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Person-reported outcomes in diabetes care: What are they and why are they so important?

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Abstract

In this review, we aim to show how person-reported outcomes (PROs) and person-reported experiences (PREs) can significantly contribute to the way diabetes care is delivered, the involvement of people with diabetes in diabetes care, and the collaboration between health care professionals and people with diabetes. This review focuses on the definition and measurement of PROs and PREs, the importance of PROs and PREs for person-centred diabetes care, and integrating the perspectives of people with diabetes in the evaluation of medical, psychological and technological interventions. PROs have been increasingly accepted by Health Technology Assessment bodies and are therefore valued in the context of reimbursement decisions and consequently by regulators and other health care stakeholders for the allocation of health care resources. Furthermore, the review identified current challenges to the assessment and use of PROs and PREs in clinical care and research. These challenges relate to the combination of questionnaires and ecological momentary assessment for measuring PROs and PREs, lack of consensus on a core outcome set, limited sensitivity to change within many measures and insufficient standardization of what can be considered a minimal clinically important difference. Another issue that has not been sufficiently addressed is the involvement of people with diabetes in the design and development of measures to assess PROs and PREs.

KEYWORDS
health economics, patient reported outcomes, type 1 diabetes, type 2 diabetes

1 | INTRODUCTION

'Nihil de nobis, sine nobis' or 'Nothing about us, without us' has long been a motto that no decision should be made without hearing the voices of those affected by the decision. A Polish political motto that appeared for the first time in 1505, when power was transferred from the monarchy to a democratic legislature,[1] this phrase has become a cornerstone of many patient organizations (e.g. Disabled People Organizations)[2] and within the diabetes community,[3] as it conveys the idea of empowerment and integration of persons with diabetes in their diabetes management. The importance of empowering people with diabetes and integrating their self-reported perspectives and experiences is an important aspect of person-centred diabetes care.[4–9]

Diabetes mellitus is a chronic condition where the long-term prognosis largely depends on the self-care behaviour of people with diabetes.[10] In response to the association between self-care behaviour and prognosis, there has been a trend in recent decades towards

Abbreviation: HbA1c, glycated haemoglobin.

greater activation and involvement of people with diabetes in diabetes management. Since the discovery of insulin, diabetes became the first chronic condition to be treated by self-injection.[4] For the past 50 years, intensive insulin therapy has required people to dose their own insulin according to their eating and exercise habits.[11] For type 2 diabetes, lifestyle changes are still an important part of diabetes management, but they cannot be achieved without the active involvement of people with diabetes in their own care. Therefore, structured diabetes self-management education and support programmes providing information and skills for diabetes self-management have become an integral part of diabetes care.[12,13] New technological developments such as decision support systems, blood glucose monitoring and automated insulin delivery systems have been further enhancing the role of people with diabetes in their diabetes management. In the last years, in contrast to physician-directed interventions, treatment approaches based on the empowerment of people with diabetes[7] and shared decision-making[8] have become a new model for person-centred and personalized care.[9]

Integrating the perspective of people with diabetes by capturing their experiences, daily functioning, symptoms and feelings can inform person-centred care.[5] Patient- or person-reported measures (PRMs) provide insight into the impact of diabetes and its treatment that other glycaemic or biological measures cannot cover by focusing on the outcomes of care [i.e. person-reported outcomes (PROs)] and experiences with the delivery of care [i.e. person-reported experiences (PREs)]. Consequently, PROs and PREs offer unique perspective on different aspects of diabetes care, such as determining and evaluating the benefits of existing treatments and new interventions (e.g. drugs and technological advances). Using PROs and PREs can help ensure that solutions for people with diabetes deliver the promised value.

The current narrative review focuses on the role of PROs and PREs in improving the involvement of people with diabetes in their diabetes care. The review also highlights the importance of PROs and PREs for person-centred diabetes care and for integrating the perspectives of people with diabetes in the evaluation of medical, psychological and technological interventions. In addition, the inclusion of outcomes and experiences evaluated by people with diabetes for reimbursement decisions and health resource allocation by regulators and other health care stakeholders is emphasized. Finally, current challenges to the assessment and evaluation of PROs and PREs, such as lack of consensus on a core outcome set, neglect of sensitivity to change in certain measures, and no standard definition of a minimal clinically important difference (MCID) are addressed.

2 | SEARCH STRATEGY AND SELECTION CRITERIA

We searched PubMed using the following term: 'diabetes mellitus'[MeSH Terms] OR ('diabetes'[All Fields] AND 'mellitus'[All Fields]) OR 'diabetes mellitus'[All Fields]) AND ('person-reported outcomes'[All Fields] OR 'patient-reported outcomes'[All Fields] OR ('person reported'[All Fields] AND ('experience'[All Fields] OR 'experience s'[All Fields] OR 'experiences'[All Fields])) OR ('patient-reported experiences'[All Fields] OR 'patient perspective'[All Fields] OR 'patient-reported'[All Fields])'. No criteria on publication data were set, and all articles in English or German were included if published before 26 November 2023. We also checked reference lists in relevant articles and Google Scholar for additional references. Literature on specific questionnaires was searched separately and specifically for that questionnaire.

3 | PERSON-REPORTED MEASURES

PRMs include any measure that captures a person's experience of living with diabetes (Box 1). A subcategory of PRMs are PROs, which have been defined as 'any report that comes directly from patients about a health condition and its treatment' and 'without interpretation of the patient's responses by a physician or anyone else'.[14] PROs in diabetes cover a wide range of measures and ratings that include different domains such as diabetes symptoms, functional status (e.g. maintaining daily activities and fulfilling social roles), self-reported health status and overall quality of life (Figure 1). PROs focus on the outcomes of care, assessing if an intervention is able to reduce diabetes symptoms or improve functional status, self-perceived health status and overall quality of life.[15,16]

The second subcategory of PRMs are PREs, which refer to the experiences of people with diabetes with their treatment or care. These PREs can contain domains such as treatment satisfaction, treatment preferences, experience of health care services, including communication with health care providers, access to care, overall health care process and general climate of health care (Figure 1). PREs frequently refer to the process-quality of health care delivery. However, there may be some overlap between PROs and PREs; for example, some PREs, such as treatment satisfaction can be considered an outcome in clinical trials, as well as an important element of the diabetes care experience, which is considered an important process variable for positive outcomes.

3.1 | Measurement of person-reported outcomes and experiences

Person-reported assessments are collected through various methods, including questionnaires, surveys, interviews, or digital health tools. Measurement tools for capturing PROs are called person-reported outcome measures (PROMs), while person-reported experience measures (PREMs) are used for collecting PREs.

The most widely used and established PROMs or PREMs are based on questionnaires, as such results are more easily quantifiable. To provide useful and interpretable data, questionnaires must show objectivity (i.e. the assessment, scoring and interpretation of the data is standardized and not influenced by subjective factors of the assessor), reliability (i.e. the questionnaire is not biased by measurement error) and validity (i.e. the questionnaire assesses the construct it purports to measure). Measurement issues regarding PROMs have been

BOX 1 Definitions of key terms

PRM	Person-reported measures (PRMs) is the umbrella term containing the two specific concepts of person-reported outcomes (PROs) and person-reported experiences (PREs). It refers to any data reported directly by people with diabetes about their health, treatment experiences and outcomes or care.
PROs	PROs are defined as 'any report that comes directly from patients about a health condition and its treatment' and 'without interpretation of the patient's responses by a physician or anyone else'.[14]
PREs	PREs refer to the experiences of people with diabetes with their treatment or care, including treatment satisfaction, treatment preferences, experience of health care services such as communication with health care providers, access to care, overall health care process and the general climate of health care.
PROMs	Measurement tools for capturing PROs are called person-reported outcome measures (PROMs).
PREMs	Measurement tools for capturing PREs are called person-reported experience measures (PREMs).
Symptoms	Symptoms are subjective indications or manifestations of a condition, illness, or disease that a person experiences and may notice including for example pain, hypoglycaemia, fatigue and nausea.
Functional status	Degree to which functions such as maintaining daily activities (physical functioning), emotional stability (psychological functioning) or social roles and responsibilities (social functioning) can be fulfilled.
Health status	Overall perception of one's own general health, including physical and mental health.
Quality of life	Quality of life is a measure of general well-being and satisfaction with different aspects of a person's life, such as physical health, mental and emotional well-being, and social connections.
MCID	Minimum clinically important difference (MCID) refers to the smallest change in a PROM or PREM or other outcome that would be considered meaningful or important by people with diabetes, clinicians, or researchers. Such an MCID can be defined by anchor-based methods (e.g. the change exceeds a certain pre-defined threshold) or distribution-based methods (e.g. the change is greater than the average change in a reference sample).
Sensitivity to change	Sensitivity to change means that a questionnaire can reliably and validly capture and measure changes in a person's health, symptom exposure, function, or quality of life because of interventions, treatments, or natural progression of a condition.

expertly reviewed by Terwee et al. who define nine measurement properties for PROMs, including structural validity, construct validity, reliability and responsiveness.[16]

Questionnaires typically assess a health or symptom state using items that relate to a recall period in the past days, weeks, or even months (e.g. 'Over the past four weeks, have you felt …'), producing an overall retrospective rating. This retrospective approach can be subject to memory or recall bias (e.g. recency effect: more recent symptoms or experiences are often better remembered than earlier ones; and peak-end rule effect: symptoms or experiences with peak intensity are more salient and often more intensively remembered, thereby influencing the overall rating more than less intense ones even if the duration of the intense experience is shorter).[17,18] Ecological momentary assessment (EMA) is a method to overcome such recall bias.[19] EMA subsumes different methods that allow the repeated daily sampling of PROs in daily life. Usually via a special smartphone app in their everyday life ('ecological validity'), people are asked once or several times a day about their current experiences or health states ('momentary'; e.g. 'how do you feel right now?'), thereby allowing for a real-time and less biased measurement or 'assessment' of PROs. In diabetes research, increasingly more studies have used EMA to analyse the psychosocial impact of living with diabetes on a daily basis.[20-28] We recently proposed EMA-based PROs that calculate the percentage of days spent with elevated diabetes or glycaemia-specific distress (e.g. time with diabetes distress and time with hypoglycaemia distress),[22] which indicated higher associations with glycaemic parameters compared with questionnaires. Søholm et al. also used EMA to measure the daily impact of hypoglycaemia and could show satisfactory psychometric properties of their Hypo-METRICS app.[25]

The use of EMA allows not only the calculation of a mean value of a PROMs or PREMs score, but the assessment of the variability of these scores both within a day and over several days (e.g. by calculating coefficient of variation or root mean score of successive differences). Thus, EMA can map the differences in the daily experiences of managing diabetes.[22,28]

However, these advantages of EMA must be balanced against limitations regarding access to technologies, the burden of multiple and repeated assessments over several days, and the potential reactivity of repeated measures (i.e. changing the observed variable by increasing the attention to the variable of interest). In addition, the reliability and validity of EMA-based PROs need to be further investigated and their sensitivity to change showed in clinical trials. We therefore call for the simultaneous use of questionnaires and EMA in clinical trials to obtain a comprehensive picture of the associations and effects regarding PROs.

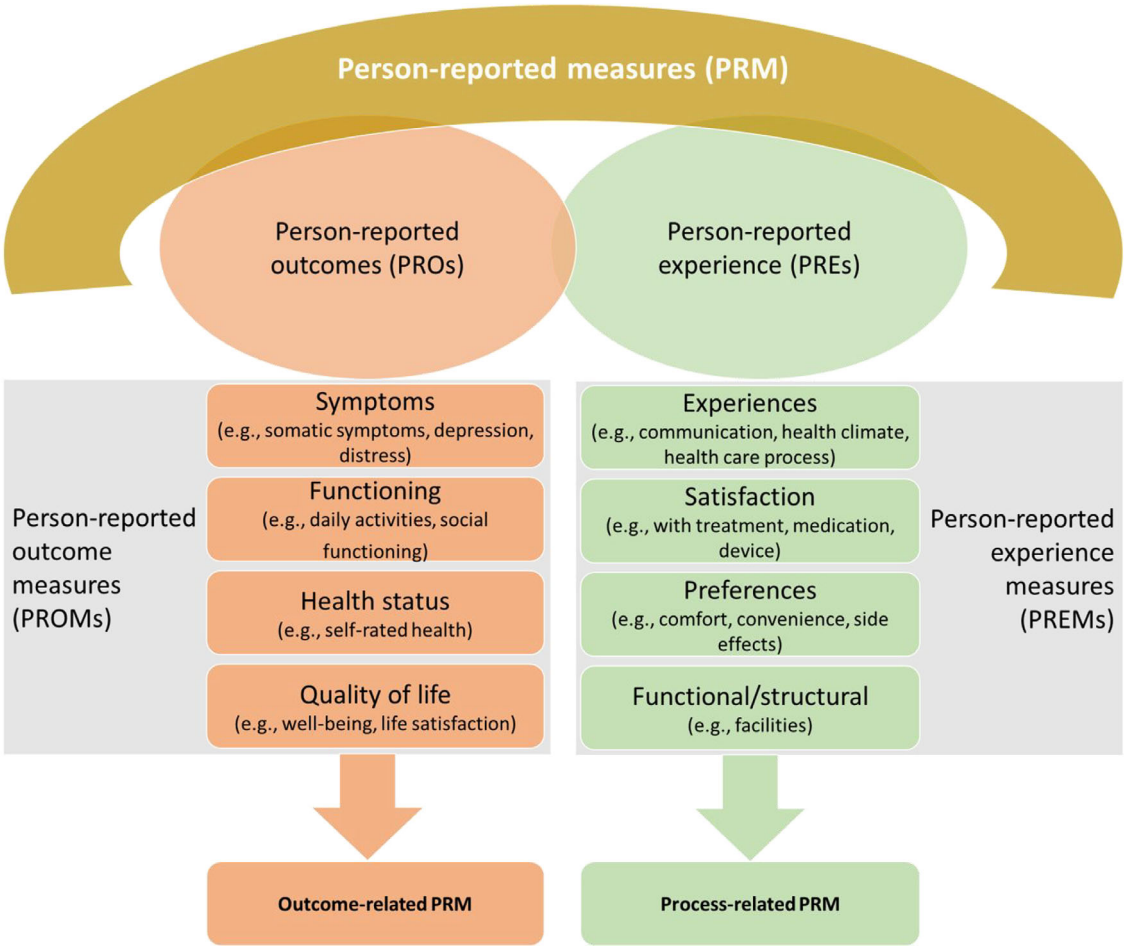

FIGURE 1 Conceptualization of person-related outcomes and experiences.

3.2 | Definition of core person-reported outcomes and experiences

There are a plethora of questionnaires assessing PROs and PREs in people with diabetes.[16,29,30] A systematic review by Hamilton et al. recently listed 53 diabetes-specific outcomes,[29] which reflects the multifaceted nature of PROMs and PREMs and the complexity of assessing the perspective of people with diabetes. However, this plethora of PROMs results in a lack of uniform assessment across studies and therefore limited comparability.[16] This lack of standardization makes it difficult to conduct meta-analysis on PROMs regarding effectiveness of interventions.[31] Therefore, there have been initiatives to define a core outcome set in diabetes.[16] The International Consortium for Health Outcomes Measurement (ICHOM) recommended measuring psychosocial well-being, diabetes distress and depression as core outcomes for clinical practice.[32] There have been several other recommendations from the United States, Germany, the Netherlands and Denmark.[33–36] A group of international experts from various interest and working groups recently formulated a consensus statement that has been endorsed by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD).[37] This consensus statement lists core domains for PROs in diabetes such as self-reported health and functioning, psychological well-being, diabetes-related distress, impact of diabetes on life quality, somatic symptom distress, hypoglycaemia episodes requiring assistance, burden of daily diabetes treatment and burden of hypoglycaemia. Based on these core domains, Table 1 lists key constructs and questionnaires for PROMs and PREMs.

In addition, there are several considerations for these constructs and questionnaires regarding their usefulness as outcome parameters, such as potential sensitivity to change and expected outcomes (Table 1). For example, depression and diabetes distress are important outcomes, but the sensitivity to change in outcome trials has differed on, for example, diabetes technology.[38] Another consideration is the specificity of the selected PROMs or PREMs to the effect of an evaluated intervention. For example, if interventions such as drugs or diabetes technology do not target the selected PROMs or PREMs but other aspects such as glycaemic control or morbidity, a positive effect on the selected PROMs or PREMs may not be expected. Rather, the absence of a worsening of, for example, diabetes distress suggests that the evaluated interventions exert no negative side-effects on the assessed outcome.

Another way to look at standardization is by integrating different items assessing the same PROs and PREs into item banks. Based on

TABLE 1 Core person-reported outcomes and person-reported experiences.

Core person-reported measures	Key constructs	Key questionnaires	Generic	Specific	Outcome considerations
Person-reported outcomes					
Self-reported health and functioning	Health status	EQ-5D[39,40]	X	-	• Important for calculating utilities and quality-adjusted life years • Utilities scores available for diabetes-related comorbidities and sensitive to the development[41] • Prone to ceiling effects: rather small effects on health status of slight or moderate problems[39,42–45] • For people with diabetes with only slight or moderate health problems: limited sensitivity to change[39,44,45] • Improvements from diabetes technology rather unlikely[38]
	Physical functioning	SF-36 physical component[46–48]	X	-	• Responsive to the development of diabetes complications[49] • Limited sensitivity to change in people with rather moderate health problems[45] • One-point lower score associated with 9% increased mortality[50] • Improvements from diabetes technology rather unlikely[38]
	Overall health	SF-36 first item[46–48] EQ-5D VAS[39,40]	X	-	• Reliability of one item can be questioned • Improvements from diabetes technology rather unlikely[38]
Psychological well-being	Well-being	WHO-5[51,52]	X	-	• Important screening tool for depression[53,54] • Responsive to psychiatric interventions[55] • Improvements from diabetes technology and medications rather unlikely because of breadth of issues beyond health[38] • Cannot be used as a medical claim because too general and not health-specific[56]
	Mental health	SF-36 mental component[46–48]	X	-	See discussion around SF-36 physical component
	Depression	• Patient Health Questionnaire (PHQ-9)[57] • Centre for Epidemiological Studies-Depression Scale (CES-D)[57]	X	-	• Data on sensitivity to change in people with diabetes is missing[57] • Improvements from diabetes technology and medications rather unlikely because of breadth of issues beyond health[38] • Non-deterioration of depressive symptoms can be seen as a positive outcome if intervention is directed at diabetes-specific outcomes • Relevant associations with somatic markers: HbA1c,[58,59] inflammation,[60,61] and complications[62]
Stress specific to diabetes	Diabetes distress	• Problem Areas in Diabetes (PAID)[63]; PAID-11[64] • Diabetes Distress Scale (DDS)[65] • T1-DDS[66]	-	X	• Rather good sensitivity to change,[67] also for the short form PAID-11[68] • Improvements from diabetes technology more likely compared with generic questionnaires (e.g., depression)[38] • Non-deterioration can be seen as a positive outcome • Can be used as a screening tool for depression[69,70] • Relevant associations with somatic markers: HbA1c[71] and heart rate variability[72]

TABLE 1 (Continued)

Core person-reported measures	Key constructs	Key questionnaires	Generic	Specific	Outcome considerations
Impact of diabetes on life quality	Diabetes-specific quality of life	Audit of Diabetes-Dependent Quality-of-Life (ADDQoL)[15,73]	-	X	• Sensitivity to change yet to be determined[15] • Consideration of individual preferences[15] • Can be difficult to assess because of difficult item wording ('if I did not have diabetes …') and scoring (multiplication of items)[74] • Difficult to compare to quality of life of other conditions
	Impact of diabetes	DAWN-2 Impact of Diabetes Questionnaire (DIDP)[15,75]	-	X	• Allows international benchmarking of the impact of diabetes[76] • Sensitivity to change yet to be determined[15] • Difficult to compare with quality of life of other conditions
Somatic symptom distress	Diabetes symptoms	Diabetes Symptoms Checklist-Revised (DSC-R)[77–79]	-	X	• Indicative of symptom-specific disease burden • Immediate outcome of glucose changes or complications • Covers a wide range of diabetes-specific symptoms: fatigue, cognitive symptoms, neuropathic pain, cardiovascular, hypoglycaemia, hyperglycaemia[78,79] • Small changes in mean symptom severity can be detected over a short time interval,[77] but long-term responsiveness needs further evaluation[78,79]
	Sleep	Pittsburgh Sleep Quality Index (PSQI)[80]	X	-	• Sleep problems associated with higher risk for comorbidities[81–83] • Important outcome also for parents of children with diabetes • Promising for evaluating the effect of automated insulin delivery systems (e.g.[84–87])
Hypoglycaemic episodes requiring assistance	Severe hypoglycaemia	Self-report	-	X	• Hard clinical endpoint • Can be used for health-economic analyses • Important adverse event • Non-occurrence can be considered a positive result • Level of assistance difficult to operationalize and standardize • Depending on recall rather than glycaemic data
Burden of hypoglycaemia	Fear of hypoglycaemia	Hypoglycaemia Fear Survey II (HFS-II)[88]	-	X	• Has been linked to health-related utility scores (EQ-5D), enabling potential health economic analyses[89] • Improvements from diabetes technology would probably be compared with generic questionnaires[38,90] • No established cut-off score for elevated fear of hypoglycaemia[91]
	Hypoglycaemia unawareness	• 'Clarke' questionnaire[92] • Gold score[93]	-	X	• Particularly suitable for epidemiological studies[94] • Risk factor for future severe hypoglycaemia[95] • Sensitivity to change can be questioned[95]
Daily diabetes treatment	Diabetes self-management	Diabetes Self-Management Questionnaire (DSMQ)[96,97]	-	X	• Rather good sensitivity to change of total score and subscales 'eating behaviour' and 'glucose monitoring'[97] • Measure of perceived self-management effort rather than actual behaviour • Assessed behaviour may not be applicable to modern diabetes technology (e.g. CGM, AID)

(Continues)

TABLE 1 (Continued)

Core person-reported measures	Key constructs	Key questionnaires	Generic	Specific	Outcome considerations
Person-reported experiences					
Satisfaction	Treatment satisfaction	Diabetes Treatment Satisfaction Questionnaire (DTSQ)[98]	-	X	• Potential outcome in clinical trials • Prone to ceiling effects[99] • Change version of DTSQ with increased sensitivity to change[100]
	Specific satisfaction	• Glucose Monitoring Satisfaction Survey (GMSS)[101] • Diabetes Impact and Device Satisfaction Scale (DIDS)[102]	-	X	• Potential outcome in clinical trials • Highly specific to users of certain diabetes technologies; difficult to compare to other studies • Increased sensitivity to change for users of diabetes technology[103,104]
Experiences	Experience of services	Patient Experience of Diabetes Services Survey (PEDS)[105]	-	X	• Not suitable as an outcome in clinical trials • Experiences often assessed via interviews[106,107]
	Health climate	Health Care Climate Questionnaire[108]	X	-	• Important variable for person-centred care[109] • Not suitable as an outcome in clinical trials
Preferences	Preference for one intervention/health service over another	No standardized questionnaires	-	X	• Important variable for person-centred care[110,111] • Not suitable as an outcome in clinical trials • Possible methods: discrete choice experiments (e.g. conjoint analysis), time trade-off exercises and willingness to pay • Highly specific; challenging to standardize[111]
Functional/structural	Satisfaction with health facilities	No standardized questionnaire	X	-	• Suitable for quality management • Not suitable as an outcome in clinical trials

item response theory, items are ranked by difficulty and presented to a person considering previous responses using a computerized adaptive testing algorithm (e.g. when assessing physical mobility, there is no need to ask a person if he/she can run 5 miles when a previous question revealed he/she cannot walk a few blocks). Such a process helps to shorten questionnaires while increasing the accuracy of measurement.[112] This approach forsakes the concept of fixed questionnaires, making a core outcome set of important PRO domains necessary but a core outcome set of specific questionnaires obsolete. Most prominently, such a computerized adaptive testing approach has been adapted by the Patient-Reported Outcomes Measurement Information System (PROMIS).[113] Although it was introduced in 2004, the routine application of the PROMIS tool in clinical practice and research in diabetes has been rather limited.[38,114]

3.3 | Different person-reported outcomes and experiences for different settings

The different approaches to reaching a consensus (e.g. ADA/EASD consensus,[37] ICHOM,[32] PROMIS[113] and H20[29]) overlap in part but vary in emphasis and focus. For example, PROMIS is more focused on promoting more generic PROMs, whereas ICHOM and the ADA/EASD consensus also advocate diabetes-specific PROMs such as diabetes distress while H20 provides an overview without specific recommendations. Generic PROMs may be more helpful for regulatory bodies and health policy makers as comparisons between conditions are possible. In contrast, diabetes-specific PROMs may be more useful for clinical practice in diabetes centres.

In addition, a core set of outcomes for different purposes may be appropriate for different uses of PROMs and PREMs. For example, fear of hypoglycaemia can be considered a core PRO, but significant changes when evaluating a lifestyle intervention for type 2 diabetes cannot be expected in contrast to the evaluation of diabetes technology. Similarly, improvements in generic quality of life may be expected from a psychosocial intervention targeting mental health, but not from a new variant of a diabetes drug. Thus, different core PROMs and PREMs may be needed for clinical practice, and evaluations of drugs, psychosocial interventions and diabetes technology. In summary, core domains of important PROs have been defined,[37] although recommendations for specific questionnaires for different purposes are still missing.

4 | BENEFICIARIES AND IMPORTANCE OF PERSON-REPORTED OUTCOMES AND EXPERIENCES

Figure 2 provides an overview of the different beneficiaries of PROs and PREs. At the top of the list are people with diabetes, followed by

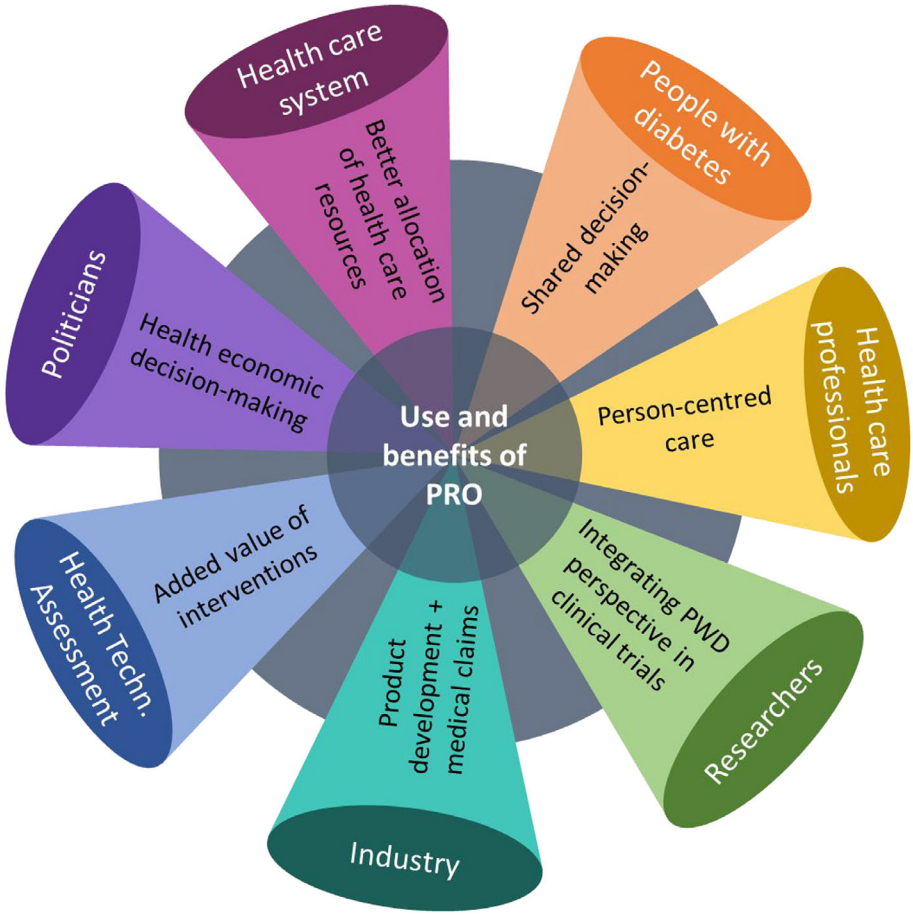

FIGURE 2 Use cases and benefits of PROs in diabetes. PRO, person-reported outcome; PWD, people with diabetes.

health care professionals. In the delivery of optimal health care, researchers, industry, regulators, policy makers and the health care system also benefit from the use of PROMs and PREMs.

Person-centred care includes shared decision-making. In shared decision-making, health care providers disclose information about the possible results, side effects and uncertainty of different therapies, while simultaneously accounting for the values, preferences and goals of the person. The monitoring of PROMs and PREMs regarding treatment delivery or diabetes management and discussing these results with persons with diabetes can empower them to communicate their preferences and concerns[115] as well as facilitate shared decision-making.[16,116] Such collaboration is essential for fostering a sense of ownership in managing the condition[8,117,118] and is recommend by guidelines.[5,6]

PROs and PREs can facilitate person-centred care, as health care professionals are able to address the context of living with diabetes from the perspective of affected persons and the impact of diabetes on a person's life along with the medical aspects.[119] Health care providers are therefore enabled to work with people to develop care plans tailored to their needs and goals, thereby promoting person-centred care, precision monitoring, and personalized medicine in diabetes.[120] The way people with diabetes view and evaluate treatment effectiveness or outcomes may differ from clinical measures alone.[121,122] For example, clinicians may focus more on the clinical effects of a treatment, whereas people with diabetes would probably highlight the adverse effects. By incorporating PROs and PREs into routine care, providers can gain valuable information about how people with diabetes view the impact of their diabetes management on their lives and how satisfied they are with specific pharmacological or technological interventions.[123-125] Furthermore, there is evidence that routine assessment of PROs can improve psychosocial well-being,[126,127] but regular assessment is required to ensure the sustaining of benefits.[128]

Including the perspective of people with diabetes can also inform outcomes research on the psychological impact of different diabetes management options.[16]

The results regarding PROs from clinical trials can then be used as labelling claims.[14] Moreover, the health care industry can use PROs at an earlier stage, for example, for product development. Integrating the perspectives of people with diabetes early in the development process can improve functionalities and acceptance of a product.[129]

Based on clinical trials, PROs can also be used by regulatory bodies to adjudicate an added value of an intervention.[122,130] If two interventions provide comparable glycaemic benefits, then results of PROs can tip the scales in favour of one or the other (e.g. if people with diabetes prefer weekly insulin injections instead of daily injections). Another dimension of PROs are health utilities to calculate quality-adjusted life years.[131] Health utilities can be expressed as preference

weights for different health-related quality of life states,[132] usually on a scale of 0 (indicating death) to 1 (indicating full health). Quality-adjusted life years are then calculated as the time a person has spent in a health state multiplied by the utility weight of that health state. This result provides a 'common currency'[132] and allows the calculation of a cost-benefit ratio of an intervention, which can be used by payers and policy makers to inform reimbursement decisions.[122,130,133] For PROs to have an impact on such decisions, health technology assessment agencies need to include PROs in their evaluation of medical devices and therapeutics. Although PROs have already been used in health technology assessment,[134,135] their systematic inclusion, particularly in digital health technologies,[136] should be more frequent.[135,136] The precedence of using PROs to claim medical benefits comes from the German Federal Institute for Drugs and Medical Devices (BfArM), who listed quality of life alongside morbidity and mortality as a hard medical outcome.[137]

Health care resource allocation can be improved by understanding the impact of a condition on the lives of the affected persons or their experiences with diabetes care delivery.[138] For example, if epidemiological data suggest that mental health problems such as depression are more common in people with diabetes, there may be a case for ongoing screening and monitoring of well-being to intervene before the adverse effects of depression become apparent in day-to-day diabetes management and long-term prognosis.[33,34,139] Thus, in the context of mental health problems, PROMs can help to identify people at risk, monitor progression and provide arguments for the timely allocation of resources.[140] Furthermore, PREMs can help to identify areas where people with diabetes feel delivery of health care is inadequate, which can help the health system to allocate appropriate resources. Box 2 summarizes the importance of PROs and PREs.

5 | INVOLVEMENT OF PEOPLE WITH DIABETES IN THE DEVELOPMENT OF PERSON-REPORTED OUTCOME MEASURES AND PERSON-REPORTED EXPERIENCE MEASURES

Current practices in the design and development of PROMs and PREMs have been driven mainly by psychometric experts. However, promoting person-centred clinical care and shared decision-making means advocating for an inclusive person-centred research and development process in the design of new PROMs and PREMs. Such a development process should aim to integrate the perspectives, experiences and expertise of people with diabetes throughout the entire process of PROMs and PREMs development, from the initial design stages through to implementation, analysis and dissemination of results.

BOX 2 Importance of patient- or person-reported measures

1. Shared decision-making: involving people with diabetes in deciding how to care for themselves is a key aspect of patient empowerment. Person-reported outcomes (PROs) facilitate shared decision-making by empowering people with diabetes to communicate their preferences and concerns with health care professionals. This cooperation is essential for the achievement of mutually agreed treatment goals.

2. Person-centred care: PROs and person-reported experiences (PREs) help to understand the experiences, preferences and priorities of people with diabetes. Understanding the impact of diabetes on a person's daily life allows health care professionals to tailor care plans to meet individual needs and goals (personalized medicine).

3. Impact of diabetes: peoples' perspectives on treatment effectiveness may differ from clinical measures alone. Including PROs gives health care professionals valuable information about how people with diabetes feel about their condition and how diabetes management affects their lives, thereby helping with the adjustment of treatment plans to improve adherence and outcomes.

4. Research and development: PROs are a valuable source of data for research efforts. They contribute to the development of more person-centred treatments and policies by providing researchers with measures of the effectiveness of different interventions on psychological functioning and quality of life.

5. Regulators: regulatory agencies can gain a more complete understanding of the impact of interventions on the lives of people with diabetes and make more informed decisions about interventions.

6. Health economic evaluation: some person-reported outcome measures can be transferred to quality-adjusted life years and thereby contribute to improved understanding of a risk-benefit ratio as well as supporting politicians and other stakeholders in health economic decision-making.

7. Health care resource allocation: allocation of health care resources can be improved by understanding the impact of diabetes on peoples' lives. Patient- or person-reported measures can also help to identify areas where additional support, education, or resources may be needed to improve the overall management of diabetes.

There are several advantages to actively involving people with diabetes in the development of PROMs and PREMs.[141] First, involving people with diabetes can help to provide assurance that the measures developed capture what matters most to people with the condition and their treatment. People with diabetes may highlight specific symptoms, side effects, or aspects of care that may otherwise be overlooked yet have a significant impact on their quality of life. This contributes to the validity of the developed measure.[142] Second, engaging people with diabetes in the development process helps ensure that measures use language and concepts that are understandable, thereby increasing the acceptability of such measures from the user's point of view and leading to an overall improvement in the usefulness of such measures in research and clinical settings.[35,142] Third, involving people with diabetes from different backgrounds, cultures and socio-economic levels can increase the likelihood that developed measures may encompass a wider range of experiences.

Furthermore, involving people with diabetes in the development of PROMs and PREMs can help to ensure that the regulatory processes for which these measures are used are more inclusive.

As mentioned, the involvement of people with diabetes in the development of PROMs and PREMs is still in its infancy.[142,143] Such integration could be achieved through early involvement of people with diabetes in the research process, their inclusion in research groups or advisory boards for this research, and a genuine desire for continual feedback from people with diabetes in the development and application phases.

6 | CHALLENGES FOR THE INTERPRETATION OF PERSON-REPORTED OUTCOME MEASURES AND PERSON-REPORTED EXPERIENCE MEASURES

Alongside a missing core outcome set and suboptimal involvement of people with diabetes in the development process, other challenges for regularly using PROMs and PREMs in clinical care and research exist. These other challenges refer to their sensitivity to change and the interpretation of changes in scores with regard to an MCID.

6.1 | Sensitivity to change

The response of a measure to changes in health-related quality of life, self-reported health status, or experiences of living with a condition has been referred to as sensitivity to change. Sensitivity to change is a requirement that is particularly important if PROs are used as outcome measures in clinical trials. In this case, it is important to be able to detect even small improvements or worsening of the participant's condition so as not to overlook a benefit or potential harm of an intervention.

Beyond clinical trials, sensitivity to change can be important in clinical practice. Monitoring and detecting changes in health states can help to identify clinically important changes to which individual treatment modifications can be made, preferably through a process of shared decision-making. Thus, sensitivity to change enables health care providers to understand and respond to changes in a patient's health status based on the patient's perspective.[144] In addition, sufficient sensitivity to change can be important for the health care system in identifying improvements or deterioration in the quality of health care.[145]

Furthermore, there are some threats to the sensitivity to change within PROMs and PREMs. The ceiling or floor effect, which means that improvements or deteriorations in the measure cannot be detected because the baseline values are already high or low, is a common problem in this context. For example, the EuroQol-5D (EQ-5D) is a commonly used health-related quality of life instrument. However, a multinational study of 3919 participants with eight disease groups, including diabetes, showed 33% reported the maximum index of '1'.[146] This meant that approximately a third of the subsample with diabetes could not show improvements because they already had the maximum score. If such a large proportion of people with diabetes have a maximum score to begin with, it becomes difficult to show a positive impact of an intervention with this PROM. Sullivan and Ghushchyan[41] showed, in a large sample of 20 705 participants, that rather significant health changes, such as the presence of a diabetes-related complication, lead to a reduction in the EQ-5D index of up to 17%, whereas the change of an antidiabetic medication, such as the addition of dapagliflozin, did not lead to a remarkable difference between the placebo and the dapagliflozin group (0.85 vs. 0.84).[147] This finding suggests that the generic EQ-5D instrument has low sensitivity to change regarding diabetes medications, leading to a decreased likelihood of detection of subtle changes in health status because of changes in diabetes management, such as the addition of specific drugs or technologies.[103,148]

In summary, sensitivity to change is an important characteristic for detecting diabetes treatment effects of small size or magnitude.

6.2 | Minimal clinically important difference

Another key issue in interpreting PROs relates to the magnitude of changes of a PROM or PREM to determine clinically important improvements respectively deteriorations. Naturally, the change in a PROM score can be interpreted using statistical significance testing, percentage of change from baseline or via standardized effect sizes (e.g. Cohen's d and Hedges' g). These methods do not usually answer the question as to what magnitude of change in a PROM or PREM is needed to be clinically significant. Thus, another way to interpret changes is the concept of MCID,[149,150] which has been described as 'the smallest difference in score in the domain of interest which patients perceive as beneficial and would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management'.[151]

There are multiple methods for determining MCID, such as anchor-based methods (e.g. change score based on a clinical assessment) and distribution-based methods (e.g. using standard error of measurement or reliable change index).[150] Useful examples of

applying distribution-based methods to define an MCID for diabetes distress were given by Fisher et al.[152] and Banks et al.[153]

The problem with anchor-based definitions such as using a cut-off [e.g. Problem Areas in Diabetes score (PAID) ≥40] is that small changes around this cut-off may lead to improvements that are considered clinically relevant (e.g. reduction in PAID scores from 41 to 39) while large improvements substantially above the cut-off (e.g. reduction in PAID scores from 60 to 41) are not considered clinically relevant. The issue concerning distribution-based methods is that clinical relevance is dependent on the specific sample studied and thus such findings are not comparable with other studies.

A proposal by the German Institute for Quality and Efficiency in Health Care (IQWIG) for evaluating the clinical importance of changes in PROMs and PREMs made the problem of a missing consensus for an MCID explicit. The IQWIG recently proposed an MCID of 15% of the scale range.[154] Translated to the CGM metric time in range, for example, this would mean a reduction of 15% of the percentage of glucose values between 70 and 180 mg/dl. To put this into perspective, automated insulin delivery systems achieve a mean increase in time in range of approximately 10%, which is clinically meaningful.[155] In addition, if this proposal were transferred to the evaluation of glycated haemoglobin improvements and we assume that glycated haemoglobin values range between 4% and 20%, the response criterion would be a reduction of approximately 2.4% points. Such a responder criterion is very uncommon, as recommendations for non-inferiority thresholds are between 0.3% and 0.4% points. Therefore, in our opinion, the high responder threshold of 15% is unnecessarily strict and (if embedded on a large scale) will be an obstacle for the integration of PROs into research and clinical care.

Furthermore, effect sizes of PROs are usually much smaller compared with glycaemic outcomes,[103] thus, a lower threshold of MCID would be appropriate. A recently published consensus statement on glycaemic outcomes considered a difference of ≥5% in time in range as clinically meaningful.[156] Such a margin of 5% of the scale range may also be a reasonable approach to MCID regarding PROs.

7 | CONCLUSION

PROs and PREs have considerable potential for people with diabetes, health care professionals, researchers and decision makers to improve diabetes care and treatment. PROMs and PREMs allow for the integration of the perspective and perceptions of people with diabetes into clinical care and research. This enables new models of care such as shared decision-making and a more personalized intervention. The evaluation of interventions and diabetes management also becomes more comprehensive by including psychosocial outcomes along with medical outcomes. In regulatory processes, the benefits or risks of diabetes management options in terms of PROs (such as reduced symptoms, reduced emotional distress, or improved quality of life) can become important criteria for the evaluation of interventions and diabetes technologies. Policy makers, payers and budget holders deciding on reimbursement issues might profit from health-economic evaluations based on PROMs. The perspectives and experiences of people with diabetes regarding the delivery of care and the perceived climate of health care can provide immediate feedback to health care providers about gaps and potential for improvement. In addition, quality of care ratings by people with diabetes can be used to benchmark diabetes care centres according to the quality of diabetes care they provide.

However, these relevant areas of potential concerning PROs and PREs can only be realized if current gaps in the assessment of PROs and PREs are addressed. One major problem is the lack of a consensus regarding core PROMs and PREMs.[29,31] For the evaluation of interventions, the plethora of questionnaires are a major barrier to the comparison of PREMs and PROMs and to aggregate the results of different trials in meta-analysis, which both usually play a major role in the outlining of evidence-based guidelines or reimbursement issues.[31] This lack of comparability may lead to an underestimation of the effect of an intervention on PROs or PREs because of a lack of aggregable studies, resulting in insufficient power to detect effects. Therefore, a consensus of experts concerning the core PROMs and PREMs is urgently needed.[31]

Many questionnaires used in outcome studies or in clinical care are not sensitive to change. This can be because of ceiling or floor effects of questionnaire scores at baseline, which make it more difficult to show improvement or deterioration of an outcome. Thus, psychometric criteria, such as item difficulty, should be accounted for when setting up a consensus about core PROMs.

Related to sensitivity to change is the discussion about MCID. When considering a change in an outcome or experience measure, the question arises if the observed change is clinically important in the desired or undesired direction. There remains no consensus about MCID in PROMs or PREMs and it is unclear how this consensus should look. Considering different scale ranges of the various questionnaires, using percentage of scale range or proportion of standard deviation, such as z- or T-scores, may be a way. Following the consensus regarding glycaemic parameters,[156] a consensus defining MCID for PROs is needed urgently because there are examples of regulatory bodies, such as the German IQWIG, defining such MCID in the absence of agreement between scientists and experts.[154]

PROMs and PREMs are usually based on questionnaires asking retrospectively about perceptions, emotions and thoughts in the past (e.g. during the last days or weeks). We argue that assessing PROs and PREs via EMA on a daily basis over several days in their everyday life can offer a more comprehensive picture of the impact of living with and managing diabetes. Mirroring the advancements of continuous glucose monitoring, aside from offering mean scores, EMA would enable calculating parameters of variability. In addition, EMA measures can easily be combined with other sensors, for example, glucose or activity sensors providing a multidimensional picture of living with diabetes.[120] However, further clarification is required on the role and potential of such digital multidimensional methods in the assessment of PROMs and PREMs and the impact on the evaluation of health care or for regulatory bodies.

Lastly, ethical considerations for the inclusion of PROs in research must be made, such as the clarity of the PRO-specific research question, literacy requirements, the schedule of PRO assessments,

monitoring for concerning responses, minimization of barriers to complete PROMs and the dissemination of results.[157]

In this review, we have described the implications of PROs and PREs for improving the integration of people with diabetes into clinical care by accounting for their assessments of outcomes and experiences. In addition, it was emphasized that PROs and PREs are important criteria when regulatory bodies or other payers involved in diabetes care are making reimbursement and health resource allocation decisions. The potential of digitization enables a more thorough and multifaceted collection of PROs and PREs in people with diabetes through the combination of EMA and traditional questionnaires. However, to take full advantage of the opportunities provided by PROs and PREs to achieve more person-centred care, the challenges outlined regarding lack of consensus on a core set of PROMs and PREMs, sensitivity to change and the non-existence of a standard MCID need to be addressed.

AUTHOR CONTRIBUTIONS

All authors reviewed the literature. NH and DE wrote the manuscript. BK contributed to the discussion and revised the content.

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CONFLICT OF INTEREST STATEMENT

NH reports Advisory Board member fees from Abbott Diabetes Care and Insulet as well as honoraria for lectures from Berlin Chemie AG, Becton Dickenson, Sanofi Germany, Roche Diabetes Care and Dexcom Germany. BK reports Advisory Board member fees from Abbott Diabetes Care, Embecta, Roche Diabetes Care, Novo Nordisk, Berlin Chemie AG and Dexcom Germany as well as honoraria for lectures from Sanofi Germany, Novo Nordisk, Abbott Diabetes Care, Roche Diabetes Care, Berlin Chemie AG, Embecta, Dexcom and Feen. In addition, BK reports support for travel and fees for scientific meetings from Sanofi, Roche Diabetes Care and Berlin Chemie AG as well as unpaid obligations as workshop leader and member of working groups of the German Diabetes Association. DE reports Advisory Board member fees from mySugr, Dexcom Germany and Roche Diabetes Care as well as honoraria for lectures from Berlin Chemie AG, Sanofi-Aventis, Dexcom Germany and Roche Diabetes Care.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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