknown
<b>Variable ID:</b>	LLULCGRAD
<b>Variable:</b>	Lower Limb Ulcers
<b>Definition:</b>	Grading

<b>Definition:</b>	If Yes, provide the most severe grade diagnosed using the University of Texas Wound Classification system
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1= Yes" to LLULC
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Grade 0: Epithelialized wound 1= Grade 1: Superficial wound 2= Grade 2: Wound penetrates to tendon or capsule 3= Grade 3: Wound penetrates to bone or joint 999= Grade unknown

<b>Variable ID:</b>	PeripheralArteryDisease
<b>Variable:</b>	Peripheral artery disease
<b>Definition:</b>	Has the patient been diagnosed with peripheral artery disease?
<b>Supporting Definition:</b>	Peripheral artery disease (ICD:10 I70.2 - Atherosclerosis of arteries of extremities) diagnosed by clinician
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown

<b>Variable ID:</b>	PADPAT
<b>Variable:</b>	Peripheral artery disease - Symptoms experienced by person with diabetes
<b>Definition:</b>	Does the person with diabetes experience symptoms of peripheral artery disease?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= No 1= Yes, intermittent claudication 2= Yes, rest pain 999= Unknown

<b>Variable ID:</b>	IschemicHeartDisease
<b>Variable:</b>	Ischemic Heart Disease
<b>Definition:</b>	Indicate whether the patient has ever been diagnosed with ischemic heart disease (including myocardial infarction)
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown

<b>Variable ID:</b>	HeartFailure
<b>Variable:</b>	Heart failure
<b>Definition:</b>	Person has been clinically diagnosed with heart failure at any point in time
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	CHRSTAGE
<b>Variable:</b>	Chronic Heart Failure Staging
<b>Definition:</b>	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)
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Stage A (At high risk of HF without structural heart disease or symptoms of HF) 1= Stage B (Structural heart disease but without signs or symptoms of HF) 2= Stage C (Structural heart disease with prior or current symptoms of HF) 3= Stage D (Refractory HF requiring specialist interventions) 4= Stage unknown 999= Not assessed
<b>Variable ID:</b>	eGFR
<b>Variable:</b>	Estimated glomerular filtration rate
<b>Definition:</b>	The persons estimated glomerular filtration rate (eGFR)
<b>Supporting Definition:</b>	eGFR as measured in milliliter per minute
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	None
<b>Variable ID:</b>	RFTACR
<b>Variable:</b>	Renal Function Tests/Moderate to Severe Kidney Disease ACR
<b>Definition:</b>	What is the person with diabetes' urinary albumin/creatinine (ACR) ratio?
<b>Supporting Definition:</b>	Provide most recent reading from the past 12 months
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients

<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= ACR <30mg/g or <3mg/mmol 1= ACR 30-300mg/g or 3-30mg/mmol 2= ACR > 300 mg/g or >30mg/mmol 3= ACR unknown
<b>Variable ID:</b>	DialysisDependent
<b>Variable:</b>	Dialysis dependent
<b>Definition:</b>	Indicate whether the person is chronically dependent on dialysis
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1= Yes 999 = Unknown
<b>Variable ID:</b>	CerebrovascularDisease
<b>Variable:</b>	Cerebrovascular disease
<b>Definition:</b>	Has the patient ever been diagnosed with cerebrovascular disease?
<b>Supporting Definition:</b>	Cerebrovascular accident (ICD10: I60 - Subarachnoid haemorrhage, I61 – Intracerebral haemorrhage, I62 – other non-traumatic intracranial haemorrhage, I63 – cerebral infarction, I64 - Stroke, not specified as haemorrhage or infarction) or transient ischaemic attack (ICD10: G45 - Transient cerebral ischaemic attacks and related syndromes) diagnosed by a clinician. May include evidence from clinical examination or investigations.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	PERIODON
<b>Variable:</b>	Periodontal Health
<b>Definition:</b>	Please provide details on the periodontal health of the person with diabetes
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Healthy 1= Gingivitis 2= Periodontitis 999= Unknown
<b>Variable ID:</b>	SexualDysfunction
<b>Variable:</b>	Sexual Dysfunction
<b>Definition:</b>	In the past 12 months, did the patient experience any sexual dysfunction?
<b>Supporting Definition:</b>	Sexual Dysfunction in persons with a penis is defined as an inability to maintain an erection sufficient for satisfying sexual activity.

Sexual Dysfunction in persons with a vagina is defined as abnormal loss of libido, decreased lubrication during sex, pain during intercourse, and/or frequent vaginal and/or renal/urinary infections.

**Displayed Value:** In the past 12 months, did the patient experience any sexual dysfunction?

**Inclusion Criteria:** All patients

**Timing:** Baseline

Annually

**Reporting Source:** Clinical

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0 = No

1 = Yes

999 = 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?"

**Displayed Value:** None

**Inclusion Criteria:** Persons on injectable insulin or non-insulin injectable therapies

**Timing:** Baseline

Annually

**Reporting Source:** Clinical

**Type:** Single answer

**Value Domain:** code

**Response Options:** 0 = No

1 = Yes

999 = Unknown

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## Healthcare Services

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**Variable ID:** HOSPADMDATE

**Variable:** Hospitalization

Admission date

**Definition:** Date of admission

**Supporting Definition:** None

**Displayed Value:** None

**Inclusion Criteria:** All patients - for every hospitalization

**Timing:** Annually

**Reporting Source:** Clinical

**Type:** Date

**Value Domain:** date

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

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**Variable ID:** HOSPDISDATE

**Variable:** Hospitalization

Discharge date

**Definition:** Date of discharge

**Supporting Definition:** None

**Displayed Value:** None

**Inclusion Criteria:** All patients - for every hospitalization

**Timing:** Annually

**Reporting Source:** Clinical

**Type:** Date

**Value Domain:** date

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

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**Variable ID:** HOSPDIAIG

**Variable:** Hospitalization - Discharge diagnosis

**Definition:** What is the discharge diagnosis?

<b>Supporting Definition:</b>	- 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
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients - for every hospitalization
<b>Timing:</b>	Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Cardiovascular causes 1= Acute Kidney Injury 2= Foot- and lower limb-related complications 3= Acute metabolic complications 4= Other 999= Unknown
<b>Variable ID:</b>	ERUTIL
<b>Variable:</b>	Emergency Room Utilization
<b>Definition:</b>	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.
<b>Supporting Definition:</b>	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 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
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients - for every emergency room attendance
<b>Timing:</b>	Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Numerical
<b>Value Domain:</b>	quantity
<b>Response Options:</b>	Numerical number of emergency room attendances (000 if unknown)
<b>Variable ID:</b>	AccessToMedicines
<b>Variable:</b>	Access to medicines and supplies
<b>Definition:</b>	Does the patient experience difficulties obtaining medicine or supplies needed to manage their condition(s)?
<b>Supporting Definition:</b>	Access to drugs is the ability to access drugs as prescribed by healthcare provider
<b>Displayed Value</b>	Do you have difficulty obtaining the medicine or supplies you need?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	ACCESPROF3
<b>Variable:</b>	Access to healthcare (Access to healthcare professionals)
<b>Definition:</b>	Access to healthcare (Access to healthcare professionals)

<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	ACCESPROFREAS3
<b>Variable:</b>	Access to healthcare professionals (Reasons for lack of access)
<b>Definition:</b>	What are the reasons for this?
<b>Supporting Definition:</b>	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.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Transportation problems 1= Difficulty paying for it 2= Not available where I live 3= Other reason 4= Unknown
<b>Variable ID:</b>	ACCESMEDREAS3
<b>Variable:</b>	Access to medicines and supplies (reasons for lack of access)
<b>Definition:</b>	What are the reasons for this?
<b>Supporting Definition:</b>	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.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Transportation problems 1= Difficulty paying for it 2= Not available where I live 3= Other reason 999= Unknown

## Survival

<b>Variable ID:</b>	VitalStatus
<b>Variable:</b>	Vital Status
<b>Definition:</b>	Indicate if the person has deceased, regardless of cause
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Annually
<b>Reporting Source:</b>	Clinical

<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0 = No 1 = Yes 999 = Unknown
<b>Variable ID:</b>	DEATHCAUSE_DIAB
<b>Variable:</b>	Cause of death
<b>Definition:</b>	The cause of death of the person
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1= Yes" to VitalStatus
<b>Timing:</b>	Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Cardiovascular 1= Acute metabolic complication of diabetes related to high or low blood glucose 2= Renal 3= Other 999= Unknown
<b>Variable ID:</b>	DEATHSOURCE
<b>Variable:</b>	Death - Source of information
<b>Definition:</b>	What is the source of the information on the person with diabetes' death
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	0= Death certificate 1= Clinical records 2= Family/ Carers 3= Other

## Psychological Wellbeing

<b>Variable ID:</b>	WHO-5
<b>Variable:</b>	WHO-5 Well-Being Index
<b>Definition:</b>	Psychological Wellbeing
<b>Supporting Definition:</b>	Measured using the 5-item WHO (Five) Well-Being Index
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	As per tool developer
<b>Value Domain:</b>	N/A
<b>Response Options:</b>	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> .
<b>Variable ID:</b>	WHO-5_Qo1
<b>Variable:</b>	Question 1 of WHO-5
<b>Definition:</b>	Please indicate for each of the 5 statements which is closest to how you have been feeling over the past 2 weeks. Over the past 2 weeks: 1. I have felt cheerful and in good spirits
<b>Supporting Definition:</b>	The raw score ranging from 0 to 25 is multiplied by 4 to give the final score from 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being
<b>Displayed Value</b>	Over the past 2 weeks: 1. I have felt cheerful and in good spirits
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually

<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5= All of the time 4= Most of the time 3= More than half the time 2= Less than half the time 1= Some of the time 0= At no time
<b>Variable ID:</b>	WHO-5_Q02
<b>Variable:</b>	Question 2 of WHO-5
<b>Definition:</b>	Over the past 2 weeks: 2. I have felt calm and relaxed
<b>Supporting Definition:</b>	The raw score ranging from 0 to 25 is multiplied by 4 to give the final score from 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being
<b>Displayed Value</b>	Over the past 2 weeks: 2. I have felt calm and relaxed
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5= All of the time 4= Most of the time 3= More than half the time 2= Less than half the time 1= Some of the time 0= At no time
<b>Variable ID:</b>	WHO-5_Q03
<b>Variable:</b>	Question 3 of WHO-5
<b>Definition:</b>	Over the past 2 weeks: 3. I have felt active and vigorous
<b>Supporting Definition:</b>	The raw score ranging from 0 to 25 is multiplied by 4 to give the final score from 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being
<b>Displayed Value</b>	Over the past 2 weeks: 3. I have felt active and vigorous
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5= All of the time 4= Most of the time 3= More than half the time 2= Less than half the time 1= Some of the time 0= At no time
<b>Variable ID:</b>	WHO-5_Q04
<b>Variable:</b>	Question 4 of WHO-5
<b>Definition:</b>	Over the past 2 weeks: 4. I woke up feeling fresh and rested
<b>Supporting Definition:</b>	The raw score ranging from 0 to 25 is multiplied by 4 to give the final score from 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being
<b>Displayed Value</b>	Over the past 2 weeks: 4. I woke up feeling fresh and rested
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5= All of the time 4= Most of the time 3= More than half the time 2= Less than half the time 1= Some of the time 0= At no time
<b>Variable ID:</b>	WHO-5_Q05
<b>Variable:</b>	Question 5 of WHO-5
<b>Definition:</b>	Over the past 2 weeks: 5. my daily life has been filled with things that interest me
<b>Supporting Definition:</b>	The raw score ranging from 0 to 25 is multiplied by 4 to give the final score from 0 representing the worst imaginable well-being to 100 representing the best imaginable well-being
<b>Displayed Value</b>	Over the past 2 weeks: 5. my daily life has been filled with things that interest me
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported

<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5= All of the time 4= Most of the time 3= More than half the time 2= Less than half the time 1= Some of the time 0= At no time

## Health-related Quality of Life/Self-Reported Health Status

<b>Variable ID:</b>	HR-HSQtL
<b>Variable:</b>	Health-related Quality of Life/Self-Reported Health Status
<b>Definition:</b>	What Health-Related Quality of Life tool are you using?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	What Health-Related Quality of Life tool are you using?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Clinical
<b>Type:</b>	Multiple answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	1= EQ5D3L 2 = WHODAS V2.0-12 3 = VR-12 4 = PROMIS GH-10
<b>Variable ID:</b>	EQ5D3L
<b>Variable:</b>	EuroQoL-5D-3L (EQ-5D-3L)
<b>Definition:</b>	Please contact license holder for the questionnaire. If you wish to participate in the ICHOM benchmarking program and have secured a licence to use the tool, ICHOM will provide you with the technical specifications on how to collect the data.
<b>Supporting Definition:</b>	The Working Group recommends the EQ-5D, but understands that some organisations may prefer to use alternative tools to assess Health-Related Quality of Life. The following tools are also acceptable for use: PROMIS Global 10, VR-12 or SF-12.
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "1 = EQ5D3" to HR-HSQtL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	N/A
<b>Value Domain:</b>	N/A
<b>Response Options:</b>	None
<b>Variable ID:</b>	WHODAS_Q01
<b>Variable:</b>	Question 1 of WHODAS 2.0
<b>Definition:</b>	This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.
<b>Supporting Definition:</b>	Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please select only one response. In the past 30 days, how much difficulty did you have in:
<b>Displayed Value</b>	S1: Standing for long periods such as 30 minutes? None
<b>Inclusion Criteria:</b>	This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.
<b>Timing:</b>	Baseline Annually
<b>Variable ID:</b>	WHODAS_V01
<b>Variable:</b>	Question 1 of WHODAS 2.0
<b>Definition:</b>	This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.
<b>Supporting Definition:</b>	Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities. For each question, please select only one response. In the past 30 days, how much difficulty did you have in:
<b>Displayed Value</b>	S1: Standing for long periods such as 30 minutes? None
<b>Inclusion Criteria:</b>	This questionnaire asks about difficulties due to health conditions. Health conditions include diseases or illnesses, other health problems that may be short or long lasting, injuries, mental or emotional problems, and problems with alcohol or drugs.
<b>Timing:</b>	Baseline Annually

<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo2
<b>Variable:</b>	Question 2 of WHODAS 2.0
<b>Definition:</b>	S2: Taking care of your household responsibilities?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S2: Taking care of your household responsibilities?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo3
<b>Variable:</b>	Question 3 of WHODAS 2.0
<b>Definition:</b>	S3: Learning a new task, for example, learning how to get to a new place?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S3: Learning a new task, for example, learning how to get to a new place?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo4
<b>Variable:</b>	Question 4 of WHODAS 2.0
<b>Definition:</b>	S4: How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S4: How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo5
<b>Variable:</b>	Question 5 of WHODAS 2.0
<b>Definition:</b>	S5: How much have you been emotionally affected by your health problems?

<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S5: How much have you been emotionally affected by your health problems?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo6
<b>Variable:</b>	Question 6 of WHODAS 2.0
<b>Definition:</b>	S6: Concentrating on doing something for ten minutes?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S6: Concentrating on doing something for ten minutes?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo7
<b>Variable:</b>	Question 7 of WHODAS 2.0
<b>Definition:</b>	S7: Walking a long distance such as a kilometer [or equivalent]?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S7: Walking a long distance such as a kilometer [or equivalent]?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Qo8
<b>Variable:</b>	Question 8 of WHODAS 2.0
<b>Definition:</b>	S8: Washing your whole body?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S8: Washing your whole body?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do

<b>Variable ID:</b>	WHODAS_Q09
<b>Variable:</b>	Question 9 of WHODAS 2.0
<b>Definition:</b>	S9: Getting dressed?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S9: Getting dressed?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Q10
<b>Variable:</b>	Question 10 of WHODAS 2.0
<b>Definition:</b>	S10: Dealing with people you do not know?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S10: Dealing with people you do not know?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Q11
<b>Variable:</b>	Question 11 of WHODAS 2.0
<b>Definition:</b>	S11: Maintaining a friendship
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S11: Maintaining a friendship
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Extreme or cannot do
<b>Variable ID:</b>	WHODAS_Q12
<b>Variable:</b>	Question 12 of WHODAS 2.0
<b>Definition:</b>	S12: Your day-to-day work?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	S12: Your day-to-day work?
<b>Inclusion Criteria:</b>	If answered "2 = WHODAS V2.0-12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = None

1 = Mild  
 2 = Moderate  
 3 = Severe  
 4 = Extreme or cannot do

<b>Variable ID:</b>	GH1
<b>Variable:</b>	Question 1 of VR-12
<b>Definition:</b>	In general, would you say your health is:
<b>Supporting Definition:</b>	The Working Group recommends the EQ-5D, but understands that some organisations may prefer to use alternative tools to assess Health-Related Quality of Life. The following tools are also acceptable for use: PROMIS Global 10, VR-12 or WHODAS 2.0
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Excellent 2 = Very good 3 = Good 4 = Fair 5 = Poor
<b>Variable ID:</b>	MH3
<b>Variable:</b>	Question 6a of VR-12
<b>Definition:</b>	These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.  How much of the time during the past 4 weeks: a. Have you felt calm and peaceful?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = All of the time 2 = Most of the time 3 = A good bit of the time 4 = Some of the time 5 = A little of the time 6 = None of the time
<b>Variable ID:</b>	MH4
<b>Variable:</b>	Question 6c of VR-12
<b>Definition:</b>	c. Have you felt downhearted and blue?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = All of the time 2 = Most of the time 3 = A good bit of the time 4 = Some of the time 5 = A little of the time 6 = None of the time

<b>Variable ID:</b>	PF2
<b>Variable:</b>	Question 2a of VR-12
<b>Definition:</b>	The following items are about activities you might do during a typical day. Does our health now limit you in these activities? If so, how much? a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Yes, limited a lot 2 = Yes, limited a little 3 = No, not limited at all
<b>Variable ID:</b>	PF4
<b>Variable:</b>	Question 2b of VR-12
<b>Definition:</b>	b. Climbing several flights of stairs
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Yes, limited a lot 2 = Yes, limited a little 3 = No, not limited at all
<b>Variable ID:</b>	SF2
<b>Variable:</b>	Question 7 of VR-12
<b>Definition:</b>	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = All of the time 2 = Most of the time 3 = Some of the time 4 = A little of the time 5 = None of the time
<b>Variable ID:</b>	VR12_Qo8
<b>Variable:</b>	Question 8 of VR-12
<b>Definition:</b>	Now, we'd like to ask you some questions about how your health may have changed. Compared to one year ago, how would you rate your physical health in general now?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Much better

2 = Slightly better  
 3 = About the same  
 4 = Slightly worse  
 5 = Much worse

<b>Variable ID:</b>	VR12_Qo9
<b>Variable:</b>	Question 9 of VR-12
<b>Definition:</b>	Compared to one year ago, how would you rate your emotional health (such as feeling anxious, depressed, or irritable) in general now?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = Much better 2 = Slightly better 3 = About the same 4 = Slightly worse 5 = Much worse
<b>Variable ID:</b>	VRE2
<b>Variable:</b>	Question 4a of VR-12
<b>Definition:</b>	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? a. Accomplished less than you would like
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = No, none of the time 2 = Yes, a little of the time 3 = Yes, some of the time 4 = Yes, most of the time 5 = Yes, all of the time
<b>Variable ID:</b>	VRE3
<b>Variable:</b>	Question 4b of VR-12
<b>Definition:</b>	b. Didn't do work or other activities as carefully as usual
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = No, none of the time 2 = Yes, a little of the time 3 = Yes, some of the time 4 = Yes, most of the time 5 = Yes, all of the time
<b>Variable ID:</b>	VRP2
<b>Variable:</b>	Question 3a of VR-12
<b>Definition:</b>	During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<b>Supporting Definition:</b>	a. Accomplished less than you would like
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = No, none of the time 2 = Yes, a little of the time 3 = Yes, some of the time 4 = Yes, most of the time 5 = Yes, all of the time
<b>Variable ID:</b>	VRP3
<b>Variable:</b>	Question 3b of VR-12
<b>Definition:</b>	b. Were limited in the kind of work or other activities
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = No, none of the time 2 = Yes, a little of the time 3 = Yes, some of the time 4 = Yes, most of the time 5 = Yes, all of the time
<b>Variable ID:</b>	VT2
<b>Variable:</b>	Question 6b of VR-12
<b>Definition:</b>	b. Did you have a lot of energy?
<b>Supporting Definition:</b>	None
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	If answered "3 = VR12" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	1 = All of the time 2 = Most of the time 3 = A good bit of the time 4 = Some of the time 5 = A little of the time 6 = None of the time
<b>Variable ID:</b>	PROMIS-10_Qo1
<b>Variable:</b>	Global01
<b>Definition:</b>	Please respond to each question or statement by marking one box per row: In general, would you say your health is:
<b>Supporting Definition:</b>	The Working Group recommends the EQ-5D, but understands that some organisations may prefer to use alternative tools to assess Health-Related Quality of Life. The following tools are also acceptable for use: PROMIS Global 10, VR-12 or SF-12.
<b>Displayed Value</b>	In general, would you say your health is:
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code

<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo2
<b>Variable:</b>	Globalo2
<b>Definition:</b>	In general, would you say your quality of life is:
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In general, would you say your quality of life is:
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo3
<b>Variable:</b>	Globalo3
<b>Definition:</b>	In general, how would you rate your physical health?
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In general, how would you rate your physical health?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo4
<b>Variable:</b>	Globalo4
<b>Definition:</b>	In general, how would you rate your mental health, including your mood and your ability to think?
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In general, how would you rate your mental health, including your mood and your ability to think?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo5
<b>Variable:</b>	Globalo5
<b>Definition:</b>	In general, how would you rate your satisfaction with your social activities and relationships?
<b>Supporting Definition:</b>	none

<b>Displayed Value</b>	In general, how would you rate your satisfaction with you social activities and relationships?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo9r
<b>Variable:</b>	Globalo9r
<b>Definition:</b>	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In general, rate how well you carry out your usual social activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor
<b>Variable ID:</b>	PROMIS-10_Qo6
<b>Variable:</b>	Globalo6
<b>Definition:</b>	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Completely 4 = Mostly 3 = Moderately 2 = A little 1 = Not at all
<b>Variable ID:</b>	PROMIS-10_Q10r
<b>Variable:</b>	Global10r
<b>Definition:</b>	In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported

<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always
<b>Variable ID:</b>	PROMIS-10_Qo8r
<b>Variable:</b>	Globalo8r
<b>Definition:</b>	In the past 7 days, how would you rate your fatigue on average?
<b>Supporting Definition:</b>	none
<b>Displayed Value</b>	In the past 7 days, how would you rate your fatigue on average?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	5 = None 4 = Mild 3 = Moderate 2 = Severe 1 = Very severe
<hr/>	
<b>Diabetes Distress</b>	
<b>Variable ID:</b>	PROMIS-10_Qo7r
<b>Variable:</b>	Globalo7r
<b>Definition:</b>	In the past 7 days, how would you rate your pain on average?
<b>Supporting Definition:</b>	Indicate pain level on a scale of 0-10, where 0 = No pain, and 10 = Worst imaginable pain
<b>Displayed Value</b>	In the past 7 days, how would you rate your pain on average?
<b>Inclusion Criteria:</b>	If answered "4 = PROMIS GH-10" to HR-HSQoL
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	code
<b>Response Options:</b>	Numerical value between 0 and 10
<b>Variable ID:</b>	PAID
<b>Variable:</b>	PAID Diabetes Distress Score
<b>Definition:</b>	Diabetes Distress
<b>Supporting Definition:</b>	Measured using the 5-item abbreviated Problem Areas in Diabetes questionnaire
<b>Displayed Value</b>	None
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	As per tool developer
<b>Value Domain:</b>	N/A
<b>Response Options:</b>	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.
<b>Variable ID:</b>	PAID_Q1
<b>Variable:</b>	Problem Areas In Diabetes Scale Question 1
<b>Definition:</b>	please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data
<b>Supporting Definition:</b>	For the PAID-5, a total score of $\geq 8$ indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of

> 33 has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.

**Displayed Value:** please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data

**Inclusion Criteria:** All patients  
**Timing:** Baseline

Annually

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** Code

**Response Options:** N/A

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**Variable ID:** PAID\_Q2

**Variable:** Problem Areas In Diabetes Scale Question 2

**Definition:** please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data

**Supporting Definition:** For the PAID-5, a total score of  $\geq 8$  indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of > 33 has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.

**Displayed Value:** please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data

**Inclusion Criteria:** All patients  
**Timing:** Baseline

Annually

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** Code

**Response Options:** N/A

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**Variable ID:** PAID\_Q3

**Variable:** Problem Areas In Diabetes Scale Question 3

**Definition:** please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data

**Supporting Definition:** For the PAID-5, a total score of  $\geq 8$  indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of > 33 has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.

**Displayed Value:** please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data

**Inclusion Criteria:** All patients  
**Timing:** Baseline

Annually

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** Code

**Response Options:** N/A

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<b>Variable ID:</b>	PAID_Q4
<b>Variable:</b>	Problem Areas In Diabetes Scale Question 4
<b>Definition:</b>	please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data
<b>Supporting Definition:</b>	For the PAID-5, a total score of $\geq 8$ indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of $> 33$ has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.
<b>Displayed Value</b>	please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	N/A
<b>Variable ID:</b>	PAID_Q5
<b>Variable:</b>	Problem Areas In Diabetes Scale Question 5
<b>Definition:</b>	please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data
<b>Supporting Definition:</b>	For the PAID-5, a total score of $\geq 8$ indicates possible diabetes related emotional distress, which warrants further assessment. On the full 20-item PAID, a score of $> 33$ has been suggested as indicative of likely emotional distress and a score of 38 is indicative of possible depression and, in each case, further assessment is warranted. Further assessment is facilitated by reference to the specific items endorsed as problematic by the patient. Local service protocols can be developed whereby patients scoring above an agreed score, or those endorsing particular problems areas, should be referred to a mental health professional or specialist nurse for psychological support and treatment.
<b>Displayed Value</b>	please contact license holder for the questionnaire. ichom will provide you with the technical specifications on how to collect the data
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	N/A

## Depression

<b>Variable ID:</b>	phq2-q01_CVD
<b>Variable:</b>	question 1 of phq-2
<b>Definition:</b>	over the past 2 weeks how often have you been bothered by any of the following problems little interest or pleasure in doing things
<b>Supporting Definition:</b>	A score $>3$ should lead to administration of PHQ-9 or Diagnostic Interview
<b>Displayed Value</b>	over the past 2 weeks how often have you been bothered by any of the following problems little interest or pleasure in doing things
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = Not at all 1 = Several days

2 = More than half the days

3 = Nearly every day

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<b>Variable ID:</b>	phq2-qo2_CVD
<b>Variable:</b>	question 2 of phq-2
<b>Definition:</b>	over the past 2 weeks how often have you been bothered by any of the following problems feeling down depressed or hopeless
<b>Supporting Definition:</b>	A score >3 should lead to administration of PHQ-9 or Diagnostic Interview
<b>Displayed Value</b>	over the past 2 weeks how often have you been bothered by any of the following problems feeling down depressed or hopeless
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day

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## Obstructive Sleep Apnea

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<b>Variable ID:</b>	STOP-BANG_Qo1
<b>Variable:</b>	STOP-Bang Questionnaire - Snoring?
<b>Definition:</b>	Do you SNORE Loudly (louder than talking or loud enough to be heard through closed doors)?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	Do you SNORE Loudly (louder than talking or loud enough to be heard through closed doors)?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Qo2
<b>Variable:</b>	STOP-Bang Questionnaire - Tired?
<b>Definition:</b>	Do you often feel TIRED, fatigued, or sleepd uring daytime?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	Do you often feel TIRED, fatigued, or sleepd uring daytime?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Qo3
<b>Variable:</b>	STOP-Bang Questionnaire - Observed?
<b>Definition:</b>	Has anyone OBSERVED you stop breathing during your sleep?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	Has anyone OBSERVED you stop breathing during your sleep?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code

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<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Q04
<b>Variable:</b>	STOP-Bang Questionnaire - Pressure?
<b>Definition:</b>	Do you have or are you being treated for high blood PRESSURE?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	Do you have or are you being treated for high blood PRESSURE?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Q05
<b>Variable:</b>	STOP-Bang Questionnaire - Body Mass Index more than 35 kg/m^2?
<b>Definition:</b>	BMI more than 35 kg/m^2?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	BMI more than 35 kg/m^2?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Q06
<b>Variable:</b>	STOP-Bang Questionnaire - Age older than 50?
<b>Definition:</b>	AGE over 50 years old?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	AGE over 50 years old?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Q07
<b>Variable:</b>	STOP-Bang Questionnaire - Neck size large?
<b>Definition:</b>	NECK circumference greater than 16 inches (40cm)?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	NECK circumference greater than 16 inches (40cm)?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Reporting Source:</b>	Patient-reported
<b>Type:</b>	Single answer
<b>Value Domain:</b>	Code
<b>Response Options:</b>	0 = No 1 = Yes
<b>Variable ID:</b>	STOP-BANG_Q08
<b>Variable:</b>	STOP-Bang Questionnaire - Gender = Male?
<b>Definition:</b>	GENDER male?
<b>Supporting Definition:</b>	High Risk of OSA: Yes 5-8; Intermediate Risk of OSA: Yes 3-4; Low Risk of OSA: Yes 0-2
<b>Displayed Value</b>	GENDER male?
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline

Annually

**Reporting Source:** Patient-reported

**Type:** Single answer

**Value Domain:** Code

**Response Options:** 0 = No

1 = Yes

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# Working Group Member Conflicts of Interest

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	Title	Declarations
Fabrizio Carinci	University of Bologna, Italy	None declared
Massimo Massi-Benedetti	Hub for International Health Research, Italy	None declared
Oluwakemi Okunade	ICHOM, United States	None declared
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
Sarah Whittaker	ICHOM, United States	None declared
Andreas Schmitt	Diabetes Center Mergentheim, Germany	None declared
Andrew Pumerantz	Western Diabetes Institute, Western University of Health Sciences, United States	Temple University Kornberg School of Dentistry – Consulting Fees and Travel, Lodging, and Meals Marwar Muslim Educational & Welfare Society – Consulting Fees Hispanic Health – Consulting Fees McKinsey & Company – Speaking Fees Diabetes Cross-Disciplinary Index - Creator
Anil Bhansali	Postgraduate Institute of Medical Education and Research, India	None declared
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

Name	Title	Declarations
Cristina García Ulloa	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico	SMID- Licence
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
Jana Klavs	University Medical Centre Ljubljana, Slovenia	None declared
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
Maria Santana	O'Brien Institute for Public Health, Canada	None declared
Mark Peyrot	Loyola University Maryland, United States	Calibra – _Consulting, advisory board Johnson & Johnson – _Speaker fees Eli Lilly – _Consulting, advisory board Novo Nordisk – _Grant, consulting Valeritas – _Consulting, speaker fees
Mark Prabhaharan	Patient Representative, Malaysia	
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/Blue Circle Voices*/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

\* affiliated until August 2017

Name	Title	Declarations
Sergio Hernández Jiménez	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, 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 Mannkind- Consulting Fees Livongo- Consulting Fees Bigfoot- Consulting Fees Roche- Consulting Fees

# Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
4.0.0	Data Dictionary, Appendix	Harmonisation updates
4.0.0	Whole Document	Wording change. Replacing 'Standard Sets' to 'Sets of Patient-Centered Outcome Measures'
		Updates were made to harmonize the Diabetes Set with other ICHOM Cardiometabolic Sets. The following changes were made:  Gender_CVD, CVDNonPharmT, CVDPharmaTx, CVDPharmaTx_Drug, CVDProcedTx, CVDComorbidities, Immun_Status, HR-HSQoL, EQ5D3L, WHODAS_Q01-WHODAS_Q12, GH1, MH3, MH4, PF2, PF4, SF2, VR12_Q08, VR12_Q09, VRE2, VRE3, VRP2, VRP3, VT2, PROMIS-10_Q01-PROMIS-10_Q07r variables were added.
5.0.1	Whole Document	STOP-BANG_Q01-STOP-BANG_Q08 were added to measure obstructive sleep apnea.  All ComorbiditiesSACQ[...], COMORB_DIAB, DIATREAT, BPLTHERA, CurrentLipidLoweringTherapy  ED was replaced by SexualDysfunction, PHQ-9 was replaced by PHQ-2 to measure depression, and PAID-20 was replaced by PAID-5 to measure diabetes distress.  BloodGlucose, BloodGlucose_Unit, MEDEFFECTS, MEDEFFECTSSPEC were updated to newer versions.  The Timepoints of the Set were updated.

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