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

הנחיות חשובות לצורך עריכת המאמר:

* Manuscript must be written in British spelling.
* Preferred style is ‘people (or person or individual) with diabetes’ or ‘in the group without diabetes’, rather than ‘diabetic people (or person)’, 'diabetic patient' or ‘non-diabetic group’.
* 'Men' and 'women' should be used in preference to 'males' and 'females'.
* ‘Participant(s)’ or ‘person’/’people is preferred to ‘patient(s)’ or ‘subject(s)’.
* Abstract (maximum 250 words), paper ) maximum 4000 words(.

**What is already known?**

* Patient-Reported Outcome Measures (PROMs), evaluate care based on valuable aspects to people with diabetes, but little is known about what truly matters to people with diabetes.

**What this study has found?**

* This study identified key aspects that matter most to people with type 2 diabetes which are significant to capture using PROMs.

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

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

**Abstract**

**Aim**

To explore diabetes related experiences and to identify valuable aspects for people with type 2 diabetes in order to provide a basis for PROMs.

**Methods**

Five focus groups were conducted including three groups with 19 adults with type 2 diabetes and two focus groups with 26 experts in diabetes healthcare. Purposive sampling generated heterogeneous characteristics. Discussions were recorded and transcribed. Thematic analyses of the transcripts followed the grounded theory approach.

**Results**

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

**Conclusions**

We recommend researchers and health care providers, who intend to utilize PROMs for diabetes care, to include the above-mentioned domains. Using a suitable diabetes-spesific instrument such as the Problem Areas in Diabetes questionnaire, which cover most of the domains. And, a generic tool is essential for measurement of physical and mental health.

# **Introduction**

In the last decades, health care becoming more patient-centered and measuring quality of care has gained increasing attention1,2. These trends have led to the emergence of Patient-Reported Outcome Measures (PROMs), that evaluate care based on valuable aspects to the patients3. Patient-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. Use of PROMs has proliferated in procedures and oncology, where it has been associated with improved symptoms management, enhanced psychological well-being, and longer survival4,5.

Diabetes care aims to prevent complications and to maintain satisfactory quality of life6. Thus the American Diabetes Association (ADA), recommend to monitor routinely these aims6,7. To date, programs that evaluate the quality of diabetes care, including the Israeli National Program for Quality Indicators in Community Healthcare (QICH) use mainly clinical quality indicators8,9. However, clinical indicators are insufficient since they do not monitor the quality of life and there is a need for measures that capture meaningful aspects to people with diabetes10. Few studies have addressed PROMs in diabetes10–13. However, only two considered perceptions of people with diabetes which are necessary as a basis for PROMs; one from Sweden14 and the other is a multinational effort in the framework of the International Consortium for Health Outcomes Measurement (ICHOM)10. Little is known about what truly matters to people with diabetes and more research is needed to gain an in-depth understanding. Thus, we aimed to identify diabetes related aspects that are valuable to persons with diabetes in order to provide a basis for PROMs.

# **Methods**

This qualitative study included five focus group discussions. Focus group research is a well-established research approach15. It is a group interview in which participants present their experiences and beliefs, also they hear from others. Participants take over some of the interviewer role and the moderator is more in the listener position. Focus groups create a rich data and in-depth understanding of the discussed topic owing to participant’s interaction and the opportunity to be exposed to ideas, and experiences in a naturalistic setting15.

This study included three focus groups with 19 adults with type 2 diabetes and two focus groups with 26 healthcare providers involved in diabetes care; diabetes nurses, family physicians, diabetes physicians, social workers, quality of care and PROM experts (experts’ groups).

To identify valuable aspects for people with diabetes, it was necessary to base on their voice. In addition, experts perceptions were taken into account as an auxiliary voice of what are important for people with diabetes. And to learn if the experts are in favor of PROMs for diabetes since their support is crucial for routine measurement.

To be included in the patient groups, people had to be 45-80 years old and with type 2 diabetes for at least six months. Eligibility for inclusion was based on clinical records, and purposive sampling (heterogeneous) aimed people with diverse demographics, diabetes duration, and diabetes-complications. Recruitment was from outpatient clinics of Hadassah Medical Center and primary clinics of the Meuhedet healthcare organisation (one of the four Israeli health maintenance organisations- HMO).

Focus groups were conducted between May 2017 and March 2018. The groups took place in a private conference room in the hospital or the HMO, and each lasted for 90 minutes.

All groups were led by the same researcher (N.A.) using a semi-structured topic guide. Participants with diabetes initially completed an anonymous short demographic questionnaire, then the discussion began, they were asked to describe their experiences of living with diabetes, opinions on diabetes care and how they identify a good quality of diabetes care. Experts’ groups began with brief introduction about PROMs, then experts were asked to describe experiences of diabetes care, what is value for people with diabetes to receive from diabetes care and what are their opinions regarding PROMs. Experts’ groups and two of the patients’ groups were run in Hebrew and one patients’ group in Arabic according to the native language of the participants. The interaction between participantes produced meaningful insights and there was a sense of motivation and openness to participat in the discussions. The discussions were recorded with participant’s consent and then were transcribed.

The data were analyzed (N.A.), using grounded theory16. Each transcript was read several times then was split into meaning units (unitizing). Meaning units belong to the same content were categorized to the same domain. Domains were labeled based on the natural language of the participants (in-vivo). The domains were re-examined (N.A.) and checked (S.R.), differences were discussed and resolved. In the fifth group, the raised domains were repetitive and no further data added substance to the analyses, i.e., data saturation has been reached.

The study was approved by the Ethical committee (Helsinki) of Hadassah Medical Center and Meuhedet healthcare organisation.

# **Results**

Participants with type 2 diabetes were 65.1 years old (range: 45.2-76.8 years), with diverse demographics (men:12 and women:7, Jews:14 and Arabs: 5, born in Israeli:12 and born abroad :7), from all religious groups, and all but three were married. Median diabetes duration was 14.5 years (range: 0.5-36 years) and 8 treated with insulin.

**Valuable aspects in diabetes**

The analyses revealed four overarching aspectsthat valuable in diabetes: (1) challenges of living with diabetes, (2) mental health aspects, (3) self-management ability and (4) patient-clinician relationship. In the following sections, these four overarching domains and the domains that consisting them are described with accompanying exemplifying quotes.

# Challenges of living with diabetes

In this section, we introduce five main challenges (reduced physical functioning, healthy lifestyle struggles, hypoglycemia, sexual dysfunction and financial burden of diabetes) which emphasized in the groups.

 **Physical functioning and fatigue** brought up frequently by participants with diabetes. Diabetes reduced physical function and charecterised with fatigue. For example, when the interviewer asked: “*to give an example of* *something that emerged after the diagnosis of diabetes”,* participant with diabetes (PWD) replied: “(…) *more tired in the afternoon*”.

Participants mentioned that fatigue affects their daily life and limits them in several aspects including home duties, physical activity and it reduces their productivity at work: *"Walking, functioning, home duties and* *dishwashing [is good] because sometimes diabetes is very exhausting"* (PWD).

A young PWD mentioned: “*You have less productivity at work (…), there are things that are hard for me to do because I suffer from fatigue, so I need workers. [Other: Do you relate it to diabetes?] Sure.”* (PWD).

Participants with diabetes want a treatment that eliminates fatigue, e.g., : “*I want a medication or how to behave to eliminate fatigue at least*” (PWD).

Participants with diabetes, mainly newly diagnosed, wondered if the fatigue that they have is related to diabetes: *“I suffer from fatigue but I did not relate it to diabetes. Now I am hearing from everybody that could be related to diabetes; I'm very tired, I cannot walk a lot, I have fatigue ... Now when I hear others, maybe it's related to diabetes, I do not know.”*

**Healthy lifestyle struggles.** Healthy lifestyle, especially diet and physical activity, emerged as one of the essential challenges for people with diabetes. People with diabetes want and invest efforts to achieve a healthy lifestyle, however, it is difficult to achieve it. Regarding diet, people with diabetes faced many restrictions; they are limited in food options and it is hard to maintain a healthy diet especially for people who work outside the home.

*“The diet is very difficult. It is so hard; do not eat glucose, salt or fat and all that. 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” (PWD).*

Regarding physical activity, people with diabetes emphasized that fatigue due to diabetes and financial factors are barriers. A PWD remarked: *"If you do sport, walking, it [glucose] reduces. I think it helps. But with fatigue it's hard”* (PWD)*.*

Support from others, especially the family, was brought up as essential for achieving a healthy lifestyle (e.g, preparing healthy meals and encouraging physical activity). On the other hand, it is a challenge when people push them to eat unhealthy foods especially in social meetings*: “Parties, at parties very hard, you know. They know I am diabetic and using insulin. It is annoying that others push me to eat things that I shouldn’t”* (PWD)*.*

## **Hypoglycemia** was described as a major problem. Participants shared with us their hypoglycemia experiences and described the events: “*I felt like a zombie; not connected to the surroundings. I almost lost conscious many times, with sweat in palms and severe weakness*” (PWD).

Hypoglycemic experiences are traumatic and participants afraid to experience it again.

“*My biggest problem (…) during four months I had severe hypoglycemic every night. I wake up in the middle of night looking for something to eat, I walked while sleeping, and I fell many times (…)* *I do not want to be hypoglycemic again”* (PWD)*.*

Experts highlighted the importance of asking about fear of hypoglycemia: *“Fear of hypoglycemia events is very important”* (Expert-E)*.*

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

 *“Diabetes influences many things badly, I was in a bad condition, depressed and it affected my social life. Let’s be more open minded when the person has a high level of glucose the life with the partner is changed and not the normal life, sincerely. Maybe the person will not talk about all this, but when I reduce the glucose level it gave [me] more power and more enjoyment.”* (PWD)*.*

The experts suggested to ask about sexual dysfunction, which is relevant for women as well as men, and the issue usually does not come up at the medical appointment. One of the diabetes physicians mentioned: *“I want to ask [using a questionnaire] for example about impotence since we usually don’t ask, and usually uncomfortable for us to ask since the patient is accompanied by a family member. And it will be more comfortable for the patient”* (E).

##  ***Financial burden*** related to diabetesmainly medication costs came up clearly and seemed to be a treatment barrier for some patients.

*"There is a new medication that is effective. But the packet costs 250 shekels [73 dollars]. Poor the worker or elderly who receives pension, how could they pay for that? They cannot”* (PWD).

In addition, gym fees and less productivity at work due to diabetes increase the financial burden. A young man mentioned: *“You have to do sports, it costs money. You have less productivity at work, it also costs money.”* (PWD). And a woman with a kidney failure said: “*I need to go to the gym. But the gym costs money. In our neighborhood there is no suitable parks for walking.” (PWD).*

## Mental health aspects

Diabetes is a demanding chronic disease that affects not only the physical health but also the mental health status. Various emotions accompanied the life with diabetes, including depression, distress, anxiety, fear, frustration and loneliness. And mental health was one of the most valuable issues that the patients and the experts emphasized.

One of the experts remarked: "*The mental aspect is important. Not just depression, to ask about fear, worry and anxiety*" (E).

A PWD mentioned: *“I think they [HMOs] should employ a health-provider; a physician or a nurse to address the psychological issue of the patient”* (PWD).

Being diagnosed with diabetes imposes lifestyle modifications and restrictions which cause depression. For example, a newly diagnosed PWD mentioned:

*“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 going to the bathroom several times”* (PWD)*.*

Another cause of depression, was the need for medications, especially among patients who need multiple medications.

*“Now go to the pharmacy, people go out as if they were in a supermarket. You collapse immediately when you carry the medications. You will be depressed just from the medications amount.”* (PWD)*.*

Anxiety and fear of developing diabetes-complications were the dominant mental aspects in all groups;*“My father had diabetes and at the age of 80, his leg was amputated, this led to many thoughts, fear and anxiety”* (PWD)*.* And a newly diagnosed PWD said: *“I read about diabetes and its complications, this scares me”*.

Prevention of diabetes complications was raised as the most valuable outcome for participant with diabetes and experts, PWD mentioned:*“I want to die healthy, I do not want all these complications, I do not want to reach these complications”* (PWD)*.* And an expert remarked: *“Need to add some questions [PROMs] concerning diabetes-complications, since this what we are trying to prevent”* (E)*.*

The experts estimated that mental health aspects do not come up usually at the medical appointment. And PROMs could help health providers as a signaling system when and with whom they should address mental health aspects.

# Self-management ability

Another meaningful domain was self-management ability; patient’s ability to manage the lifestyle modifications inherent in living with diabetes, as well as management of symptoms and the treatment.

The person with diabetes is the cornerstone in the treatment process, a PWD emphasized: *“The treatment of everybody is into her own hands [in the responsibility of the patient] and not of the physician (…) I was determined reducing glucose levels*” (PWD).

Also,a diabetes physician mentioned:  *"Lack of treatment empowerment is one of the problems. Patients should advance the success of treatment" (E).*

People with diabetes make daily decisions regarding food, activity and medications. And to be able to take the write decisions they need guidance from the health providers. Empowerment of the patient, i.e. to be informed about the disease and treatment stood out as essential for the success of self-management. However, patients mentioned that they did not receive enough information from the health providers.

*“There is 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 am doing”* (PWD)*.*

Lack of knowledge about the disease, especially among newly diagnosed, causes a confusing. And to prevent confusing, participants prefer to receive the relevant information from the health providers instead of searching for it online.

*“The problem is, I am talking about myself, I do not know! There is diabetes type 1 and type 2. I have read a lot but I do not 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 [other patient: more worried, more scared] yes more scared but also more confused”* (PWD).

Raising awareness about diabetes and the treatment will increase compliance, due to PWDs.

*“Today patients have many sources of information, to read about diabetes, I think it could be problematic. If we have an informative/educational group, what is diabetes? what are the complications? What might happen? It could increase patient’s compliance”* (PWD).

# Patient-clinician relationship

Patient-clinician relationship was prominently reflected in all the discussions and included mainly participants’ demands.

***Dedication*** of clinicians was emphasized by the PWDs as a critical factor that increases their adherence.
*“I'm going to be checked by him [the physician] after a while and I know he devoted so much. He wants to help me and I will not listen to him? No. He helped me so much” (PWD).*

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

And another remarked:*“The key question is: Does the patient believe in his treatment? It is highly important in diabetes while it may not be for other diseases such as cancer and multiple sclerosis where the patients believe completely in their treatment. In diabetes it much less and patients want natural treatment”* (E).

Indeed, PWDs mentioned that they do not trust the antidiabetic medications and they believe that medications are harmful and cause complications, a PWD noted: *“The pills are harmful, 40% of the patients who complicated with kidney disease because of medications”* (PWD).

And in another group, a newly diagnosied PWD mentioned: *"I have read about medications that harm. Yes, they are harmful in the long-term. Maybe not for the short-term but if you take medications for years it is not good"* (PWD).

One of the PWDs summarized the discussion regarding medications: *“I think we need someone to guide the patients who do not want medications/ pills. So maybe in a natural way, alternative medicine. Why the health plan cannot suggest a solution for this? Or they have but we do not know about that.” (PWD)*.

## ***Shared decision-making*** was one of the demands, people with diabetes want an informative treatment plan and to have the option to choose another treatment plan if they do not accept the proposed treatment; medications or a diet.

 *“Not to be in a limited approach, what did the dietitian tell me? ("This is the diet that I give you and if you do not (…) [accept] I have nothing to add”). 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: O.K. there is A and there is B. Should be more than one option but that does not exist”* (PWD)*.*

***Multidisciplinary care*** under one roof and at the same visit emerged by the patients as highly important, and lack of it could be a treatment barrier.

 *“When it's all under one roof 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.”* (PWD).

The above-detailed domains were found as valuable to people with diabetes. We performed a literature search to identify well-validated questionnaires and the Problem Areas in Diabetes (PAID)17 was found to cover most of the domains that have arisen in the present study.

**Discussion**

This study identified valuable aspects for people with diabetes that can be used as the basis for PROMs in diabetes. The analyses revealed four overarching aspects. First, several challenges have been found to face people with diabetes including decrease in physical function and fatigue, healthy lifestyle struggles, hypoglycemia, sexual dysfunction and financial burden. Second, various negative emotions found to be accompany the life with diabetes; anxiety, distress, loneliness and depression. Third, self-management ability arose in the discussions as a cornerstone in the treatment process which can be improved with guidance and support by the health providers. Fourth, the patient-clinician relationship was emphasized in the groups, including shared decision-making, trust in the clinicians and antidiabetic medications. To the best of our knowledge, this is the first study in Israel that addressed PROMs in diabetes care.

The current study identified several challenges of living with diabetes that were of importance to people with diabetes, such as fatigue and reduced physical functioning, hypoglycemia, healthy lifestyle struggles. The results indicate, in aggrement with previous studies12,13,18,19, that these challenges lowers the individual’s quality of life and interrupted daily activities. Another challenge that arose in the current study was sexual dysfunction, and experts suggested that PROMs could be helpful in addressing such a sensitive issue which usually does not address at the medical appointment. Sexual dysfunction is highly prevalent (up to 85%) in people with type 2 diabetes20 and it is a central concern for both men and women21. However, the problem is often neglected, since health providers usually does not address the issue and patients expect from them to initiate this discussion21. Another challenge that arose in the discussions was diabetes related financial burden (medication costs, gym fees and less productivity at work). Also in the U.S., people with diabetes face financial burden of diabetes22,23. Noteworthy, in Israel, all residents enjoy the coverage of universal health insurance including some of the antidiabetic medications cost. However, medications cost is still a challenge, and 10% of people with diabetes non-adherent to medications due to cost24. Although several previous studies have identified challenges of living with diabetes, our study have identified which of the challenges were relevant to capture using PROMs.

Diabetes had a major effect on the mental health as reflected in the results. Similarly to 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 depression22,23,25. The current study add to the previous studies and suggests that mental health aspects are relevant to capture using PROMs. The term “diabetes distress” is commonly used to capture the wide range of emotional status26. Diabetes distress is highly prevalent among adults, has negative impacts on self-care behaviors26 and it was recommended to be monitored routinely in diabetes care6,10.

The current study found that self-mangement ability is a valuable aspect to persons with diabetes, and health providers had a crucial role in enhancing persons’ ability to mange diabetes by supplying information about the disease and the treatment. Howevere, participants in this study and in studies from others countries12,27,28 noted that insufficient information was being provided for them by clinicians or they do not understand the provided information.

Our findings showed that patient-clinician relationship is a valuable issue for the people with diabetes, it affects self-care behaviors and adherence to treatment. Previous studies have shown that people with diabetes who trusted their clinicians were more likely to have a higher self-efficacy and a better adherence29. And physicians should give their patients more information and to engage them in shared decision-making to enhance the patient trust30.

Expert discussions revealed that health-providers are in favor of PROMs in diabetes care and even in need for these measures which could help them to improve the treatment process particularly for sensitive issues such as mental status and sexual dysfunction. One of the experts summarized: *"I think these measures (PROMs) more important than some measures that we have today, I say this sharply I would like to see more of these measures and less of the clinical measures"* (E)*.*

The ADA recommend to monitor routinely PROMs in diabetes care using standardized and validated tools6,7. Numerous diabetes-specific tools exist in the literature, a recent review presented approximately ten of these tools, such as the PAID, and the Audit of Diabetes Dependent Quality of Life31. PAID is a well validated and widely used questionnaire17 which was found to be the most suitable questionnaire to cover the domains that have arisen in the present study. Moreover, recently ICHOM recommended PAID as the standardized diabetes-specific tool for PROMs10. PROMs are usually collected using two types of questionnaires, generic and disease-specific32. Our results indicate that diabetes affects the general (physical and mental) health but the latter usually not directly attributed to diabetes as expressed by the participants with diabetes. Thus, we recommended to use a generic tool for measurement of general health (e.g., the Global Health PROMIS-1033 or the Short Form Health Survey SF-1234) . In addition, we highly recommend to add items that measuring four important issues to people with diabetes which were not covered by the above questionnaires: sexual dysfunction, financial burden, shared decision-making and multidisciplinary care under one roof.

Our study has few limitations. First, we chose to focus on type 2 diabetes (accounts for 90% of all diabetes cases) thus issues that valuable specifically in type 1 diabetes were not heard. Second, this study does not represent all the people with type 2 diabetes or experts in Israel. Thus, there may be more voices that were not heard. However, we deliberately sampled heterogeneous participants and considered domains that stood out strongly.

Our study also has some strengths. First, we based on voices of people with diabetes which is necessary for PROMs. Second, we add information from experts’ perceptions and assessed whether the experts are in favor of PROMs in diabete routine care. Third, the recruitment aimed toward participants with diverse characteristics which strengthened the study credibility. Finally, the suitable diabetes-spesific questionnaire that we found (PAID) was recommended also by ICHOM.

**In conclusion**, this study has identified valuable aspects perceived to be most important for people with type 2 diabetes that as the first step in future routine use of PROMs. PROMs are essential to patients and experts for addressing issues which mostly were not addressed in routine diabetes care. We recommend researchers and health care providers, who intend to utilize PROMs for routine diabetes care, to consider the above mentioned domains, using a suitable diabetes-specific instrument such as PAID, which cover most of the domains. And, a generic tool is essential for measurement of physical and mental health. For next steps in implementation of PROMs in diabetes care, we plan to assess the associations between socio-demographic variables and clinical quality indicators with PROMs.

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