Received: 29 March 2023 | Accepted: 6 November 2023

DOI: 10.1111/dme.15259

DIABETIC Medicine

RESEARCH: EDUCATIONAL AND PSYCHOLOGICAL ASPECTS

Standardising personalised diabetes care across European health settings: A person-centred outcome set agreed in a multinational Delphi study

Ann-Kristin Porth[1] | Anouk Sjoukje Huberts[2] | Alizé Rogge[3] | Angèle Helene Marie Bénard[4] | Angus Forbes[5] | Anja Strootker[6] | Carmen Hurtado Del Pozo[7] | Dagmar Kownatka[8] | David Hopkins[9,10] | David Nathanson[11] | Henk-Jan Aanstoot[12] | Jeanette Soderberg[7] | Katarina Eeg-Olofsson[13,14] | Kathryn Hamilton[5] | Laure Delbecque[15] | Lyudmil Ninov[16] | Mette Due-Christensen[5] | Michael Leutner[1] | Rafael Simó[4,17,18,19] | Sara Vikstrom-Greve[11] | Sophia Rössner[11] | Vanesa Flores[4,18] | Yuki Seidler[20] | Yvonne Hasler[6] | Tanja Stamm[20,21] | Alexandra Kautzky-Willer[1]

Correspondence
Tanja Stamm, Section for Outcomes Research, Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna, Vienna, Austria.
Email: tanja.stamm@meduniwien.ac.at

Funding information
European Federation of Pharmaceutical Industries and Associations; Innovative Medicines Initiative; Juvenile Diabetes Research Foundation United States of America; Trial Nation

Abstract

Objective: Standardised person-reported outcomes (PRO) data can contextualise clinical outcomes enabling precision diabetes monitoring and care. Comprehensive outcome sets can guide this process, but their implementation in routine diabetes care has remained challenging and unsuccessful at international level. We aimed to address this by developing a person-centred outcome set for Type 1 and Type 2 diabetes, using a methodology with prospects for increased implementability and sustainability in international health settings.

Methods: We used a three-round questionnaire-based Delphi study to reach consensus on the outcome set. We invited key stakeholders from 19 countries via purposive snowball sampling, namely people with diabetes ($N=94$), healthcare professionals ($N=65$), industry ($N=22$) and health authorities ($N=3$), to vote on the relevance and measurement frequency of 64 previously identified clinical and person-reported outcomes. Subsequent consensus meetings concluded the study.

Results: The list of preliminary outcomes was shortlisted via the consensus process to 46 outcomes (27 clinical outcomes and 19 PROs). Two main collection times were recommended: (1) linked to a medical visit (e.g. diabetes-specific well-being, symptoms and psychological health) and (2) annually (e.g. clinical data, general well-being and diabetes self management-related outcomes).

For Affiliation refer page on 13.

Conclusions: PROs are often considered in a non-standardised way in routine diabetes care. We propose a person-centred outcome set for diabetes, specifically considering psychosocial and behavioural aspects, which was agreed by four international key stakeholder groups. It guides standardised collection of meaningful outcomes at scale, supporting individual and population level healthcare decision making. It will be implemented and tested in Europe as part of the H2O project.

KEYWORDS

diabetes mellitus, Type 1, diabetes mellitus, Type 2, patient-reported outcome measures, patient-centred care, person-centred care, person-reported outcomes, value-based healthcare

1 | INTRODUCTION

Diabetes care seeks to help people with diabetes achieve stable, near-normal blood glucose levels to avoid complications while promoting physical and emotional well-being.[1] Despite improvements in monitoring and treatment, many people with diabetes do not achieve at least one of these goals.[2,3]

Aiming to improve outcomes, treatment satisfaction and quality of care, person-centred diabetes care is being advocated, including individualised treatment and strengths-based communication, and considering personal factors and needs in addition to commonly used metabolic measurements (e.g. HbA_{1c}).[4] Person-reported outcomes (also referred to as 'patient-reported outcomes') (PROs) that map a person's subjective health can be used to support this approach.[5] Assessing PROs with questionnaires (PROMs) can facilitate valuable interactions between people with diabetes and healthcare providers, as it can help both to better prepare for their visits. When actively using PROM results in consultations, healthcare providers can dedicate time to and specifically ask about identified concerns, while answering PROMs can help people with diabetes to self-reflect and identify priority issues they wish to discuss. Both can foster more meaningful conversations at eye-level.[6,7] This may also support effective time and resource allocation.[5,8]

Efforts have been made to standardise this approach by defining diabetes outcome sets that combine clinical outcomes and PROs to allow for comparison of holistic health data over time and across individuals. They differ in composition and scope, including clinical trials,[9,10] benchmarking diabetes care nationally[11] and internationally,[12] and supporting local diabetes care delivery.[13] However, scalable implementation of these sets in routine diabetes care has not been successful to date.[14,15] Key barriers to implementation include uncertainty about which aspects truly matter to people with diabetes[15] and how healthcare providers should use PRO data,[8] as well as a lack of administrative and infrastructural requirements for data collection and management.[12,16]

Novelty Statement

What Is Already Known?

Considering person-reported outcomes in diabetes management supports precision monitoring and helps improve diabetes outcomes. Large integrated data sets have been developed to facilitate standardised consideration of these factors. Their scalable implementation has not yet been successful.

What This Study Has Found?

We have developed a person-centred diabetes outcome set considering psychosocial and behavioural aspects, enabling standardised recording of diabetes outcomes at scale, which were unanimously rated meaningful by international stakeholders.

What Are the Implications of the Study?

Implementing the outcome set can improve diabetes management by supporting person-centred communication, including shared decision making. The data collected can inform research and policy to enhance diabetes care. The H2O project supports the set's uptake and sustainability.

The Health Outcomes Observatory (H2O) project aims to tackle these challenges by developing person-centred outcome sets and a data governance and infrastructure in Europe that will enable standardised collection of health outcomes and facilitate their integration into healthcare decision making.[16]

Here, we report on the development of the person-centred outcome set for adults with Type 1 and Type 2 diabetes. The objective was to propose a standard for collecting key diabetes outcomes in routine care that can

be of value for different stakeholders, benefitting diabetes care at multiple levels and thus be adopted in a more sustainable way. While its use in individual practice can support person-centred communication and individualised treatment decisions,[6,7] it can simultaneously generate data that is comparable across individuals, enabling mutual learning between healthcare providers as well as research with real-world data, including assessment of effectiveness and quality of care and new risk stratifications.[17] Furthermore, such data can be used to identify population health needs and inform public health decisions.[18] For all these areas, the value of PROs, particularly well-being (incl. symptoms and functioning), health behaviours and coping skills, has been consistently demonstrated.[17,18]

For this reason, we aimed to achieve consensus among different international stakeholders on relevant outcomes and develop an outcome set that can serve multiple purposes and with a high potential for widespread acceptance and implementation. Subsequent H2O activities will build on this to overcome implementation challenges.

2 | METHODS

An online questionnaire-based three-round multi-stakeholder Delphi study was undertaken to achieve consensus on the outcome set[19] followed by two consensus meetings.

This study was participatory, involving healthcare professionals, industry representatives and people with diabetes in the planning and conduct to ensure that key stakeholders' perspectives were considered from the outset. The study protocol was published previously[16] and ethical approval was obtained (Medical University Vienna: EK 1803/2021 and Vall d'Hebron University Hospital: PR(AG)466/2021). We followed the COS-STAR-guidelines for reporting our results.[20]

2.1 | Participants

We included four stakeholder groups, including people with diabetes and community advocates, healthcare professionals and/or academic researchers, representatives of industry and regulatory and health authority representatives. We recruited through community networks, diabetes societies and industry partners using purposive snowball sampling, considering gender, diabetes type and sociodemographic background for the seed sample ($N = 145$). Invitations to participate focused on four European countries that will initially implement the outcome set (Austria, Germany, the Netherlands and Spain) with additional participants recruited from other countries using team member networks (convenience sampling). Based on the available literature on the Delphi method,[19] we aimed to include between 5 and 8 people per stakeholder group from each location leading to a total number of 120–180 participants for the first survey. Table 1 shows the eligibility criteria and a rationale for involving each stakeholder group.

TABLE 1 Eligibility criteria and rationale for involving each stakeholder group.

Group	People with diabetes	Healthcare professionals	Industry	Authorities
Eligibility criteria	≥18 years of age Sufficient proficiency in English, German, Dutch or Spanish Consent to study			
	Living with Type 1 or Type 2 diabetes or representing people with diabetes (e.g., through their role in a lived-experience organisation or as relatives or informal carers)	Experts in diabetes care (incl. physicians, nurses, psychologists, dietitians, and other professions involved in diabetes management) and/or academic diabetes and/or outcomes research	Associated with a pharmaceutical or medical device company that conducts research and development or has an interest in diabetes	Work for regulatory agencies or health authorities in Europe (due to the scope of the H2O project)
Rationale for involvement	Experts for what everyday life with diabetes is like and what is needed for successful self-management	Extensive knowledge about healthcare practices and methodological aspects; can advise on clinical meaningfulness and feasibility aspects	Familiarity with using health and quality of life outcomes for medical claims; can advise on methodological aspects and on which person-reported information may be particularly relevant for informing health policies	Can provide insight into what clinical and person-reported information might be relevant for health policymaking

2.2 | Information sources

The preliminary outcomes presented in the first Delphi round were based on 53 PROs identified via a systematic literature review[21] and 54 clinical variables extracted from a national diabetes register[22] and the ICHOM diabetes outcome set.[12] We conducted focus groups with people with diabetes and healthcare professionals to identify which outcomes they considered important for diabetes management and used the results to shortlist the person-reported and clinical outcomes to 64 outcomes. The focus group findings, the pre-identified PROs and clinical outcomes (including a rationale for inclusion or exclusion) and a list of the outcomes presented in the first Delphi round (including a brief description for each) are available in Data S1.

2.3 | Consensus process

The Delphi study consisted of three consecutive survey rounds presented via www.soscisurvey.de. Responses were anonymous, but basic demographic data was collected, including gender, age, stakeholder group, location, diabetes type and H2O project involvement. The second and third rounds included a summary of responses by stakeholder group from the previous questionnaire (generated using SPSS[23]) allowing participants to consider others' perspectives before re-assessing each outcome. Surveys were available in German, Dutch, Spanish and English, and pre-tested by at least one person with diabetes and clinical expert in each language. Before completing the questionnaire, participants provided informed consent. To promote retention, they received reminder emails regarding survey deadlines (2–3 per round).

In the first survey, participants were asked to choose a measurement frequency for each outcome ('daily', 'weekly', 'monthly', 'annually' or 'before a medical visit'), including the option to exclude the outcome ('never'). For PROs, this decision was required for a single question assessment and a standardised multi-item questionnaire. Participants could specify other measurement intervals and outcomes which were added to the list if they had been proposed at least twice.

The second survey included a revised outcome list and top-ranking measurement frequencies based on the results of the preceding round. We devised the following thresholds based on group size to give similar weight to the votes of all stakeholders: (1) outcomes were excluded if 'never' was endorsed by ≥10% of people with diabetes, ≥15% of healthcare professionals, ≥25% of industry and authority representatives or ≥10% of all; (2) for each outcome, measurement frequencies were included if endorsed by ≥12% of people with diabetes, ≥15% of healthcare professionals and ≥20% of industry and authority.

Participants were asked to rate the importance of inclusion in the outcome set for each outcome at each candidate measurement frequency (on a 10-point Likert scale ranging from 1, meaning 'not relevant at all' to 10, meaning 'of highest importance').

Outcomes were included in the third round with the measurement frequencies that received the highest percentage of votes ≥7 in any stakeholder group. In this last round, participants were asked to rate the importance of including each outcome in the outcome set (on the same 10-point Likert scale) and their agreement with each candidate measurement frequency (on a 10-point Likert scale ranging from 1, meaning 'I do not agree at all' to 10, meaning 'I fully agree'). Consensus was achieved when ≥70% of the members in all stakeholder groups regarded an outcome as highly relevant (vote of ≥7). These thresholds, including the Likert scales, had been defined previously for the entire H2O project.[16] Outcomes that reached 70% approval in two or three stakeholder groups were marked as ambiguous and discussed at the consensus meeting. All other outcomes were considered to have not reached consensus. However, outcomes considered to be highly relevant by people with diabetes were designated 'community-important' and carried forward to the consensus meeting on that basis to add weight to the lived-experience perspective in refining the outcome set. The same criteria applied to the measurement frequencies.

We invited selected Delphi participants to a virtual consensus meeting to resolve disagreement and finalise the outcome set. Selection criteria included having completed at least two survey rounds and being comfortable participating in a group discussion in English. Moreover, the invitations were made in a way that an equal distribution of 6–8 people per stakeholder group as well as of H2O members and external participants, hospital-employed and non-hospital-employed healthcare providers and people with (experience in) Type 1 and Type 2 diabetes could be achieved. During the meeting, the group could either agree to include or exclude outcomes or flag outcomes as desirable on which study team members with different expertise would make a final decision in a subsequent consensus meeting.

3 | RESULTS

3.1 | Participants

The first survey was accessed by 327 people, of whom 183 responded (56%), 125 out of 144 who accessed the second

survey (87%) and 116 out of 126 who accessed the third survey (94%) responded, respectively, resulting in response rates of 68% for the second and 63% for the third round.

Participants were from 19 countries and 54% were women. People with diabetes comprised the largest group in all rounds (>51%). Among them, 52% were women, 60% lived with Type 2 diabetes and about half were over 60 years old (30% between 41 and 60, and 20% between 18 and 40). They represented Austria, Belgium, Cyprus, France, Germany, Ireland, Italy, Norway, Romania, Serbia, Spain, Sweden, Switzerland, the Netherlands and the United Kingdom (Table 2).

3.2 | Outcomes

After the first Delphi round, four outcomes were added to the subsequent surveys: depression, anxiety, eating problems and sexual health. Adjustments were made to some initially listed outcomes based on participants' comments, that is, using more accessible language or combining them (based on congruent voting results) into one outcome category (and scoring them together) to ensure user-friendliness. Outcomes included in the second and third rounds ($N = 57$), along with round 1 voting results, are available in Data S1.

After the third round, consensus on inclusion in the outcome set had been reached for 29 outcomes, including six PROs: psychological well-being, diabetes distress, diabetes-specific quality of life, health status, hypoglycaemia unawareness, treatment satisfaction and 23 clinical outcomes reflecting glycaemia, laboratory values, blood pressure, hypo- and hyperglycaemia episodes and diabetes complications. Seventeen outcomes were classified as ambiguous and marked for further discussion in the consensus meeting (14 PROs and three clinical outcomes). Nearly all of them were considered highly relevant by people with diabetes with four exceptions: depression, eating problems, social support (considered relevant by people with Type 1 diabetes only) and sexual health (considered relevant by people with Type 2 diabetes only).

Outcomes considered important by people with diabetes only were lifestyle behaviour, side effects and eye and foot screening documentation.

Stigma, coping skills, skills and competencies, diabetes knowledge and anxiety were excluded at this stage as no consensus was indicated in the Delphi process.

In terms of measurement frequency, consensus was reached for all clinical outcomes ($N = 27$) for which participants suggested recording them either once a year or every 3 or 6 months, and for most PROs ($N = 14$) for which it was also suggested recording them either once a year or else before a medical visit. For seven PROs, there was no consensus on how often they should be measured (diabetes-specific quality of life, self care performance, perceived importance of self care, depression, eating problems, social support and sexual health). Here, all stakeholder groups seemed undecided, that is, several measurement frequencies achieved a similar proportion of votes ≥7, but they mostly showed a preference for the same measurement frequency. The proportion of votes ≥7 per stakeholder group for all measurement frequencies in the third Delphi survey is available in Data S1.

Figure 1 presents a graphical summary of the Delphi process and results. Table 3 shows round 3 voting results per stakeholder group.

The first consensus meeting was attended by 19 participants, a chairperson, a moderator and two note takers. Participants included four people with Type 1 diabetes, one community advocate for Type 1 and Type 2 diabetes each, eight healthcare professionals, including physicians, a psychologist and a nurse and five industry representatives. Each outcome was presented with a definition and the Delphi results and was discussed for 3–5 min. The discussion and final decision were recorded in writing and all entries of the 'chat' were saved.

Consensus for inclusion was reached for 13 of the 17 outcomes that were discussed, and two main collection times were recommended: (1) linked to a medical visit (diabetes-specific well-being, symptoms, altered glucose events, psychological health and lifestyle behaviour); (2) annually (clinical data, general well-being, treatment satisfaction, diabetes self management behaviour and health beliefs). It was suggested to document blood glucose and pressure every 3–6 months.

Social support was excluded with agreement of all participants, as it was considered key for self management but not an outcome to be monitored.

Three outcomes were considered desirable and final consensus on inclusion was deferred to the study team during the second consensus meeting: self care performance, capacity for self care and perceived importance of self care. This was based on concerns regarding including numerous interconnected self care-related PROs.

The second consensus meeting was attended by clinical experts ($N = 3$), psychology and diabetes researchers ($N = 2$), industry representatives ($N = 1$) and community advocates ($N = 2$, one for Type 1 and Type 2 diabetes each) who made the following decisions: side effects was subsumed within the 'symptoms' PRO (including all symptoms attributable to diabetes itself, its complications and management) because of the complexity in measuring it as a standalone PRO. All self care behaviour-related

TABLE 2 Participant characteristics of all Delphi rounds.

Participants	Round 1		Round 2		Round 3	
	N	%	*N*	%	*N*	%
Total	183	100.0%	125	100.0%	116	100.0%
Stakeholder groups						
People with diabetes	94	51.4%	76	60.8%	60	51.7%
Healthcare professionals	65	35.5%	41	32.8%	45	38.8%
Industry	22	12.0%	6	4.8%	8	6.9%
Authority	2	1.1%	2	1.6%	3	2.6%
Age						
18–40	40	21.9%	22	17.6%	22	19.0%
41–60	72	39.3%	47	37.6%	42	36.2%
60+	71	38.8%	56	44.8%	52	44.8%
Gender						
Women	99	54.1%	69	55.2%	62	53.5%
Men	83	45.4%	56	44.8%	54	46.5%
Other/diverse	1	0.5%	0	0.0%	0	0.0%
Type of diabetes[a]						
Type 1	49	26.8%	35	28.0%	33	28.5%
Type 2	72	39.3%	57	45.6%	42	36.2%
Both	62	33.9%	33	26.4%	38	32.8%
H2O affiliation						
Internal	31	16.9%	23	18.4%	17	14.7%
External	117	63.9%	102	81.6%	97	83.6%
Not known	35	19.1%	0	0.0%	2	1.7%
Country						
Austria	40	21.9%	28	22.4%	30	25.9%
Belgium	2	1.1%	3	2.4%	2	1.7%
Cyprus	1	0.5%	0	0.0%	0	0.0%
Denmark	4	2.2%	2	1.6%	1	0.9%
France	0	0.0%	0	0.0%	1	0.9%
Germany	20	10.9%	12	9.6%	16	13.8%
Ireland	3	1.6%	1	0.8%	0	0.0%
Italy	8	4.4%	8	6.4%	8	6.9%
Netherlands	61	33.3%	43	34.4%	31	26.7%
Norway	1	0.5%	0	0.0%	1	0.9%
Romania	1	0.5%	1	0.8%	1	0.9%
Serbia[b]	1	0.5%	0	0.0%	0	0.0%
Spain	8	4.4%	13	10.4%	8	6.9%
Sweden	11	6.0%	6	4.8%	9	7.8%
Switzerland	3	1.6%	3	2.4%	2	1.7%
Turkey[b]	1	0.5%	0	0.0%	0	0.0%
UK	14	7.7%	3	2.4%	5	4.3%
USA	3	1.6%	2	1.6%	1	0.9%
Australia	1	0.5%	0	0.0%	0	0.0%

[a]The indication of diabetes type was a multiple-choice answer indicating which type a person lives with, which type(s) they represent (community advocates) or which type(s) they specialise in (e.g. healthcare providers). In round 3, three participants (two health professionals/academic researchers and one industry representative) stated that they had no particular specialism in Type 1 and/or Type 2 diabetes, suggesting that they specialise in outcomes research, based on the inclusion criteria (disclosed at the beginning of the survey) (refer to Table 1).

[b]Low- and middle-income countries.

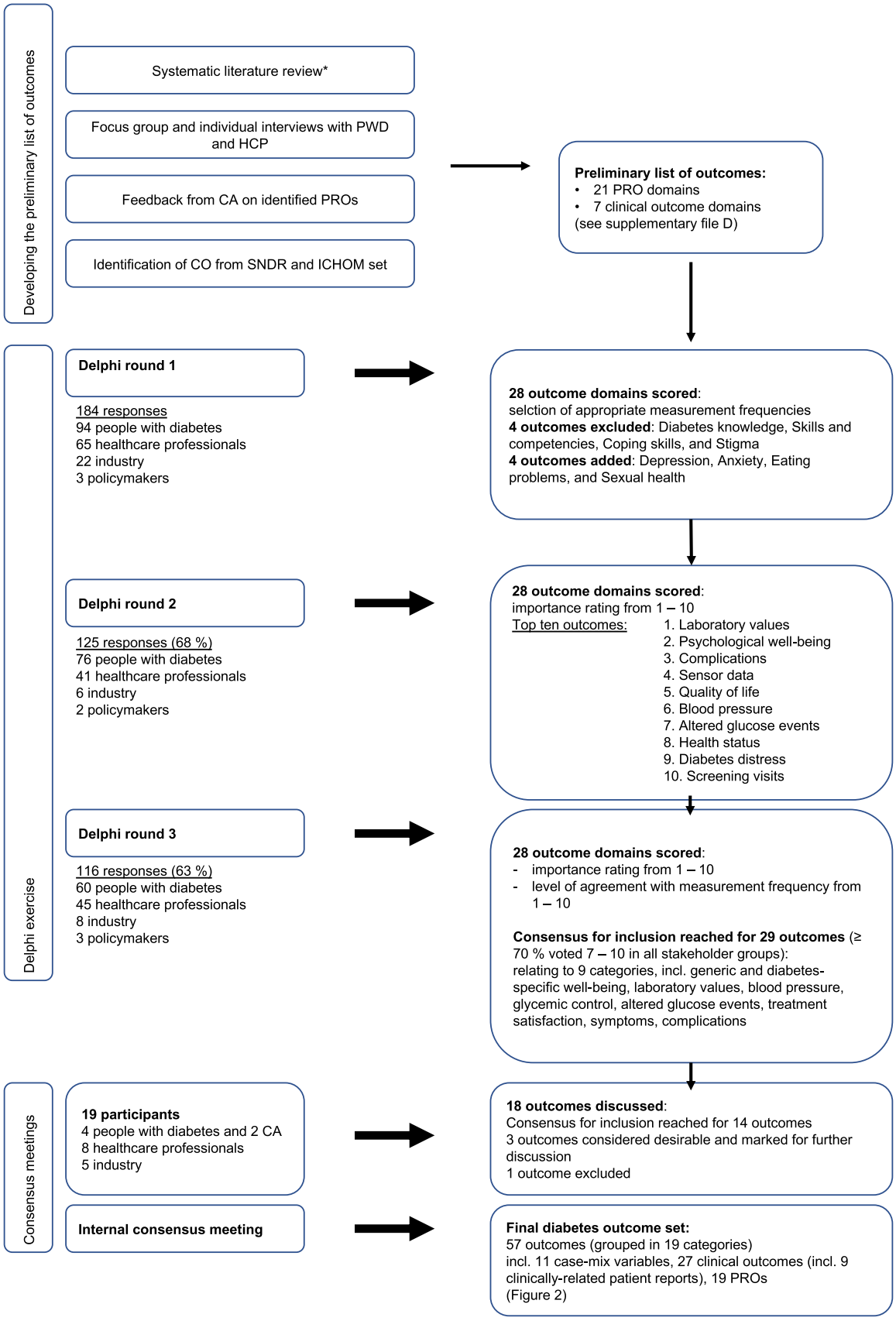

FIGURE 1 Graphical summary of the study flow and results. * Data published elsewhere.[21] CA, community advocates; CO, clinical outcome; HCP, healthcare professionals; ICHOM, International Consortium for Health Outcomes Measurement; PRO, person-reported outcome; PWD, People with diabetes; SNDR, Swedish National Diabetes Register.

TABLE 3 Voting results of the third Delphi round.

	People with diabetes			Healthcare professionals			Industry			Authority		
Outcome Score	**1–3 (%)**	**4–6 (%)**	**7–10 (%)**	**1–3 (%)**	**4–6 (%)**	**7–10 (%)**	**1–3 (%)**	**4–6 (%)**	**7–10 (%)**	**1–3 (%)**	**4–6 (%)**	**7–10 (%)**
Psychological well-being	1.7	20.0	78.3	4.4	15.6	80.0	0.0	0.0	100.0	0.0	0.0	100.0
Depression	6.7	31.7	61.7	11.1	35.6	53.3	12.5	25.0	62.5	0.0	33.3	66.7
Anxiety	10.0	38.3	51.7	8.9	40.0	51.1	12.5	25.0	62.5	33.3	33.3	33.3
Eating problems	5.0	35.0	60.0	4.4	40.0	55.6	12.5	25.0	62.5	66.7	0.0	33.3
Diabetes distress	1.7	13.6	84.7	4.4	24.4	71.1	0.0	25.0	75.0	0.0	0.0	100.0
HbA_{1c}	5.1	8.5	86.4	2.2	4.4	93.3	0.0	0.0	100.0	0.0	0.0	100.0
Other laboratory values	0.0	16.7	83.3	4.4	26.7	68.9	0.0	0.0	100.0	0.0	0.0	100.0
Quality of life	0.0	13.3	86.7	6.7	8.9	84.4	12.5	12.5	75.0	0.0	33.3	66.7
Health status	3.3	15.0	81.7	6.7	31.1	62.2	12.5	12.5	75.0	0.0	0.0	100.0
Symptoms	0.0	11.7	88.3	8.9	35.6	55.6	0.0	12.5	87.5	0.0	0.0	100.0
Blood pressure	3.3	21.7	75.0	4.4	20.0	75.6	0.0	12.5	87.5	0.0	0.0	100.0
Height and weight	8.3	26.7	65.0	13.3	31.1	55.6	0.0	25.0	75.0	0.0	0.0	100.0
Self management	3.3	13.3	83.3	2.2	31.1	66.7	0.0	37.5	62.5	0.0	0.0	100.0
Capacity for self care	3.3	15.0	81.7	13.3	26.7	60.0	12.5	50.0	37.5	0.0	0.0	100.0
Perceived importance of self care	3.3	11.7	85.0	26.7	31.1	42.2	25.0	50.0	25.0	0.0	0.0	100.0
Motivation for self care	1.7	16.7	81.7	20.0	24.4	55.6	25.0	25.0	50.0	0.0	0.0	100.0
Sensor data	5.0	15.0	80.0	6.7	6.7	86.7	0.0	0.0	100.0	0.0	0.0	100.0
Altered glucose events	0.0	21.7	78.3	2.2	6.7	91.1	0.0	0.0	100.0	0.0	0.0	100.0
Hypoglycaemia unawareness	3.3	21.7	75.0	2.2	15.6	82.2	0.0	0.0	100.0	0.0	0.0	100.0
Treatment satisfaction	3.4	8.5	88.1	6.7	22.2	71.1	0.0	25.0	75.0	0.0	0.0	100.0
Social support	8.3	25.0	66.7	11.1	42.2	46.7	12.5	50.0	37.5	0.0	0.0	100.0
Perceived control over diabetes	8.3	13.3	78.3	8.9	28.9	62.2	0.0	50.0	50.0	0.0	0.0	100.0
Side effects	1.7	28.3	70.0	4.4	42.2	53.3	0.0	37.5	62.5	0.0	33.3	66.7
Complications	0.0	25.0	75.0	0.0	20.0	80.0	0.0	0.0	100.0	0.0	0.0	100.0
Sleep quality	0.0	23.3	76.7	17.8	44.4	37.8	0.0	37.5	62.5	0.0	0.0	100.0
Lifestyle	3.3	23.3	73.3	11.1	33.3	55.6	12.5	37.5	50.0	0.0	33.3	66.7
Prevention and screening	3.3	16.7	80.0	6.7	42.2	51.1	0.0	37.5	62.5	0.0	33.3	66.7
Sexual health	6.7	28.3	65.0	6.7	31.1	62.2	25.0	50.0	25.0	33.3	0.0	66.7

Note: Table legend: The table shows the percentages of each stakeholder group scoring each outcome as 1–3 ('not important'), 4–6 ('somewhat important') or 7–10 ('very important') on the 10-point Likert scale (ranging from 1, meaning 'not relevant at all' to 10, meaning 'of highest importance') (People with diabetes: $N = 60$; Healthcare professionals: $N = 45$; Industry: $N = 8$; Authority: $N = 3$).

outcomes (performance, capacity, perceived importance and motivation) were clustered and arranged hierarchically, such that issues with performance of self care behaviours would trigger the administration of follow-up questionnaires, for example, on capacity of self care. This acknowledges the variables' interrelatedness and highlights their potential to provide a holistic understanding of targetable barriers and enablers for self care.

Ultimately, 46 outcomes (27 clinical outcomes, and 19 PROs) and 11 case-mix variables were included in the diabetes outcome set (Table 4). Figure 2 shows the outcome set, including proposed measurement intervals, and indicating overlaps with other outcome sets to highlight commonalities and novelties.

4 | DISCUSSION

We developed an outcome set for routine diabetes care that was agreed by international key stakeholders and includes PROs and clinical outcomes, with a focus on psychosocial and behavioural aspects.

We propose to collect outcomes annually (e.g. as part of the annual diabetes check-up) or promptly before routine consultations. This can enable well-informed and personalised interactions between people with diabetes and healthcare providers, as it can help people with diabetes to reflect on their health and identify issues they want to discuss and encourage healthcare providers to review PROs and clinical data together to gain a more holistic understanding of individual challenges and structure the conversation accordingly. In this way, implementing the outcome set can support person-centred communication during consultations as well as precision monitoring, enabling better informed treatment decisions and holistic diabetes care.[6,7,24]

By providing precise definitions of community-relevant outcomes, the outcome set offers a framework for large-scale data comparability and enables the alignment of generic PROs between different conditions, both promoting implementation and contributing to high-quality and scalable outcome assessment.[25,26] In this way, data from routine care can inform assessments of effectiveness and quality of care and identify population-level needs, potentially substituting observational studies and contributing to diabetes research and health policy.

Holistically, evaluating treatment effect is a shared interest of people with health problems, healthcare providers, researchers, payers and regulators alike.[27] Involving these stakeholders in developing a standard for measuring diabetes outcomes has likely contributed to the outcome set's acceptability and sustainability.[17] The outcome set reflects responses from 19 countries, which is conducive to its international applicability. Additionally, we aimed to increase its implementability by asking participants to consider practicability and burden when assessing outcome relevance, and providing the option to vote on feasibility aspects, such as measurement frequency and PRO assessment with single questions versus questionnaires.

The study design allowed us to place particular emphasis on the lived-experience voice, as people with diabetes were involved in the study design, prioritising outcomes for the Delphi survey, and the consensus process itself, where their voice carried more weight (i.e. all outcomes considered important by ≥70% of people with diabetes were included in the consensus meeting). This was instrumental in developing an outcome set capturing health data that really matter to people with diabetes, which is key to successful implementation.[15]

Effective implementation further relies on systems and infrastructures for collecting and managing health data.[12] Being rooted in the H2O initiative is a major asset of this study as H2O directly addresses this by creating these structures and supporting coordinated implementation in international contexts.[16] Supportive measures include training materials that have been developed for both healthcare providers and people with diabetes to help them integrate PROs into their existing diabetes management routines and use them for person-centred communication.

The outcome set shows commonalities with two national diabetes outcome sets developed in Denmark for routine care[13] and in Sweden for benchmarking and advancing evidence-based care[11] (Figure 2), suggesting synergies that may promote its adoption. The clinical outcomes and measurement frequencies agreed in this study are in line with practice guidelines[1,4] and other outcome sets, including the ICHOM set.[12] However, the extent of included PROs distinguishes our outcome set from that of the ICHOM initiative: Both include the generic PROs psychological well-being and depression, and the diabetes-specific PRO diabetes distress.[12] However, our set adds another 10 diabetes-specific and four generic PROs. While the ICHOM set might be well suited for broader contexts and benchmarking purposes, our set allows for collecting comprehensive person-reported data enabling enhanced consideration of the individual context to support person-centred diabetes care.

We recognise that we are proposing a large number of PROs and that it will be necessary to examine the feasibility and utility of using the outcome set. Long-term data on the acceptability of using PROs in clinical diabetes consultations are scarce.[6,7,15,28] For this reason, we are currently preparing a feasibility study under the H2O project aiming to identify aspects that require refinement. At the same time, we are exploring different alternatives to assessing

TABLE 4 Clinical and person-reported outcomes (domains) of the final diabetes outcome set.

#	Outcome	Definition
1	Glycaemia	Commonly used measures for evaluating blood glucose levels including HbA1c and data derived from sensor-based glucose monitoring including mean sensor glucose (over last 2 weeks), standard deviation of mean sensor glucose (over last 2 weeks), tie in range (TIR; % of time over last 2 weeks), and time in hypoglycaemia (TIH; % of time over last 2 weeks).
2	Blood pressure	Systolic and diastolic pressure of the blood in the circulatory system.
3	Height and weight	Measures of human size and shape enabling the calculation of the body mass index (BMI)
4	Laboratory values	Laboratory values including commonly evaluated blood and urine values related to Lipids status (including total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides) and Kidney function (including creatinine, urine albumin-creatinine ratio, albuminuria).
5	Screening attendance	Attendance of medical visits and examinations that serve to detect diabetes complications in time, specifically foot examination (incl. the assessment of risk foot level) and eye examination (incl. the assessment of level of retinopathy, and eye complication treatment).
6	Hypoglycaemia episodes	Frequency and severity of hypoglycaemia, especially frequency of severe hypoglycaemia episodes (defined as an episode of low blood sugars that one is unable to treat themselves, leading to confusion or an inability to think straight).
7	Hyperglycaemia emergencies	The frequency of hyperglycaemic emergencies (incl. diabetic ketoacidosis and hyperosmolar hyperglycaemic state).
8	Complications	The presence of acute and/or chronic complications associated with diabetes including cardiovascular events (i.e., heart attack, chronic heart failure or stroke, peripheral artery disease), peripheral neuropathy, lower limb ulcers and amputations, chronic kidney disease (incl. the need for dialysis), diabetes retinopathy, and visual impairment.
9	Diabetes distress	The emotional response to specific aspects of living with and managing diabetes including but not limited to fear/worry about hypoglycaemia and fear of complications.
10	Diabetes-specific quality of life	The cognitive response (considered thoughts) about the extent of impact of diabetes (or an aspect of this, e.g., a diabetes complication) on the individual's life (not just their health) in ways that are important to the individual (i.e., the impact on domains that are important to them such as productivity).
11	Psychological well-being	Aspects of (general) mental health including but not limited to negative well-being (e.g., depression, anxiety); this can also include other aspects for example stress, positive well-being.
12	Depression	Depressive symptoms; persistent sadness and a lack of interest or pleasure in previously rewarding or enjoyable activities.
13	Eating problems	Abnormal eating behaviours that can threaten health, including those reflecting common eating disorders (especially binge eating) and those that are diabetes-specific for example intentional insulin omission (also includes psychological aspects of common eating disorders).
14	Diabetes symptoms	The subjective experience of all diabetes-related symptoms (incl. treatment side effects), including the occurrence/presence and the perceived burden of physical and psychological symptoms related to diabetes and its possible complications. Symptom burden refers to the impact of diabetes symptoms on functional goals e.g. work, school, family, leisure activities.
15	Hypoglycaemia unawareness	The failure to sense a fall in blood glucose below normal levels.
16	Lifestyle behaviour	Health behaviours aimed at health promotion and disease prevention (not only prescribed for managing diabetes), including specifically smoking behaviour and alcohol consumption.
17	Health status	The presence of biological, physiological and psychological dysfunction, symptoms and functional impairment (and impairments to social functioning); reflects 'quality of health' rather than '(health-related) quality of life'.
18	Sleep quality	Sleep quality/patterns; self-reported perceptions of sleep quality, depth, and restoration, and the impact of diabetic peripheral neuropathy on this.

TABLE 4 (Continued)

#	Outcome	Definition
19	Sexual health	Sexual and reproductive health including sexual dysfunction (i.e. the various ways in which an individual is unable to participate in a sexual relationship as they wish (core dimensions incl. desire, arousal, orgasmic, and sexual pain disorders)), as well as contraception and family planning.
20	Self-care performance	Performance of health behaviours (i.e., overt behavioural patterns, actions and habits that relate to health maintenance, to health restoration and to health improvement) specifically prescribed for managing diabetes, including exercise/physical activity, diet/nutrition, self-monitoring of blood glucose, foot care, medication taking (oral and injectable), and engaging with health services.
21	Capacity for self-care	Subjective perception of one's capacity to adhere to their individual treatment recommendations for diet and physical activity (i.e., how they feel they are currently managing to perform the behaviour); does not presume an "ideal" regimen or that all individuals have the same regimen.
22	Perceived importance of self-care	How important the dietary, physical activity and blood glucose self-monitoring aspects of self-management are perceived to be.
23	Motivation for self-care	The degree of intrinsic motivation to engage in diabetes self-management behaviours (as opposed to behaving because of a demand or threat from an external agent, e.g., a family member or healthcare provider, or because of a rigidly held belief that one behave in a certain way to avoid shame). Based on Self-Determination Theory, intrinsic/autonomous motivation = engaging in a behaviour because it is consistent with internal goals/satisfies 3 innate psychological needs: autonomy (i.e. feeling in control of one's behaviour and being able to take direct action that will result in real change), competence (i.e. feeling one has the skills needed for success) and relatedness (i.e. a sense of belonging and attachment to other people) and because it emanates from the self (i.e. the behaviour is self-determined).
24	Perceived control over diabetes	Diabetes-specific health belief: An appraisal of the extent to which one feels as though they have their diabetes under control (comprises an assessment of self-efficacy for performing diabetes self-management behaviours and whether one has an internal or external locus of control; internal locus of control beliefs refer to the extent to which individuals believe that the control of events that affect them is a function of what they, themselves, do, whereas external locus of control beliefs refer to the belief that events in one's life are caused by outside factors, such as the behaviour of other people or luck, over which they have less control). Also including the extent to which people feel they have control over blood sugar.
25	Treatment satisfaction	An individual's subjective appraisal of their experience of treatment (both process and outcomes), including ease of use, side effects and efficacy.

all recommended PROs with full PROMs to reduce the potential burden and optimise utility and meaningfulness. This includes offering a more pragmatic 'clinical module' containing a reduced number of core PROMs, using short forms or open screening questions which can prompt the use of full PROMs, and employing a branching approach where PROs that are relevant for most people with diabetes are used to identify areas requiring further exploration and trigger assessment of more targeted outcomes. Such approaches may involve computerised adaptive testing, which has been shown to reduce respondent burden.[29] This would allow the outcome set, developed universally for all adults with Type 1 and Type 2 diabetes, to be adaptable to different subgroups and their specific needs and challenges. We observed that, among our study participants, only people with Type 1 diabetes considered regular screening for depression, and eating problems to be important, while only people with Type 2 diabetes endorsed screening for sexual health, suggesting that adaptability may be both necessary and helpful. It will be crucial to find the right balance between a universal core outcome set that can guide basic diabetes management and capture comparable data from all people with diabetes (who share the challenge of managing a lifelong metabolic disease), and a flexible tool that can be adapted to individual circumstances in a person-centred way (e.g. considering that managing Type 1 and Type 2 diabetes presents different challenges).[12] The H2O project foresees stratification analyses on the basis of which the outcome set will be refined over time. Such analyses can help to understand culture- and/or location-specific issues and needs and to assess the impact of different health systems on health outcomes. For example, residential country has been shown to play a significant role in the quality of life

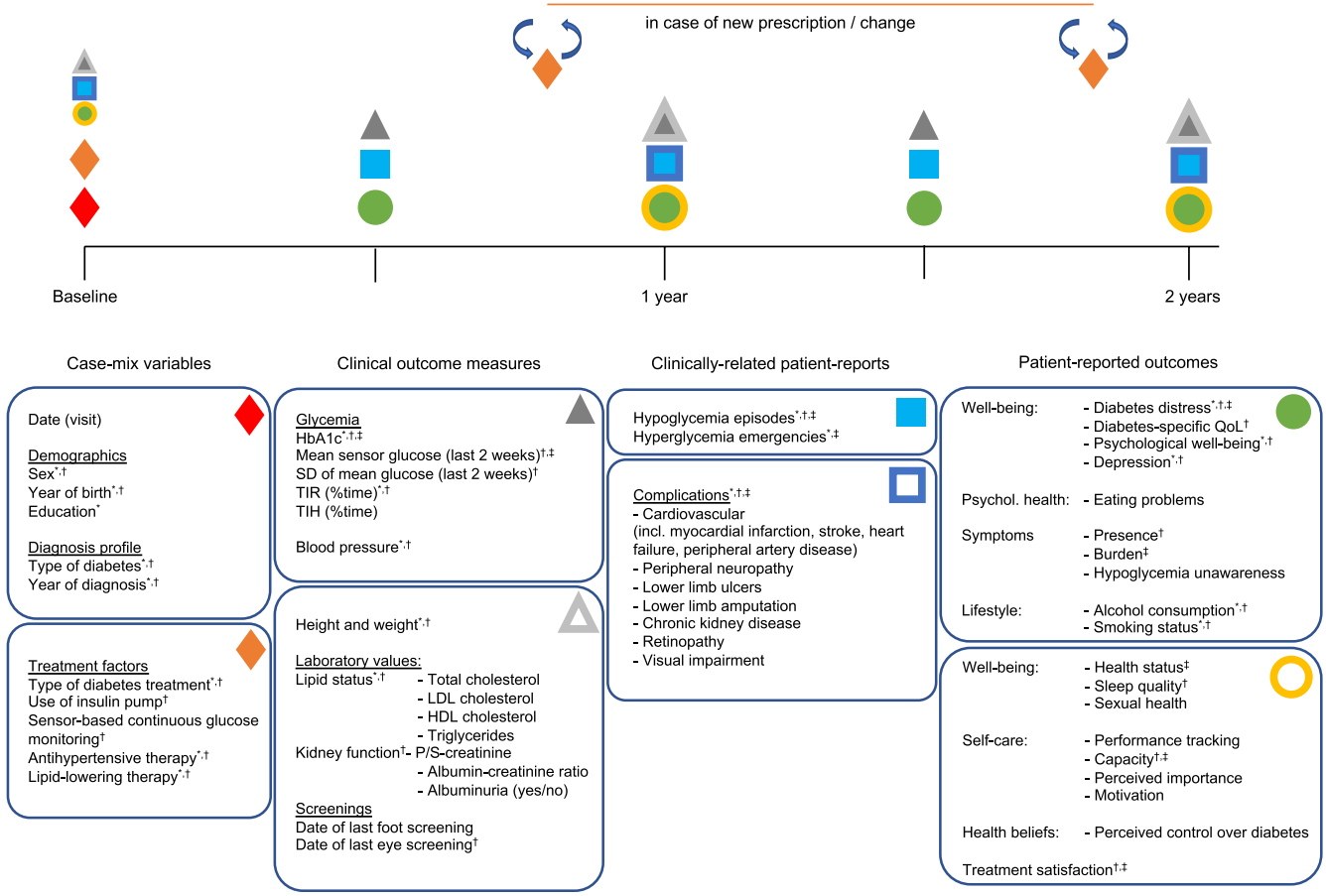

FIGURE 2 Final diabetes outcome set including recommended measurement frequencies. The style of illustration is adapted from that of Nano, et al. (ICHOM set of person-centred outcomes for diabetes mellitus, 2020).*Outcome is included in the ICHOM set for diabetes. †Outcome is included in the Swedish National Diabetes Register (SNDR) or SNDR Diabetes Questionnaire respectively. Note that complications recorded in the SNDR are limited to 'cerebrovascular disease ever', 'ischemic heart disease ever' and 'stroke ever'; and symptoms include "polyuria" and 'polydipsia'. Regarding matched person-reported outcomes, the SNDR Diabetes Questionnaire includes the dimensions 'General well-being', 'Mood and energy' (including item 3: 'Have you felt depressed in the past four weeks?'), 'Free of worries about blood sugar', 'Not limited by diabetes', 'Not limited by blood sugar', 'Capabilities to manage your diabetes', as well as the item 'How have you slept in the past four weeks?' (Item 2 of the dimension 'General Well-being') and a comprehensive person-reported experience measure including the dimensions 'Support from Diabetes Care', 'Access to Diabetes Care', 'Continuity in Diabetes Care' and 'Medical Devices and Medical Treatment'. ‡Outcome is included in the Danish National Diabetes outcome set. Note that for glycaemia, the Danish set records 'BGM/FMM measurements' only. Regarding matched person-reported outcomes, the Danish set includes 'Impact of diabetes on life quality', 'Somatic symptom distress', 'Burden of daily diabetes treatment (incl. side effects)', 'Self-reported health and functioning', 'Confidence in ability to perform diabetes self-management', and 'Confidence and comfort in adequate access to person-centred diabetes care'. P/S, plasma/serum; SD, standard deviation; TIH, time in hypoglycaemia; TIR, time in range.

and perceived barriers of people with diabetes.[30] The use of our outcome set can expand this research, providing important insights for both healthcare providers and policymakers working in different local contexts.

Limitations to our study include the low response rate between Delphi rounds 1 and 2, likely due to the end-of-year holidays and onset of another wave of the COVID-19-pandemic. Moreover, the small number of policymakers, industry representatives, young people with diabetes and participants from Eastern and Southern Europe (regions comprising low- to middle-income countries) may have limited the generalisability of our findings. The sampling method and online setting may have introduced recruitment bias, especially among people with diabetes, however, we endeavoured to reach out to diverse groups and provided questionnaires in different languages to add to the study's inclusiveness. Rather than selecting a representative sample, we aimed to include qualified experts with in-depth knowledge and experience to enable a group decision reflecting different people's needs and interests, which corresponds to the Delphi methodology.[19] Furthermore, the number of policymakers was similar to

other studies using the Delphi method to define health outcome sets.[9,10,12] Considering the industry perspective separately is unique to our study. Although their interests differ from those of stakeholders actively involved in person-centred care, it was important for us to include industry representatives as they are essential drivers of health policy needed to initiate change and normalise the use of PROs in clinical care.[31]

PROs are currently captured rarely in diabetes care and in a non-standardised way. We address this by proposing a person-centred diabetes outcome set agreed by key stakeholders and supported by the H2O initiative.

The proposed outcome set will be tested and refined with the aim of contributing to person-centred diabetes care in Europe in the long term. We intend to update this initial outcome set based on developments in diabetes management and initial implementation experiences, for example, by introducing new variables and context-specific adjustments.

AUTHOR CONTRIBUTIONS

All authors contributed to the study design. Ann-Kristin Porth, Alizé Rogge, Anouk Sjoukje Huberts, Angèle Helene Marie Bénard, Vanesa Flores and Yuki Seidler conducted and analysed the focus group interviews. David Nathanson and Katarina Eeg-Olofsson guided the selection of clinical outcomes. Ann-Kristin Porth, Laure Delbecque, Kathryn Hamilton and Yuki Seidler contributed to the shortlisting of the candidate outcomes list. Ann-Kristin Porth and Yuki Seidler designed the Delphi surveys and conducted the data analysis. Ann-Kristin Porth, David Hopkins, Lyudmil Ninov and Anouk Sjoukje Huberts facilitated the consensus meetings. Angus Forbes, David Hopkins, Henk-Jan Aanstoot, Michael Leutner, Sara Vikstrom-Greve, Sophia Rössner, Vanesa Flores, Rafael Simó and Alexandra Kautzky-Willer provided mentorship and clinical insight. Anja Strootker, Carmen Hurtado Del Pozo, Dagmar Kownatka, Laure Delbecque, Jeanette Soderberg, Lyudmil Ninov, Mette Due-Christensen, Yvonne Hasler, Yuki Seidler and Tanja Stamm provided mentorship and methodological support. Ann-Kristin Porth drafted the article. All authors contributed to the revision of the article and approved the final version to be published. Ann-Kristin Porth and Tanja Stamm are the guarantors of this work and, as such, had full access to all the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis.

AFFILIATIONS

[1]Department of Internal Medicine III, Divison of Endocrinology and Metabolism, Medical University Vienna, Vienna, Austria
[2]Department of Quality and Patientcare, Erasmus University Medical Center, Rotterdam, The Netherlands
[3]Charité Center for Patient-Centered Outcomes Research, Department of Psychosomatic Medicine, Center for Internal Medicine and Dermatology, Charité - Universitätsmedizin Berlin, Berlin, Germany
[4]Vall d'Hebron Institute of Research (VHIR), Vall d'Hebron Barcelona Hospital Campus, Barcelona, Spain
[5]Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, Kings College London, London, UK
[6]Medtronic International Trading Sàrl, Tolochenaz, Switzerland
[7]JDRF International, New York, New York, USA
[8]Roche Diabetes Care GmbH, Mannheim, Germany
[9]Department of Diabetes, King's College London, London, UK
[10]Institute for Diabetes, Endocrinology and Obesity, King's Health Partners, London, UK
[11]Department of Medicine, Karolinska Institutet, Karolinska University Hospital Huddinge, Huddinge, Sweden
[12]Diabeter, Center for Focussed Diabetes Care and Research, Rotterdam, The Netherlands
[13]Department of Molecular and Clinical Medicine, Institute of Medicine, University of Gothenburg, Göteborg, Sweden
[14]National Diabetes Register, Göteborg, Sweden
[15]Eli Lilly and Company, Indianapolis, Indiana, USA
[16]European Patients' Forum (EPF), Brussels, Belgium
[17]Centro de Investigación Biomédica en Red Instituto de Salud Carlos III (CIBERDEM (ISCIII)), Madrid, Spain
[18]Vall d'Hebron University Hospital, Barcelona, Spain
[19]Autonomous University of Barcelona, Barcelona, Spain
[20]Section for Outcomes Research, Center for Medical Statistics, Informatics and Intelligent Systems, Medical University of Vienna, Vienna, Austria
[21]Ludwig Boltzmann Institute for Arthritis and Rehabilitation, Vienna, Austria

ACKNOWLEDGEMENTS

The authors thank everyone who participated in the Delphi study and consensus meetings. We are especially grateful to the people with diabetes and their advocates including the members of our 'patient advisory board'. The authors acknowledge the valuable advice on the design and conduct of this study provided by the wider H2O project team.

FUNDING INFORMATION

This project has received funding from the Innovative Medicines Initiative (IMI) 2 Joint Undertaking under grant agreement No. 945345-2. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation program, EFPIA, Trial Nation and JDRF. The funding source was not involved in the study design; the collection, analysis and interpretation of data; the writing of the report or the decision to submit the article for publication. The article reflects only the authors' views. The European Union and IMI are not responsible for any use that may be made of the information it contains. IMI is the world's most extensive public–private partnership (PPP) in the life sciences. http://www.imi.europa.eu/.

CONFLICT OF INTEREST STATEMENT

This study is part of the Innovative Medicines Initiative (IMI) Health Outcomes Observatory (H2O) project. The public grant funding of the H2O project is matched with in-kind contributions of EFPIA partners. Some of the authors are employees of EFPIA members: A.S. and Y.H. work for Medtronic International Trading Sàrl, D.K. works for Roche Diabetes Care GmbH and Laure Delbecque works for Eli Lilly and Company. C.H.D.P. and J.S. work for JDRF, which receives funding from pharmaceutical companies and device manufacturers. L.N. works for EPF, which receives funding from pharmaceutical companies and device manufacturers. TS reports personal fees from AOP Health, AbbVie, Pfizer, Roche and Takeda, outside the submitted work.

PRIOR PRESENTATION

Parts of this study were presented in abstract form at the 50th Annual Meeting of the Austrian Diabetes Society 2022, Salzburg, Austria, 17–19 September 2022. A non-peer-reviewed version of this article was submitted to the recognised preprint server zenodo (https://zenodo.org/record/7386600#.Y5Bub-zMI-Q) on 1 December 2022 with restricted access (access is limited to members of the H2O consortium).

ORCID

Ann-Kristin Porth https://orcid.org/0000-0001-7651-2967
Angus Forbes https://orcid.org/0000-0003-3331-755X
David Hopkins https://orcid.org/0000-0002-0451-0900
Mette Due-Christensen https://orcid.org/0000-0003-2604-3730
Tanja Stamm https://orcid.org/0000-0003-3073-7284
Alexandra Kautzky-Willer https://orcid.org/0000-0002-3520-4105

REFERENCES

1. Holt RIG, DeVries JH, Hess-Fischl A, et al. The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2021;44(11):2589-2625.
2. Prigge R, McKnight JA, Wild SH, et al. International comparison of glycaemic control in people with type 1 diabetes: an update and extension. *Diabet Med*. 2022;39(5):e14766.
3. Lautsch D, Boggs R, Wang T, et al. Individualized HbA_{1c} goals, and patient awareness and attainment of goals in type 2 diabetes mellitus: a real-world multinational survey. *Adv Ther*. 2022;39(2):1016-1032.
4. Davies MJ, Aroda VR, Collins BS, et al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia*. 2022;65(12):1925-1966.
5. Terwee CB, Elders PJM, Blom MT, et al. Patient-reported outcomes for people with diabetes: what and how to measure? A narrative review. *Diabetologia*. 2023;66:1357-1377.
6. Skovlund SE, Troelsen LH, Noergaard LM, Pietraszek A, Jakobsen PE, Ejskjaer N. Feasibility and acceptability of a digital patient-reported outcome tool in routine outpatient diabetes care: mixed methods formative pilot study. *JMIR Form Res*. 2021;5(11):e28329.
7. Svedbo Engström M, Johansson UB, Leksell J, Linder E, Eeg-Olofsson K. Implementing the digital diabetes questionnaire as a clinical tool in routine diabetes care: focus group discussions with patients and health care professionals. *JMIR Diabetes*. 2022;7(2):e34561.
8. Skovlund SE, Lichtenberg TH, Hessler D, Ejskjaer N. Can the routine use of patient-reported outcome measures improve the delivery of person-centered diabetes care? A review of recent developments and a case study. *Curr Diab Rep*. 2019;19(9):84.
9. Harman NL, Wilding JPH, Curry D, et al. Selecting Core Outcomes for Randomised Effectiveness trials In Type 2 diabetes (SCORE-IT): a patient and healthcare professional consensus on a core outcome set for type 2 diabetes. *BMJ Open Diabetes Res Care*. 2019;7(1):e000700.
10. Byrne M, O'Connell A, Egan AM, et al. A core outcomes set for clinical trials of interventions for young adults with type 1 diabetes: an international, multi-perspective Delphi consensus study. *Trials*. 2017;18(1):602.
11. Svedbo Engström M, Leksell J, Johansson UB, et al. A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: development and evaluation of content validity, face validity, and test-retest reliability. *Patient Educ Couns*. 2018;101(1):139-146.
12. Nano J, Carinci F, Okunade O, et al. A standard set of person-centred outcomes for diabetes mellitus: results of an international and unified approach. *Diabet Med*. 2020;37(12):2009-2018.
13. Skovlund SE, Troelsen LH, Klim L, Jakobsen PE, Ejskjaer N. The participatory development of a national core set of person-centred diabetes outcome constructs for use in routine diabetes care across healthcare sectors. *Res Involv Engagem*. 2021;7(1):62.
14. Chen YT, Tan YZ, Cheen M, Wee HL. Patient-reported outcome measures in registry-based studies of type 2 diabetes mellitus: a systematic review. *Curr Diab Rep*. 2019;19(11):135.
15. Hernar I, Graue M, Richards DA, et al. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: the DiaPROM randomised controlled pilot trial. *BMJ Open*. 2021;11(4):e042353.
16. Stamm T, Bott N, Thwaites R, et al. Building a value-based care infrastructure in Europe: the health outcomes observatory. *NEJM Catalyst*. 2021;2(3). https://doi.org/10.1056/CAT.21.0146
17. Ahmed S, Ware P, Gardner W, et al. Montreal accord on patient-reported outcomes (PROs) use series - paper 8: patient-reported outcomes in electronic health records can inform clinical and policy decisions. *J Clin Epidemiol*. 2017;89:160-167.
18. Mamiya H, Lix LM, Gardner W, Bartlett SJ, Ahmed S, Buckeridge DL. Montreal Accord on Patient-Reported Outcomes (PROs) use series - paper 5: patient-reported outcomes can be linked to epidemiologic measures to monitor populations and inform public health decisions. *J Clin Epidemiol*. 2017;89:142-147.
19. Belton I, MacDonald A, Wright G, Hamlin I. Improving the practical application of the Delphi method in group-based

judgment: a six-step prescription for a well-founded and defensible process. *Technol Forecast Soc Change*. 2019;147:72-82.
20. Kirkham JJ, Gorst S, Altman DG, et al. Core Outcome Set-STAndards for Reporting: The COS-STAR statement. *PLoS Med*. 2016;13(10):e1002148.
21. Hamilton K, Forde R, Due-Christensen M, et al. Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme. *Patient Educ Couns*. 2023;116:107933.
22. Eliasson B, Gudbjörnsdottir S. Diabetes care – improvement through measurement. *Diabetes Res Clin Pract*. 2014;106(Suppl 2):S291-S294.
23. IBM Corp. *IBM SPSS Statistics for Macintosh*. IBM Corp.; 2020.
24. Hermanns N, Ehrmann D, Shapira A, Kulzer B, Schmitt A, Laffel L. Coordination of glucose monitoring, self-care behaviour and mental health: achieving precision monitoring in diabetes. *Diabetologia*. 2022;65:1883-1894.
25. Terwee CB, Zuidgeest M, Vonkeman HE, Cella D, Haverman L, Roorda LD. Common patient-reported outcomes across ICHOM standard sets: the potential contribution of PROMIS®. *BMC Med Inform Decis Mak*. 2021;21(1):259.
26. Langendoen-Gort M, Groeneveld L, Prinsen CAC, et al. Patient-reported outcome measures for assessing health-related quality of life in people with type 2 diabetes: a systematic review. *Rev Endocr Metab Disord*. 2022;23:931-977.
27. Squitieri L, Bozic KJ, Pusic AL. The role of patient-reported outcome measures in value-based payment reform. *Value Health*. 2017;20(6):834-836.
28. Snoek FJ, Kersch NYA, Eldrup E, et al. Monitoring of Individual Needs in Diabetes (MIND)-2: follow-up data from the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study. *Diabetes Care*. 2012;35(11):2128-2132.
29. Hung M, Stuart AR, Higgins TF, Saltzman CL, Kubiak EN. Computerized adaptive testing using the PROMIS physical function item Bank reduces test burden with less ceiling effects compared with the short musculoskeletal function assessment in orthopaedic trauma patients. *J Orthop Trauma*. 2014;28(8):439-443.
30. Pilv L, Vermeire EIJJ, Rätsep A, et al. Diabetes-related quality of life in six European countries measured with the DOQ-30. *Eur J Gen Pract*. 2021;27(1):191-197.
31. Vijayasingham L, Bischof E, Ateghang-Awankem B, et al. Acting on sex and gender in medical innovation is good for business. *BMJ*. 2023;381:e072242.

SUPPORTING INFORMATION

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

How to cite this article: Porth A-K, Huberts AS, Rogge A, et al. Standardising personalised diabetes care across European health settings: A person-centred outcome set agreed in a multinational Delphi study. *Diabet Med*. 2024;41:e15259. doi:10.1111/dme.15259