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Research: Care Delivery

A standard set of person-centred outcomes for diabetes mellitus: results of an international and unified approach

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Abstract

Aims   To select a core list of standard outcomes for diabetes to be routinely applied internationally, including patient-reported outcomes.

Methods   We conducted a structured systematic review of outcome measures, focusing on adults with either type 1 or type 2 diabetes. This process was followed by a consensus-driven modified Delphi panel, including a multidisciplinary group of academics, health professionals and people with diabetes. External feedback to validate the set of outcome measures was sought from people with diabetes and health professionals.

Results   The panel identified an essential set of clinical outcomes related to diabetes control, acute events, chronic complications, health service utilisation, and survival that can be measured using routine administrative data and/or clinical records. Three instruments were recommended for annual measurement of patient-reported outcome measures: the WHO Well-Being Index for psychological well-being; the depression module of the Patient Health Questionnaire for depression; and the Problem Areas in Diabetes scale for diabetes distress. A range of factors related to demographic, diagnostic profile, lifestyle, social support and treatment of diabetes were also identified for case-mix adjustment.

Conclusions   We recommend the standard set identified in this study for use in routine practice to monitor, benchmark and improve diabetes care. The inclusion of patient-reported outcomes enables people living with diabetes to report directly on their condition in a structured way.

Diabet. Med. 37, 2009–2018 (2020)

> **What's new?**
>
> • Standardized monitoring of diabetes care can improve quality through routine audit and benchmarking. Inconsistencies between measures adopted in different countries hamper this process and undermine international comparisons.
>
> • This study was the first multinational effort to recommend a standard list of outcomes that matter most to people with diabetes, and that can be used in routine clinical practice to monitor, benchmark and improve diabetes care.
>
> • The essential outcomes relate to diabetes control, acute events, chronic complications, health service utilisation and survival, measured using routine administrative data and/or clinical records. Three instruments were recommended for annual measurement of patient-reported outcome measures (PROMs): the WHO Well-Being Index for psychological well-being; the depression module of the Patient Health Questionnaire for depression; and the Problem Areas in Diabetes scale for diabetes distress.

Introduction

Diabetes care aims to reduce diabetic complications and improve quality of life. These goals should be continuously monitored to ensure they are effective. The current focus on clinical measurements, such as HbA_{1c}, does not always translate into better overall health [1,2]; therefore, there is a need to measure the outcomes that matter most to people with diabetes.

In this context, value-based healthcare is gaining momentum by incorporating people's needs into measures of utility gained per unit cost [3]; however, the need to measure standardized outcomes consistently over time and across clinical settings presents a challenge to large-scale application of such healthcare [4]. Countries differ in terms of medical practice, diagnostic criteria and classification systems, making indicators difficult to compare [5–7]. The same type of inconsistencies have also been reported in clinical trials [8]. Diabetes registries have been used to overcome the above problems, but their implementation has also been heterogeneous [9,10].

To facilitate the shift towards value-based healthcare, the International Consortium for Health Outcomes Measurement (ICHOM) aimed to identify measures reflecting the concerns and experiences of people with diabetes.

The primary aim of the present study was to report the standard set of outcomes that were identified as those that mattered most to people with diabetes internationally, including patient-reported outcome measures (PROMs). A secondary aim was to define how often these outcomes should be measured and which case-mix variables should be used for risk adjustment.

Methods

The study was conducted between September 2017 and August 2018 by a working group convened by the ICHOM. The working group included people with diabetes and experts from high- to low-income countries who had published relevant work in this field.

Working group

The working group included 26 clinicians, scientists, epidemiologists and people with diabetes from six continents (Table S1). All completed a conflict of interest form and code of conduct agreement.

The working group agreed to target measures for adults (aged ≥18 years) with type 1 or type 2 diabetes. Children/adolescents were excluded because of their specific needs/preferences, and people with gestational diabetes or secondary diabetes were excluded because of their specific clinical characteristics.

The standard set of outcomes was developed after seven plenary conference calls, conducted on the basis of a shared agenda and background materials distributed by the project team after structured literature reviews (Fig. 1). Several sub-meetings were also conducted with working group members to capture the perspective of people with diabetes or to seek specific advice from field experts.

Literature search

A comprehensive systematic literature search was performed, using key terms related to clinical outcomes, PROMs and case-mix variables to extract papers published between 12 July 2007 and 12 July 2017 (Table S2). Documents (*n*=3555) were selected either as a result of the search or from additional sources, e.g. guidelines and materials from diabetes registries (Tables S2 and S3). Two members of the project team (J.N. and M.W.) independently screened all articles for eligibility criteria to extract candidate items and discuss them at each conference call until consensus was reached.

Selection procedure

A modified Delphi approach was used to reach consensus on the inclusion of the proposed outcomes (Fig. S1). Briefly, working group members rated each item independently on a Likert scale of 1 to 9 (1–3 = not important; 4–6 = nice to have; 7–9 = very important). Items were included if rated 7–9 by at least 80% of the working group, or excluded if rated 1–3 by 80% or below (Fig. S1). Inconclusive items were presented for a second vote, along with the results of the first
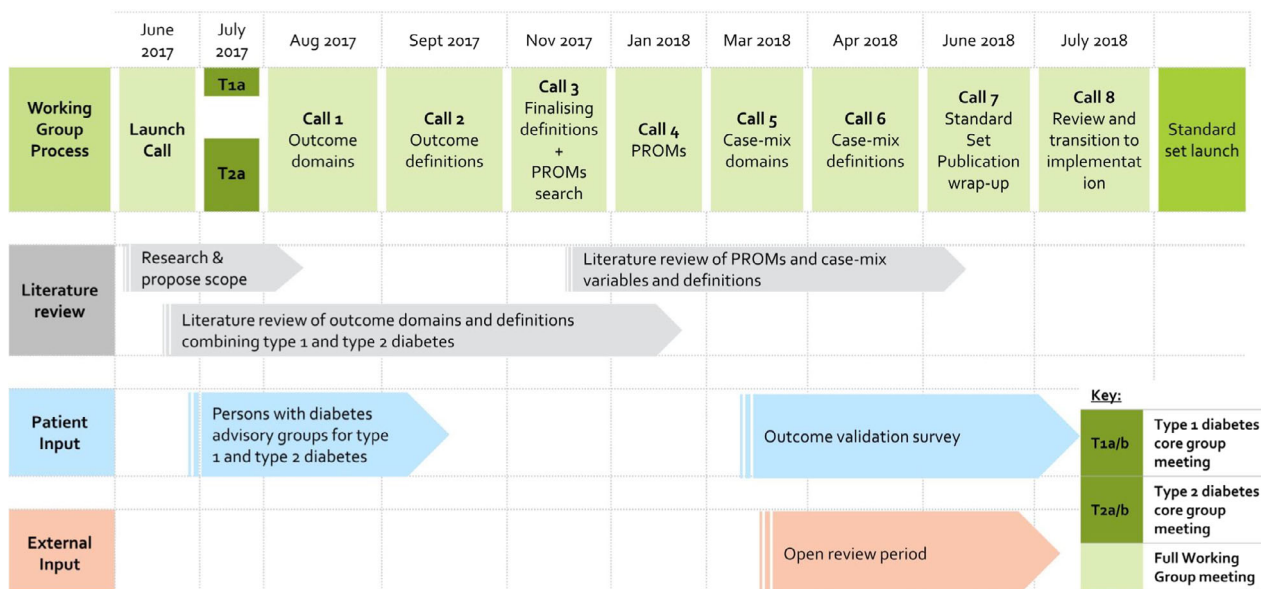
FIGURE 1 Schematic overview of the project flow. PROMs, patient-reported outcome measures.

round and additional documentation from the project team. Items unresolved after the second round were discussed jointly in an additional call, before being submitted to a final vote where inclusion/exclusion was determined by a majority rule.

The selection of outcomes was based on five criteria: 1) importance to people with diabetes; 2) clinical relevance; 3) sensitivity to changes in healthcare delivered; 4) feasibility of capturing the outcome in clinical practice; and 5) validity across cultures/internationally.

Thirty-three instruments for PROMs were selected out of the 172 initially identified, based on their ability to cover multiple dimensions. The final choice was based on descriptions of tool properties available in an external database of clinical outcome assessments (https://eprovide.mapi-trust. org/about/about-proqolid), existing reviews (Table S2) and psychometric properties referenced by the working group (Table S4).

Case-mix variables were selected according to: 1) feasibility of collection in routine clinical care; 2) validation as a case-mix variable (significantly associated with the outcomes of interest and widely used); and 3) validity across settings/regions/cultures.

The working group also agreed on time points for data collection for each of the selected items.

Feedback from external stakeholders

The ICHOM obtained ethical approval for conducting an online survey from the relevant institutional bodies in each country. The recruitment of people with diabetes was carried out via the ICHOM website and social media channels, working group members' professional networks and the

patient networks of the JDRF, USA and Imperial College London Diabetes Centre, Abu Dhabi.

The final list of outcomes was reviewed by 128 people with diabetes (type 1: $n = 28$; type 2: $n=100$) living in Mexico, United Arab Emirates, the UK and the USA, who participated in a survey collecting comments through an anonymous online tool available in English, Spanish and Arabic. Respondents were predominantly aged 18–65 years (86%), and included slightly more women (59%). Most respondents were actively treated with either insulin or non-insulin therapy (94%), whilst the remaining group were on lifestyle intervention (6%). Respondents were asked to rank selected outcomes in order of importance, based on the same 1–9 Likert scale as that used by the experts, with an option to mention additional outcomes in free text.

In addition, healthcare professionals ($n=176$) with an interest in diabetes and/or outcome measures provided feedback on the final draft of the standard set through a separate online survey.

Ethics

No study in human or animal subjects was conducted for the present paper, therefore, ethics committee approval was not required.

Results

The final standard set of 27 outcomes was approved unanimously by all members of the working group. Clinical outcome measures were categorized into the domains 'diabetes control', 'acute events', 'chronic complications', 'health services' and 'survival' (Table 1), with defined time

points for data collection (Fig. 2). For detailed results, see Tables S5–S8.

Diabetes control

For disease management, the working group recommended including blood pressure, lipid profile, BMI and HbA_{1c}, without specifying target values. For HbA_{1c}, the working group extensively debated the timing of data collection: every 6 months was deemed appropriate for benchmarking. For those on continuous glucose monitoring, the working group considered including the percentage of time in range as an informative measure [11].

Acute events

The working group recommended for their clinical relevance the frequency of episodes of Diabetic Ketoacidosis, Hyperosmolar Hyperglycaemic Syndrome, and Hypoglycaemia recorded by any source. The working group adopted level 2 and level 3 definitions of hypoglycaemia, consistent with a recent publication of core outcomes in type 1 diabetes [11].

Chronic complications

The working group included conditions related to long-term micro-/macrovascular complications. Autonomic neuropathy was included for its association with sudden cardiovascular death [12]. Peripheral neuropathy and peripheral artery disease were both included and assessed using clinical indicators and patient-reported symptoms. Peripheral artery disease was defined as an ankle-brachial pressure index < 0.8 (if ankle-brachial pressure index is unavailable, the working group recommended using the absence of pedal pulses) [13].

The working group also included ischaemic heart disease and heart failure, according to the guidelines from the American College of Cardiology and the American Heart Association (ACC/AHA). The ACC/AHA guidelines consider all people with diabetes to have at least stage A disease, encouraging early intervention to prevent progression to structural heart disease with symptoms [14].

For visual complications, the working group recommended the adoption of two thresholds for visual acuity: (1) <20/40 for visual impairment, corresponding to a loss of sight that hampers social participation, e.g. the right to drive; and (2) <20/200 for severe visual impairment used by the WHO, also an established criterion for legal blindness in many countries.

In addition, the working group recommended measuring diabetic retinopathy, by class of severity, and macular oedema. Other diabetes-related ocular pathologies, such as cataract and glaucoma, were excluded because of their high prevalence in the general population and scarce evidence to suggest that tighter diabetes control might alter their natural course.

The working group also recognized the relevance of periodontal health with its documented association with glycaemic control in people with diabetes [15]. As a standard classification is still lacking for this often neglected complication, the working group suggested marking the presence of 'healthy gums', 'gingivitis' or 'periodontitis' at visits.

The working group also recommended reporting data on erectile dysfunction. Concerning sexual dysfunction in women, the working group acknowledged its presence but could not identify a specific indicator for the standard set.

Lipodystrophy at injection sites was also included in the outcomes set, given that it could affect the absorption of subcutaneous therapy.

Health services

Three measures of health service utilisation were selected: the number of hospitalizations per year; the number of emergency department attendances per year; and discharge diagnoses in major diabetes-related categories (cardiovascular, acute kidney injury, foot and lower limb-related complications, acute metabolic diagnoses, and other/unknown diagnoses) [16,17].

The working group also recommended: (1) collecting the perceived financial barriers to care because of their impact on determining a person's ability to access care, especially in countries without universal healthcare coverage; and (2) assessing financial barriers using simple questions regarding difficulties paying for healthcare.

Survival

The working group recommended using diabetes-related deaths for the survival outcome. Being aware of the limitations of data quality, particularly on death certificates, the working group highlighted the need to record the cause of death in order to attribute diabetes as a primary cause more reliably.

Patient-reported outcome measures

The working group identified a set of key domains to be captured using PROMs and that were important to people with diabetes and those involved in clinical diabetes care. These included self-reported health, mental health, impact of diabetes on multiple aspects of quality of life, including diabetes-related emotional distress, symptoms, treatment burden and impact of hypoglycaemia. The group extensively discussed and decided to prioritize the assessment of well-being, depression and diabetes-related emotional distress. Starting with 33 tools initially identified by the literature search, the working group conducted an in-depth evaluation, followed by a discussion on a core selection of eight generic and eight diabetes-specific tools in order to identify tools that would provide the best possible domain

Table 1 Summary of the standard set of outcomes for diabetes

Measure	Supporting information	Timing of assessment	Data source
Diabetes control			
Glycaemic control	HbA$_{1c}$ and time in range. Time in range is only measured for people with diabetes who already have access to continuous glucose monitoring as part of their care	Baseline and 6-monthly	Clinician/healthcare provider
Intermediate outcomes	Includes disease management goals, such as blood pressure, lipid profile and BMI	Annually	Clinician/healthcare provider
Acute events			
Diabetic ketoacidosis and hyperosmolar hyperglycemic syndrome	Diabetic ketoacidosis includes euglycaemic and hyperglycaemic ketoacidosis	Baseline and 6-monthly	Clinician/healthcare provider
Hypoglycaemia	Level 2 hypoglycaemia is defined as a measurable glucose concentration <54 mg/dl (3.0 mmol/l) that needs immediate action. Level 3 hypoglycaemia is defined as a hypoglycaemic event needing assistance	Baseline and 6-monthly	Clinician/healthcare provider or person with diabetes
Acute cardiovascular events (stroke and myocardial infarction)	Presence of conditions	Baseline and annually	Clinician/healthcare provider or person with diabetes
Lower limb amputation	If more than one procedure in the past 12 months, state the most severe level	Baseline and annually	Clinician/healthcare provider or person with diabetes
Chronic complications			
Autonomic neuropathy	Presence of condition	Baseline and annually	Clinician/healthcare provider
Peripheral neuropathy	Presence of condition	Baseline and annually	Clinician/healthcare provider
Charcot's foot	Presence of condition	Baseline and annually	Clinician/healthcare provider
Lower limb ulcers	Presence of active lower limb ulcers; staging and grading using the University of Texas wound classification system	Baseline and annually	Clinician/healthcare provider
Peripheral artery disease	Evaluation of symptoms and clinical evidence based on ankle-brachial-pressure-index < 0.8 or absence of pedal pulses	Baseline and annually	Clinician/healthcare provider
Ischaemic heart disease	Presence of condition	Baseline and annually	Clinician/healthcare provider or person with diabetes
Chronic heart failure	Stage of the condition according to the American College of Cardiology/American Heart Association criteria	Baseline and annually	Clinician/healthcare provider
Chronic kidney disease and dialysis	Readings of estimated glomerular filtration rate and urinary albumin/creatinine	Baseline and annually	Clinician/healthcare provider
Cerebrovascular disease	Presence of condition	Baseline and annually	Clinician/healthcare provider
Vision	Measurement of visual impairment (acuity) and other diabetes-related sight-threatening conditions	Baseline and annually	Clinician/healthcare provider or person with diabetes
Periodontal health	If not healthy, specify whether gingivitis, periodontitis or unknown	Baseline and annually	Clinician/healthcare provider
Erectile dysfunction	Only in men with diabetes	Baseline and annually	Clinician/healthcare provider or person with diabetes
Lipodystrophy	Only in people on injectable insulin or non-insulin injectable therapies	Baseline and annually	Clinician/healthcare provider
Health services			
Hospitalization	Admission and discharge date; discharge diagnosis	Annually	Clinician/healthcare provider
Emergency department attendance	Number of emergency department attendances in the past year	Annually	Clinician/healthcare provider
Financial barriers to care	Perceived financial barrier to care	Annually	Clinician/healthcare provider
Survival			
Vital status	If not alive, report cause of death and source of this information	Annually	Clinician/healthcare provider
Patient-reported outcome measures			
Psychological well-being	Captured using WHO-5	Baseline and annually	Person with diabetes
Diabetes distress	Captured using PAID	Baseline and annually	Person with diabetes
Depression	Captured using PHQ-9	Baseline and annually	Person with diabetes

PAID, Problem Areas in Diabetes; PHQ-9, Patient Health Questionnaire; WHO-5, WHO Well-Being Index.
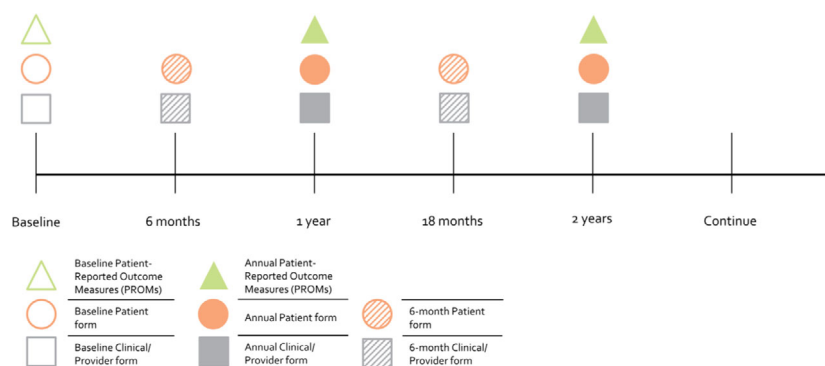A detailed definition of each outcome is provided in the online reference guide (available free at https://www.ichom.org/medical-conditions/diabetes/).

FIGURE 2 Follow-up timeline of data collection for the diabetes standard set of outcomes.

coverage, while fulfilling the requirements for brevity, acceptability, validation and global availability (Tables S9 and S10).

At the end of this process, the working group selected two generic and one diabetes-specific tool: the five-item WHO Well-Being Index (WHO-5), the Patient Health Questionnaire-9 (PHQ-9) to measure depression, and the Problem Areas in Diabetes (PAID) scale. Many pragmatic reasons drove this selection, in particular, the instruments had to be free for use in clinical practice and easily scored, preferably by hand. Other factors that were considered were the number of available translations, good psychometric properties and the domain coverage of the PROM. The PAID scale was selected because of its broad coverage of the diabetes-specific domains considered relevant by the working group, despite not ranking highest in terms of psychometric properties. A brief instrument such as PAID-5 was considered, but it offered a general level of diabetes-related distress measure, without providing detailed insights. The PAID scale has been validated in research and clinical settings and is available in 17 languages. The instrument is a diabetes-specific tool composed of 20 items measuring diabetes-related emotional distress and a broad set of problem areas often reported by people with type 1 or type 2 diabetes. Scales such as the T1-Diabetes Distress Scale or others were also discussed but were considered inferior to the PAID scale as it represents a comprehensive measure for both types of diabetes [18,19].

The WHO-5 tool assesses subjective mental well-being and has been validated in both the general population and among people with diabetes, with 31 translations available [20].

The working group adopted the PHQ-9 to measure depression, as suggested from previous similar work [21]. The PHQ-9 scores each of the nine symptoms of major depression according to the *Diagnostic and Statistical Manual of Mental Disorders* to assess the severity of depressive symptoms and response to treatment. The questionnaire has been validated and made available in 79 translations [22]. While the WHO-5 has the advantage of being positively worded (which may help in reducing response bias), it does not map directly to the criteria for a diagnosis of depression as the PHQ-9, which is essential for persuading healthcare providers to take action and initiate treatment for depression. However, a consensus was reached to maintain both questionnaires because of the significance of both in assessing positive mental well-being as an indicator of quality of life and depression symptoms in accordance with diagnostic criteria [23].

In addition to the recommended PROMs, healthcare providers may find it useful to adopt additional instruments depending on their needs, considering the agreed key domains.

Case-mix variables for risk adjustment

To enable fair comparisons across practices and/or geographical jurisdictions, 16 variables were included for case-mix adjustment (Table 2). Several aspects were emphasized during conference calls.

Regarding ethnicity, given the lack of standardized classifications, the working group recommended criteria endorsed by the International Diabetes Federation [24]. Level of education was included as a surrogate for socio-economic status. The working group decided to assess social support by asking whom the person with diabetes lives with. With the increasing role of social media as a source of support, the working group might consider including this in future iterations as well. For taking treatment, given the drawbacks associated with existing questionnaires (expense and time burden, and reliability/validity issues), the working group selected key questions regarding advice from the healthcare provider on diet, exercise, blood sugar monitoring, prescribed medication and/or insulin use. Similarly, for access to healthcare, questions were limited to 'difficulties' seeing a healthcare provider or obtaining medication.

Feedback from external parties

In general, the online survey on the final list of outcomes showed that people with diabetes ranked all included

Table 2 Summary of case-mix variables for the standard set of diabetes outcomes

Outcome domain/ measure	Supporting information	Timing of assessment	Data source
Demographic factors			
Sex	Sex at birth	Baseline	Clinician/healthcare provider
Year of birth	Calculate age	Baseline	Clinician/healthcare provider
Ethnicity	This definition was based on categories in the International Diabetes Federation consensus Worldwide Definition of the Metabolic Syndrome	Baseline	Person with diabetes
Education level	Education level is based on the International Standard Classification of Education	Baseline and every 5 years	Person with diabetes
Diagnosis pProfile			
Diabetes type	This set was developed with a focus on type 1 and type 2 diabetes. This will allow the two groups to be analysed separately	Baseline	Clinician/healthcare provider
Year of diagnosis	The estimated year of diagnosis based on people with diabetes' estimate or clinical records	Baseline	Clinician/healthcare provider or person with diabetes
Comorbidities	The reference guide contains a list of conditions	Baseline and annually	Clinician/healthcare provider
Lifestyle and social factors			
Smoking	Current status	Baseline and annually	Person with diabetes
Alcohol Consumption	Amount and frequency	Baseline and annually	Person with diabetes
Physical Activity	Being active is defined in accordance with the WHO guidelines	Baseline and annually	Person with diabetes
Social Support	Whom the person with diabetes lives with	Baseline and annually	Person with diabetes
Treatment factor			
Diabetes treatment	Pharmacological or non-pharmacological therapy	Baseline and annually	Clinician/healthcare provider
Blood pressure-lowering therapy	Report on treatment	Baseline and annually	Clinician/healthcare provider
Statins/lipid-lowering therapy	Report on treatment	Baseline and annually	Clinician/healthcare provider
Taking treatment	Not validated: use with caution. The questions on this domain rate how well the individual sticks to advice on diet, exercise, blood sugar monitoring and prescribed medication.	Baseline and annually	Person with diabetes
Access to healthcare	Assesses the level of difficulty (and reasons) in accessing healthcare professionals or obtaining medicines or other medical supplies	Baseline and annually	Person with diabetes

A detailed definition of each case-mix variable is provided in the online reference guide (available free at https://www.ichom.org/medical-conditions/diabetes/).

outcomes very highly. Interestingly, psychosocial outcomes were ranked lower than visual and kidney complications, circulation and lower limb amputations (Fig. S2, Table S8). As this finding is not supported by the literature, various sources of bias related to the composition of respondents, e.g. selection bias, sample size or the effect of social desirability might have influenced the result. Free-text responses showed that access to treatment or equipment were also considered important.

The online survey of health professionals and care providers confirmed decisions of the working group on the majority of outcomes. Concerns were expressed regarding the feasibility and reliability of the following items: time in range, hypoglycaemia level 3 and PROMs, reported via questionnaires such as WHO-5 and PAID.

Discussion

In the present paper, we present the results of an ICHOM-led initiative to deploy a standard set of outcomes, identified in a scientific and collegial manner, as a means to monitor quality of diabetes care routinely. To the best of our knowledge, this is the first coordinated, multinational effort that achieves the goal of standardizing the outcomes that most matter to patients.

Previous efforts, such as the WHO International Classification of Functioning, Disability and Health, focused primarily on clinical considerations and were not necessarily aligned with the views and primary concerns of people with diabetes [25]. Other sets of outcomes proposed in clinical practice were shown to be highly heterogeneous [26].

These results can facilitate the implementation of value-based healthcare, as the set can be applied across practices and jurisdictions such as local healthcare authorities, provinces, regions and entire countries. This could be relevant for international comparisons, as the same indicators can now be applied consistently across federated networks sharing a common infrastructure [9].

A fundamental output of this work includes the selection of clinical outcomes that are still rarely reported in audits and performance reports, such as hypo-/hyperglycaemic events, periodontal health and erectile dysfunction.

As far as PROMs are concerned, we identified mental well-being, diabetes distress and depression as the key domains that should be monitored on a regular basis. The reliability and interpretation of these measures, particularly for psychosocial factors, is still largely debated [27]. Reportedly, only 10% of diabetes clinical trials used PROMs to take preferences and values of people with diabetes into account. The inclusion of selected PROMs in our standard set aligns with recent recommendations for patient-centred management of hyperglycaemia [28] and clinical diabetes management [29]. The selected WHO-5, PHQ-9 and PAID are well-established instruments with only a few items.

For case-mix, the working group identified demographic and clinical characteristics to be used for risk adjustment, so that fair comparisons can be correctly carried out *ex post*.

The specification of time intervals at which data items should be collected is considered key to ensuring the actionability of the standard set. For data collection, the working group indicated the intervals should be: time zero (baseline); 6 months (outcomes related to diabetes control); and annually (with all other variables, with the exception of general education status, to be measured every 5 years).

The implementation of the standard set may be challenging, but the implementing teams can learn from the many success stories of routine data collection in diabetes around the world [30].

The content of the standard set of outcomes may not completely overlap with data elements available in existing data sources; however, in many cases, they can be either adapted or mapped directly to the existing databases. The experience of the specialized international EUBIROD network shows the shared development of analytical platforms can speed up harmonization through collaboration and mutual learning [31,32].

In more complex situations, data collection systems may need to be substantially upgraded or built from scratch with dedicated investment. In these cases, the active participation of local stakeholders will be key to overcoming many existing barriers.

Several registries have already reported the routine use of PROMs [33], while others are still in their experimental phase. The most advanced permanent data collection is currently run in Sweden, where the majority of data elements included in the set can be derived through linkage across quality registries yy[34,35].

The most advanced experiences of data collection in diabetes show that systematic data collection of multidimensional items requires specific policies and clear governance mechanisms. Introducing the standard set of outcomes in everyday practice, be it a single provider or a regional area, may have significant costs in terms of human resources, which may not be easy to cover. Moreover, countries have different cultures and very diverse information systems, so the application of best practice, for example, linked electronic health records, may not always be reproducible.

Further research is needed, to make sure that implementation is matched by better evidence on the use of all data elements in everyday practice, particularly for PROMs.

We need to know more about their properties in terms of patient acceptability, feasibility across different patient subgroups and the ethical implications of administering questionnaires that can inadvertently cause undesired consequences when exploring scales included in the standard set, for example, depression.

As language and framing of diabetes at clinical care encounters are of substantial importance to people with diabetes and their caregivers, we need to understand better how outcome measures have an impact on their life at different stages of the disease. This will require involving people with diabetes directly in the evaluation of PROMs, particularly as they will be requested to consent on data collection on a routine basis.

To help with implementation, ICHOM has provided a summary reference guide for general use, including details of all items in the data dictionary and recommended timelines for data collection (http://www.ichom.org/medical-conditions/diabetes/).

For next steps, ICHOM plans to establish a Steering Committee including selected working group members to progress the following phases: (1) preparation: engaging clinical leaders and people with diabetes to create multidisciplinary teams governing the process; (2) diagnosis: examining data flows and identifying gaps that must be resolved to strengthen the information infrastructure; (3) roll-out, to pilot data collection; and (4) measurement, to apply the standard set, perform statistical analyses and gather feedback. As the standard set will provide a broader basis for permanent data collection, long-term implementation must be the goal, including the need for regular updates and continuous improvement to the set.

Finally, some limitations of the present study are worth outlining. Firstly, the production of the standard set of outcomes was based on the professional opinion of a limited group of experts. Nonetheless, many of the experts work directly (e.g. provide care) or indirectly (e.g. conduct qualitative interviews) with people with diabetes so their views are informed. Further, the working group included the most relevant types of stakeholders, including people with diabetes.

Secondly, feedback received from people with diabetes came from a small sample originating from four high-income/upper-middle-income countries. In lower-income countries, managing diabetes is more complex, with scarce resources and varying degrees of literacy, which might call into question the applicability of the recommended measures. Nevertheless, the relevance of included domains for lower-income countries was also taken into account in the selection process.

Thirdly, the working group acknowledged that challenges in the management of type 1 diabetes differ significantly from those of type 2 diabetes. As such, there might well be differences in the relative importance of selected outcomes and PROMs. The final selection leaves room for type-specific

measures that stakeholders may wish to consider, whenever appropriate. The fact that both types of diabetes are lifetime conditions with a multitude of possible and variable combinations of different comorbidities, other therapies and socioeconomic contexts may also hamper an objective comparison of the results obtained by applying this set.

Finally, the choice of specific PROMs was made on pragmatic grounds, including their accessibility and acceptability in different settings. We cannot ensure that the standard set can be uniformly applied across providers and systems under different arrangements, e.g. insurance- vs national-driven health systems. Future work is needed to clarify the details of implementation under different conditions.

In conclusion, the ICHOM diabetes working group delivered a core set of patient-centred outcomes perceived to be most important for individuals with diabetes. The standard set is recommended for use in clinical practice. Its wide adoption can help improve monitoring and benchmarking of quality and outcomes in diabetes across clinical settings and jurisdictions. Further studies are needed to evaluate the results of its implementation formally and to update the dictionary with feedback from a broader audience.

Competing interests

Declarations on the conflict of interest of all working group members can be found at https://ichom.org/files/medical-cond itions/diabetes-in-adults/dia-reference-guide.pdf (page 36).

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Delphi method on decision process for the outcome and case-mix variable selection.

Figure S2. Outcome validation survey results from the people with diabetes.

Table S1. Diabetes Standard Set Working Group Members.

Table S2. Literature search strategy.

Table S3. Additional search for outcomes in diabetes registries worldwide.

Table S4. Selection criteria applied to the evaluation of PROMs.

Table S5. Voting results of 2-round Delphi method by working group on outcomes.

Table S6. Voting results of 2-round Delphi method by working group on case-mix variables.

Table S7. Voting results of outcomes measured by PROMs.

Table S8. Results of online review survey among 128 people with diabetes on the proposed outcomes.

Table S9. Psychometric properties for general PROMs included.

Table S10. Psychometric properties for diabetes specific PROMs included.