**What is Valuable for Persons with Diabetes: Forming a Basis for Patient-Reported Outcome Measures**

**What is already known?**

* Patient-reported outcome measures (PROMs) evaluate care based on aspects that are deemed valuable for people with diabetes, but little is known about what truly matters to people with diabetes.

**What has this study found?**

* This study identified key aspects that matter most to people with Type 2 diabetes, which we argue are important to capture with the use of PROMs.

**What are the implications of the study?**

* In order to evaluate care based on aspects deemed valuable for people with diabetes, we recommend using: (1) The Problem Areas in Diabetes questionnaire; (2) a generic tool for measuring general health; and (3) measures of sexual dysfunction, financial burden, shared decision-making, and multidisciplinary care under one roof.

**Abstract**

**Aim**

This paper aims to explore diabetes-related experiences and identify aspects valuable for people with Type 2 diabetes that can serve as a basis for patient-reported outcome measures (PROMS).

**Methods**

There were five focus groups: three groups totalling 19 adults with Type 2 diabetes and two with 26 experts in diabetes healthcare. Purposive sampling enabled recruitment of heterogeneous participants. Discussions were recorded and transcribed. Thematic analyses of the transcripts were performed in accordance with the grounded theory approach.

**Results**

The analyses revealed four overarching domains that were deemed valuable for people with diabetes: (1) challenges of living with diabetes (reduced physical functioning, hypoglycaemia, healthy lifestyle struggles, sexual dysfunction and financial burden), (2) mental health issues (depression, distress, anxiety, fear, frustration and loneliness), (3) self-management abilities (management of lifestyle modifications and treatment, knowledge about the disease and treatment), (4) patient-clinician relationship (dedication of clinicians, trust in clinicians and treatment, shared decision-making and multidisciplinary care under one roof).

**Conclusions**

We recommend that researchers and health care providers, who intend to utilize PROMs for diabetes care, consider the aforementioned domains. Further, we recommend the use of a suitable diabetes-specific instrument, such as the Problem Areas in Diabetes questionnaire, which covers most of the identified domains from the current study, as well as a generic tool for measuring physical and mental health.

# **Introduction**

Healthcare has become more patient-centred, and the measurement of quality of care has gained increasing attention.1,2 Consequently, patient-reported outcome measures (PROMs evaluating care based on aspects deemed valuable to patients have emerged.3 PROMs-reported outcomes are defined as ‘any report coming directly from patients, without interpretation by physicians or others, about how they function or feel in relation to a health condition and its therapy’.3 PROMs, increasingly used in procedures and oncology, are associated with improved symptoms management, enhanced psychological well-being, and longer survival rates.4,5

Diabetes care aims to prevent complications and maintain patients’ quality of life.6 Thus, the American Diabetes Association (ADA) recommends routine monitoring.6,7 Today, programs evaluating diabetes care quality, including the Israeli National Program for Quality Indicators in Community Healthcare (QICH), primarily use clinical quality indicators.8,9 However, these are insufficient, as they do not monitor quality of life; thus, there measures that capture meaningful quality of life aspects among people with diabetes are needed.10 Some studies have addressed PROMs in diabetes.10–13 However, only two, one from Sweden14 and the other a multinational project of the International Consortium for Health Outcomes Measurement (ICHOM),10 considered perceptions of people with diabetes, which are necessary for forming a basis for PROMs. Little is known about what concerns people with diabetes and more research is needed to better understand their needs. Thus, we aimed to identify diabetes-related aspects that are valuable for persons with diabetes in order to provide a basis for PROMs.

# **Methods**

This qualitative study included five focus groups. Focus group research is a well-established approach15 in which participants present their experiences and beliefs in a group setting. Participants assume some parts of the interviewer role and the moderator becomes more of a listener. Focus groups create a rich dataset, enabling in-depth understanding of a particular topic due to interactions among participants and their exposure to others’ ideas and experiences in a realistic setting.15

This study included three focus groups of 19 adults with Type 2 diabetes and two focus groups of 26 healthcare providers involved in diabetes care: diabetes nurses, family physicians, diabetes physicians, social workers, and quality of care and PROMs experts. To identify valuable aspects for people with diabetes, the study had to be based on their own voices. In addition, experts’ perceptions were included to provide more testimony about what is valuable for people with diabetes, and to learn whether experts are in favour of using PROMs for diabetes, since their support is crucial for routine measurement.

To be included in the patient groups, individuals had to be between 45–80 years old and have had Type 2 diabetes for at least six months. Inclusion criteria were based on clinical records. Purposive sampling (heterogeneous) was utilized to recruit people with diverse demographics, diabetes duration, and diabetes complications. Participants were recruited from the outpatient clinics of Hadassah Medical Center and primary clinics of the Meuhedet healthcare organisation [one of Israel’s four health maintenance organisations (HMO)].

Focus group sessions were conducted between May 2017 and March 2018, in a private conference room in the hospital or at the HMO, and each lasted for 90 minutes. All groups were led by the same researcher using a semi-structured topic guide. Prior to beginning the discussion, patient participants completed an anonymous short demographic questionnaire. The patients’ discussion began with asking participants to describe their experiences living with diabetes, opinions on diabetes care and how they identify good quality care. The experts’ groups began with a brief introduction about PROMs, followed by questions asking them to describe their experiences of diabetes care, perceptions of valuable aspects of diabetes care for patients and opinions regarding PROMs. The expert groups and two of the patient groups were conducted in Hebrew, with the third conducted in Arabic, the participants’ native language. Interactions between participants provided meaningful insights and there was a sense of motivation and openness among participants in the discussions. The discussions were recorded with participants’ consent and later transcribed.

The data were analysed by the researcher who led the groups using grounded theory.16 Each transcript was read several times and then divided into meaningful units (unitizing). Meaningful units within the same topic were categorized into the same domain. Domains were labelled based on the natural language of the participants (in-vivo). Domains were then re-examined by the researcher who led the groups and checked by a second researcher. Differences were discussed and resolved. Analyses of the discussions of the fifth group resulted in repetitive domains; thus, it was concluded that no further data added substance to the analyses, i.e., data saturation had been reached. The study was approved by the Ethics Committee (Helsinki) of Hadassah Medical Center and the Meuhedet healthcare organisation.

# **Results**

Participants with Type 2 diabetes had a mean age of 65.1 years old (range: 45.2–76.8). Participants were diverse: 12 men, 7 women; 14 Jewish, 5 Arab; and 12 born in Israel and 7 born abroad. All religious groups were represented among Jewish and Arab participants, and all but three participants were married. The median time since diagnosis was 14.5 years (range: 0.5–36 years) and 8 participants were receiving insulin treatment.

**Valuable aspects for diabetes**

The analyses revealed four overarching aspectsdeemed valuablewith diabetes: (1) challenges of living with diabetes, (2) mental health issues, (3) self-management abilities and (4) the patient-clinician relationship. The following describes and provides examples of these domains and their sub-domains.

# Challenges of living with diabetes

This section introduces five main challenges emphasized in the groups: reduced physical functioning, healthy lifestyle struggles, hypoglycaemia, sexual dysfunction and financial burden due to diabetes.

 **Physical functioning and fatigue** were raised frequently by participants with diabetes. Diabetes reduced physical functioning, which was characterised by fatigue. For example, a participant with diabetes (PWD) reported that after his diabetes diagnosis he was: ‘(…) *more tired in the afternoon’.* Participants mentioned that feelings of fatigue affected their daily lives, limiting them in several respects, including performing home duties, engaging in physical activity and work productivity: ‘*Walking, functioning, home duties and* *dishwashing [is good] because sometimes diabetes is very exhausting’.* Additionally, a young PWD noted: ‘*You are less productive at work (…), there are things that are hard for me because I suffer from fatigue, so I need workers. [Other: Do you relate it to diabetes?] Of course’.*

Many participants voiced a desire for a treatment to eliminate fatigue: ‘*I want a medication or advice on how to behave to eliminate fatigue, at least’.* Others, mainly newly diagnosed patients, wondered if fatigue was related to diabetes: ‘*I suffer from fatigue, but I don’t relate it to diabetes. Now I am hearing from everybody that it could be; I'm very tired, I cannot walk for a long time, I feel fatigued...Now when I hear from others, maybe it is related to diabetes, I don’t know’.*

**Healthy lifestyle struggles.** Leading a healthy lifestyle, especially regarding diet and physical activity, emerged as essential challenges for people with diabetes, who claimed they wanted and tried to achieve a healthy lifestyle, but it was difficult to achieve. Regarding diet, people with diabetes noted that they faced many restrictions, stating that they were limited in their food options and that maintaining a healthy diet was difficult, particularly for those working outside the home.

*‘The diet is very difficult, it’s so hard. I don’t eat glucose, salt or fat, or any of those things. The biggest question is how to manage in life without eating anything, just vegetables all the time. And it's hard because I'm often outside the home’.* Regarding physical activity, people with diabetes emphasized that fatigue (due to diabetes) and financial factors were barriers. One remarked: *’If you engage in physical activity, even walking, it [glucose] decreases. I think it helps, but with the fatigue, it's hard’.*

Support from others, especially family, was raised as essential for achieving a healthy lifestyle (e.g., preparing healthy meals and encouraging physical activity). However, participants also found it challenging when others pressured them to eat unhealthy foods, especially in social meetings*: ‘Parties, at parties it’s very hard, you know. They know I’m diabetic and using insulin. It’s annoying when others pressure me to eat things that I shouldn’t’.*

## **Hypoglycaemia** was described as a major problem. Participants shared their hypoglycaemic experiences and described the events: ‘*I felt like a zombie; not connected to my surroundings. I almost lost consciousness many times, I had sweaty palms and felt severely weak’.*

Hypoglycaemic experiences were described as traumatic and participants feared experiencing them again: ‘*My biggest problem (…) was that for four months I had severe hypoglycaemia every night. I woke up in the middle of night looking for something to eat, I walked while sleeping, and I fell many times (…)* *I don’t want to be hypoglycaemic again*’.

Experts highlighted the importance of asking patients about their fear of hypoglycaemia: ‘*Fear of hypoglycaemic events is very important’.*

**Sexual dysfunction**due to diabetes was raised in the groups by both people with diabetes and experts. A young PWD mentioned:

‘*Diabetes negatively influences many things, I was in bad condition, I was depressed, and it affected my social life. Let’s be honest, when a person has a high glucose level, their life with their partner changes, it’s not a normal life. Maybe the person won’t talk about all this, but when I lowered my glucose level, it gave [me] more power and more enjoyment’.*

The experts suggested asking patients about sexual dysfunction, which is relevant for both sexes. However, they also noted that this issue usually does not arise at medical appointments. One diabetes physicians said: *‘I want to ask [using a questionnaire], for example, about impotence since we usually don’t ask, and it’s usually uncomfortable for us to ask since the patient is accompanied by a family member. And it will be more comfortable for the patient’.*

##  *The* ***financial burden*** from diabetes,primarily due to medication costs, was evident from participants’ responses and appeared to be a barrier to treatment for some patients.

*‘There’s a new medication that’s effective. But the packet costs 250 shekels [73 USD]. What about the worker or elderly who live off of their pension, how could they pay for that? They cannot’.*

In addition, gym fees and the loss of productivity at work increased patient participants’ financial burden. A young man remarked: ‘*You have to work out, it costs money. You’re less productive at work, that also costs money’.* Additionally, a woman who experienced kidney failure said: ‘*I need to go to the gym. But the gym costs money. In our neighbourhood, there are no suitable parks for walking’.*

## Mental health aspects

Diabetes is a demanding chronic disease, affecting physical and mental health. Individuals with diabetes experience a variety of emotions and mental health disorders, including depression, distress, anxiety, fear, frustration, and loneliness. Mental health was one of the most prominent issues emphasized by patients and experts. One expert remarked: ‘*The mental aspect is important. It’s important to ask not only about depression, but also fear, worry and anxiety’.* A PWD suggested: ‘*I think they [HMOs] should employ a health-provider: a physician or a nurse to address the patient’s psychological issues’.*

A diabetes diagnosis requires that patients implement lifestyle modifications and restrictions, which may cause depression. For example, a newly diagnosed PWD reported:

*‘Diabetes causes depression because suddenly you have to change your lifestyle completely. You have to think about what you put in your mouth, what you do, you need to sleep well without getting up to go to the bathroom several times’.*

Another cause of depression patients mentioned was needing medications, especially among those needing multiple medications.

*‘When going to the pharmacy, people act as if they’re in a supermarket. You collapse immediately when carrying the medications. You’ll be depressed just from the number of medications’.*

Anxiety and fear over developing diabetes complications were the dominant mental health related aspects mentioned across all groups: *‘My father had diabetes and, at age 80, his leg was amputated. This led to many thoughts, to fear and anxiety’.* A newly diagnosed PWD related: ‘*I read about diabetes and its complications; it scares me’.*

Preventing complications was considered the most valuable outcome among participants with diabetes and experts. As one PWD mentioned: *‘I want to die healthy, I don’t want all these complications, I don’t want to reach a point that I experience these complications’.* An expert remarked: *‘We need to add some questions [PROMs]concerning diabetes complications, since this is what we’re trying to prevent’.* The experts explained that mental health aspects typically do not arise during medical appointments, suggesting that health providers could use PROMs as a signalling system to help assess when and with whom they should address mental health issues.

# Self-management abilities

Another meaningful domain was patients’ self-management abilities; essentially, patients’ ability to manage the lifestyle modifications inherent in living with diabetes, and symptoms and treatment. The person with diabetes is the cornerstone of the treatment process, as a PWD emphasized: ‘*The treatment is in her own hands [the patient’s responsibility] and not in that of the physician’s (…) I was determined to reduce my glucose levels’.* A diabetes physician mentioned: ‘*Lack of treatment empowerment is one of the problems. Patients should advance the success of their treatment’.*

People with diabetes make daily decisions regarding food, activity and medications. To make the right decisions, patients need guidance from their health providers. Patient empowerment, being informed about one’s disease and treatment, stood out as essential for successful self-management. However, patients complained that they did not receive enough information from their health providers: *‘There’s a lack of information. I have no idea what to do. I would like to comprehend the information and not only to receive instructions, to understand what I’m doing’.*

Lack of knowledge about the disease, especially among the newly diagnosed, caused confusion. To prevent confusion, participants preferred receiving relevant information from health providers rather than online.

*‘The problem is that, even though I’m talking about myself and my own illness, I just don’t know! There is diabetes type 1 and type 2. I’ve read a lot, but I don’t know what is relevant* *to me and what is not. I mean, the lack of knowledge (…) Since there is lack of knowledge, the more I read, the more I’m [other patient: more worried, more scared], yes, more scared but also more confused’.*

Patients believed that raising awareness about diabetes and its treatment would increase compliance:

*‘Today, patients have many sources of information to read about diabetes. I think it could be problematic. If we have an informative/educational group, we can learn about diabetes, its complications and what might happen in the future. It could increase patient compliance’.*

# Patient-clinician relationship

The patient-clinician relationship was prominent in all the discussions and primarily reflected participant demands.

*The* ***dedication*** of clinicians was emphasized by the PWDs as a critical factor increasing increases their adherence*: ‘I go to my check-up by him [the physician] after some time has passed and I know he’s devoted so much to my care. He wants to help me and then, what? I won’t listen to him? No, he’s helped me so much’.*

***Trust in*** clinicians and the treatment is a key component of the treatment process according to the experts. One diabetes physicians stated: ‘*A very simple question I ask myself with every patient is, does the patient believe in me? Does the patient believe in the medications I give him? These are two main questions’.*

Another physician remarked: ‘*The key question is: Does the patient believe in his treatment? It is highly important for diabetes care. It may not be so important for other diseases, such as cancer and multiple sclerosis, for which patients believe completely in their treatment. In diabetes, there is much less belief and patients want natural treatment’.*

Indeed, PWDs stated that they do not trust antidiabetic medications and believe they are harmful and cause complications. As one PWD noted: *‘The pills are harmful, 40% of patients have kidney disease complications because of medications’.* In another group, a newly diagnosed PWD reported: *‘I have read about medications that cause harm. Yes, they’re harmful in the long term. Maybe not in the short term, but if you take medications for years it’s not good’.* One PWD summarized: ‘*I think we need someone to guide patients who don’t want to take medications/pills, maybe to go in a natural way, use alternative medicine. Why can’t the healthcare organizations suggest a solution for this? Or maybe they do, but we don’t know about it’.*

## ***Shared decision-making*** was another demand that people with diabetes raised. They wanted an informative treatment plan and the option to choose another treatment plan if they do not accept the proposed treatment, medications, or diet.

*‘I don’t want to be given a limited approach. What did the dietitian tell me? This is the diet that I give you and if you don’t (…) [accept], I have nothing more to say. Also, the physician said, “Why are you coming to me if you don’t agree with the treatment?” There should also be an alternative (…) they should tell me, okay, there is A and there is B. There should be more than one option but that does not exist’.*

***Multidisciplinary care*** under one roof and during the same visit was a highly important factor among individuals with diabetes. They indicated that not having this could be a treatment barrier.

*‘When it's all under one roof and provided at the same time, it's much more efficient (…) it's easier. It's not that today I'm going to a family physician or a diabetes physician and on Thursday I have to go to a dietitian’.*

The domains described here were found valuable for people with diabetes. After running the focus groups, we performed a literature search to identify well-validated questionnaires. We found that the Problem Areas in Diabetes (PAID)17 questionnaire covered most of the domains that arose in this study.

**Discussion**

This study identified valuable aspects for people with diabetes that can be used as the basis for PROMs in diabetes care. The analyses revealed four overarching aspects. First, several challenges that people with diabetes reported facing included decreased physical functioning, fatigue, struggles implementing a healthy lifestyle, hypoglycaemia, sexual dysfunction and financial burdens. Second, various negative emotions and mental health issues accompanied life with diabetes, including anxiety, distress, loneliness and depression. Third, self-management ability arose as a cornerstone of the treatment process which could be improved with guidance and support by health care providers. Fourth, the patient-clinician relationship was emphasized, including the importance of shared decision-making, and trust in the clinicians and prescribed antidiabetic medications. This is apparently the first study in Israel addressing PROMs in diabetes care.

This study identified several significant challenges for people with diabetes, including fatigue and reduced physical functioning, hypoglycaemia, and struggles implementing a healthy lifestyle. Consistent with previous studies,12,13,18,19 results indicated that these challenges lowered individuals’ self-reported quality of life and interrupted their daily activities. Another challenge was sexual dysfunction. Experts suggested that PROMs could be helpful in addressing this sensitive issue, which is usually not discussed during medical appointments. Sexual dysfunction is highly prevalent in people with Type 2 diabetes (up to 85%),20 and is a central concern for both men and women.21 However, the problem is often neglected since patients expect health providers to initiate this discussion, and they usually do not.21 Another challenge was the financial burden (medication costs, gym fees and lost productivity at work). In the United Sates, studies have shown that people with diabetes face a financial burden specifically because of their diabetes.22,23 Noteworthy is that in Israel, all residents enjoy universal healthcare, which covers some of the antidiabetic medications’ costs. However, medication cost is still a challenge, and 10% of people with diabetes are non-adherent with medications due to cost.24

Although several previous studies have identified challenges of living with diabetes, our study has specified which of the challenges are important to capture using PROMs.

The results show that diabetes has a major effect on patient mental health. Consistent with our results, previous studies have shown that diabetes is associated with a wide range of emotional consequences, including shock, stress, anxiety, fear, frustration, loneliness, guilt and depression.22,23,25 This study expands on previous studies, suggesting that mental health aspects are relevant and important to capture using PROMs. The term ‘diabetes distress’ commonly used refers to the wide range of emotional states patients experience.26 It is highly prevalent among adults, has negative impacts on self-care behaviors26 and is recommended for routine monitoring in diabetes care.6,10

This study found that self-management ability is a valuable aspect for persons with diabetes, and health providers have a crucial role in enhancing patients’ abilities to manage their diabetes by supplying information about the disease and its treatment. However, participants in this study and prior studies conducted in other countries12,27,28 noted that patients receive insufficient information from clinicians, or do not understand the provided information.

Our findings indicated that the patient-clinician relationship is an important aspect for people with diabetes, affecting self-care behaviours and treatment adherence. Previous studies have shown that people with diabetes who trusted their clinicians were more likely to have higher self-efficacy and greater treatment adherence.29 It is recommended that physicians provide patients with more information and engage them in shared decision-making to enhance patient trust.30

Expert discussions revealed that health providers favour using PROMs in diabetes care and even need them to help improve the treatment process, particularly for sensitive issues such as mental states and sexual dysfunction. One of the experts summarized: ‘*I think these measures [PROMs] are more important than some measures that we have today. I say this definitively, I would like to see more of these measures and less of the clinical measures’.*

The ADA recommends routinely monitoring PROMs in diabetes care using standardized and validated tools.6,7 Numerous diabetes-specific tools exist in the literature, and a recent review presented approximately ten of these tools, such as PAID and the Audit of Diabetes Dependent Quality of Life.31 PAID a well-validated and widely-used questionnaire,17 was found to be the most suitable for addressing the domains that arose in this study. Moreover, recently, ICHOM recommended using PAID as the standardized diabetes-specific tool for PROMs.10 PROMs are usually accessed with two types of questionnaires: generic and disease-specific.32 Our results indicated that diabetes affects general (physical and mental) health, but that the latter is usually not directly attributed to diabetes, according to participants with diabetes. Thus, we recommend using a generic measurement tool for assessing general health (e.g., the Global Health PROMIS-1033 or the Short Form Health Survey SF-12).34 In addition, we strongly recommend adding items addressing important issues not covered in these questionnaires that arose in this study: sexual dysfunction, financial burden, shared decision-making and multidisciplinary care under one roof.

Our study had some limitations. First, we focused on Type 2 diabetes (accounting for 90% of all diabetes cases); thus, meaningful issues specific to Type 1 diabetes were not investigated. Second, this study does not represent all people with Type 2 diabetes or all experts in Israel; consequently, there may be more perspectives. However, we deliberately included a heterogeneous participant sample and identified prominent domains.

Our study had several strengths. First, it was based on the voices of people with diabetes, which is necessary for PROMs. Second, we added experts’ perceptions and assessed whether experts were in favour of PROMs for diabetes routine care. Third, recruitment efforts were aimed toward participants with diverse characteristics, strengthening our study’s credibility. Finally, the suitable diabetes-specific questionnaire that we found to be in accordance with our results (PAID), was also recommended by ICHOM, reinforcing our findings.

In conclusion, this study identified aspects perceived to be most valuable to people with Type 2 diabetes, representing an important first step in the future routine use of PROMs. PROMs are essential for patients and experts in addressing issues largely not addressed in routine diabetes care. We recommend that researchers and health care providers intending to utilize PROMs for routine diabetes care consider the aforementioned domains and use a suitable diabetes-specific instrument, such as PAID, which covers most of them. Additionally, we note that a generic tool is essential for assessing physical and mental health. In future research regarding incorporating PROMs into diabetes care, we plan to assess associations between socio-demographic variables and clinical quality indicators using PROMs.

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