

Patient-reported outcome measures in diabetes outpatient care: a scoping review

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ABSTRACT

Background Patient-reported outcome (PRO) measures are increasingly used in clinical diabetes care to increase patient involvement and improve healthcare services. The objectives were to identify instruments used to measure PROs in outpatient diabetes clinics and to investigate the use of these PRO measures alongside the experiences of patients and healthcare personnel in a clinical setting.

Research Design and Methods A scoping review was conducted according to the framework of Arksey and O'Malley with scoping searches of Cinahl, EMBASE, Medline and Health and Psychosocial Instruments. Studies reporting on adults with diabetes in a clinical setting where the PRO measure response directly affected patient care were eligible for inclusion.

Results In total, 35 197 citations were identified, of which 7 reports presenting 4 different PRO measures were included in the review. All four of the included items measured psychosocial aspects of diabetes, and three included elements of the Problem Areas in Diabetes scale. All the patients were satisfied with the use of PRO measures in clinical care, whereas the level of satisfaction among healthcare personnel with PRO measures varied within and among studies.

Conclusions The limited number of eligible studies in this review suggests that research on PRO measures for diabetes outpatient care is scarce. Patients welcome the opportunity to express their concerns through the systematic collection of PRO measures, and some healthcare personnel value the broader insight that PRO measures provide into the impact of diabetes on patients' lives. However, the heterogeneity among services and among patients challenges the implementation of PRO measures. Research is needed to explore how PRO measures in clinical outpatient care affect healthcare personnel workflow.

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KEY MESSAGES

- ⇒ Subjective patient-reported outcome (PRO) measures may complement clinical parameters that reflect objective measures of diabetes and self-management.
- ⇒ Four PRO measures for diabetes were identified, all covering psychosocial aspects of diabetes.
- ⇒ Heterogeneity among clinics has consequences for the development, implementation and relevance of PRO measures.
- ⇒ It seems that patients with diabetes are more satisfied with the use of PRO measures in clinical care compared with healthcare personnel.

diabetes self-management can compromise quality of life.^{9–10} To better support individuals in diabetes self-management, there remains a need for ongoing and continuous diabetes care in the healthcare service. Over the last decade, attention on flexible, user-led, patient-centered services has increased.^{11–12} Flexible services that are reliable for both the patient and healthcare personnel rely on valid, reliable and trustworthy data. Such data can be obtained directly from patients if they have the opportunity to systematically self-report their current health status and health needs.¹³ In clinical settings, patient self-reporting is increasingly applied to gather subjective reports from patients through patient-reported outcome (PRO) measures. Allowing patients to self-report their personal experiences and needs relating to their diabetes alongside clinical parameters, such as blood glucose values, time-in-range, time-out-of-range or hemoglobin A1c (HbA1c), can enable healthcare personnel to assess the need for contact or consultations with healthcare services.¹¹

In a clinical setting, for example, in an outpatient consultation, PRO measures are intended to promote communication between patients and healthcare professionals to enable person-centred, individualized

BACKGROUND

Diabetes is a complex disease requiring continuous self-management to reduce and prevent late complications. Diabetes self-management can be associated with psychological issues, such as distress,^{1–2} anxiety,^{3–4} depression,^{5–6} fear of late complications⁷ and episodes of hypoglycemia or hyperglycemia.⁸ As a result,



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care.^{12 14} Research has shown that patients value PRO measures preconsultation, particularly free-text fields where they can add details to standardized questions.¹⁵ In this way, subjective PRO measures may complement the clinical measures that reflect the objective side of the disease and self-management. According to the Norwegian National Health and Hospital Plan for 2020–2023, the use of PROs can both individualize care and increase the effectiveness of care.¹⁶ However, to fulfil their potential, PRO measures should address patient-specific concerns.^{17 18} In addition, healthcare personnel need guidance and training in using and interpreting PRO measures.¹⁵

According to the literature, there is a lack of systematic research on the application of PRO measures in diabetes care in clinical settings, including research in which PRO measures may be most useful. According to previous research, PRO measures appear to be effective in general¹⁹ in supporting communication between patients and providers.²⁰ However, the success of digital PRO measures rely on a successful implementation.²¹ Given the reduction in hospital beds and, consequently, the rise in outpatient care, the use of PRO measures has the potential to guide more flexible and resource-effective outpatient diabetes care. To guide the rapid development of PRO-based and flexible diabetes outpatient care, a scoping review of the available research and its characteristics is warranted.

The objectives were to identify instruments used to measure PROs in outpatient diabetes clinics and to investigate the use of these PRO measures alongside the experiences of patients and healthcare personnel in a clinical setting.

METHODS

An a priori protocol for this scoping review has been archived in the Open Science Framework database.²²

Design

The scoping review was carried out according to the framework of Arksey and O’Malley.²³ According to this framework, the following five steps were followed: (i) identifying the research question, (ii) identifying relevant studies, (iii) selecting eligible studies, (iv) charting the data and (v) collating and summarizing the results. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews statement guided our report.²⁴

Identifying the research question

The main research question this scoping review set out to answer was: What are the currently available instruments to measure PRO measures in diabetes outpatient care, how are these PRO measures used and what are the experiences with these instruments? To transform this research question into a searchable format, we applied the population, concept and context tool.²⁵ The *population* of interest included adults with type 1 or type 2

diabetes, and the *concept* of interest was PRO measures in an outpatient clinical *context*.

Identifying relevant studies

After discussion with a librarian on the preliminary search string, use of Medical Subject Headings terms or keywords and search results, we adjusted the search strategy in line with the research question and the population, concept and context tool.²⁵ An initial search of the following databases was conducted on September 18, 2020 and repeated on May 12, 2022 and March 4, 2023: Cinahl, EMBASE, Medline and Health and Psychosocial Instruments. The search string, including search terms related to ‘patient-reported outcome measurements’ and ‘diabetes’, was tailored to each database. Gray literature was not included in the present review. The Medline search string can be found in online supplemental file 1.

Selecting eligible studies

The target *population* in this scoping review consisted of adults with diabetes mellitus treated in the *context* of ambulatory/outpatient care (table 1). Studies on individuals with type 1 and type 2 diabetes were included in the review. Studies that included individuals with prediabetes or gestational diabetes were not included. Studies that described the use of PRO measures or patient-reported experience measures in ambulatory/outpatient consultations were included. In addition, studies describing parallel/related measurements surveying patients’ disease experiences, with qualitative, quantitative or mixed-method designs, were included. Previous reviews were excluded. All the included literature had to be peer-reviewed and published in the scientific literature between 2015 and 2022 in English or Scandinavian.

The search results were uploaded and managed using the software Covidence.²⁶ The studies were screened by title and abstract and then assessed for full-text eligibility. Two reviewers independently screened these in both phases, and potential conflicts were resolved by discussions between the first and last authors until consensus was reached. The first and last author assessed the first 300 citations to evaluate the specificity of the inclusion and exclusion criteria before the remaining reviewers were granted access to start their assessments.

Charting the data

The data were charted in Covidence²⁶ using a predefined form developed and tested by the first and last author to generate a detailed summary of the use of PRO measures in diabetes care in outpatient clinic consultations. Preliminary defined categories were the study characteristics (author, year, country, context, study design and methods), participants’ characteristics (number of patients, type of diabetes, age, gender and/or number of healthcare personnel), PRO measure focus, PRO measures used and results and experiences related to the use of these PRO measures. The categories were discussed during the data charting process.

**Table 1** Characteristics of the included reports (n=7)

| Study, country | Aim as described in the reports | Methods | Setting | Participants |
|--|---|--|--|---|
| Bachmeier et al, ²⁹ Australia | To assess the usage and acceptance of a Diabetes Psychosocial Assessment Tool and to profile the clinical and psychosocial characteristics of young people with diabetes. | Experimental cross-sectional study | Tertiary center diabetes multidisciplinary clinic | N=155 patients 87 females (56%), 96% with type 1 diabetes Mean age: 20.7 (2.2) 18–25 years |
| Haugstvedt et al, ^{*30} Norway | To explore nurses' and physicians' experiences of diabetes consultations in general and the use of dialogue tools in the DiaPROM pilot trial. | Qualitative study with semi-structured in-depth interviews | Diabetes outpatient clinic | N=14 healthcare personnel Nine physicians and five nurses |
| Hernar et al, ³³ Norway | To examine the feasibility and acceptability of capturing PRO measures electronically using a touchscreen computer in clinical diabetes practice. | Feasibility study using cross-sectional data and field observations | Outpatient clinic in a university hospital | N=69 patients 34 females (49%), all with type 1 diabetes Median age: 51 years (40–74) |
| Hernar et al, ^{*27} Norway A | To pilot test the proposed DiaPROM trial components and address uncertainties associated with conducting a full-scale randomized controlled trial to evaluate whether such a trial is feasible. | Randomized controlled trial | Endocrinology outpatient clinic in a university hospital | N=80 patients 40 females (50%), all with type 1 diabetes Mean age: 27.2 (5.0) years |
| Hernar et al, ^{*31} Norway B | To explore young adults' experiences of outpatient follow-up appointments, completing electronic PRO measures and using the Problem Areas in Diabetes scale during the DiaPROM pilot trial. | Qualitative study with semi-structured interviews | Diabetes outpatient clinic | N=19 patients 11 females (58%), all with type 1 diabetes Mean age: 30 (5.2) years |
| Jensen et al, ^{†34} | To investigate patients' experiences using DiabetesFlex Care. | Qualitative study with semi-structured interviews | Diabetes outpatient clinic | N=36 patients 23 females (64%), all with type 1 diabetes Mean age: not reported |
| Laurberg et al, ^{†28} Denmark | To assess the impact of healthcare-initiated visits versus patient-controlled flexible visits on clinical and PROs in individuals with type 1 diabetes. | Randomized controlled trial | A large publicly funded outpatient clinic | N=343 patients 151 females (47%), all with type 1 diabetes Mean age: 48 (14) years |
| Skovlund et al, ³² Denmark | To evaluate the feasibility, acceptability and perceived benefits and impacts of using a digital PRO diabetes tool, DiaProfil, in routine outpatient diabetes care. | A formative, mixed-methods, single-arm, acceptability, feasibility pilot study | Diabetes outpatient clinic | N=12 patients Seven females (58%), eight with type 1 diabetes (67%) and four with type 2 diabetes (33%) Median age: 56.6 (24–79) years N=4 healthcare personnel (two nurses and two physicians), three female (75%) All had >5 years of diabetes care experience, with some previous involvement with the design of the PRO diabetes tool |

*Reports from the same project intervention.

†Reports from the same project intervention.

DiaPROM, Diabetes Patient-Related Outcome Measures; PRO, patient-reported outcome.

Collating and summarizing the results

The first and last author reviewed and summarized the extracted data in Excel and Word. The findings were systematized in tables according to our study aim and descriptively presented in the text. Preliminary versions of the result tables were presented to the three remaining authors for comments, insights, reflections and any new contributions to the analysis. Based on these reflections, the results were collated and a disposition for the discussion was established. A methodological appraisal was not conducted, as this was a scoping review.

Consultation exercises

For increased relevance of our review's contribution to both the clinical and academic environment, we undertook two consultation exercises. There is no definite consensus on how to proceed with and conduct consultation exercises.²³ Our purpose was to add legitimacy to our findings, by inviting stakeholders to review and discuss preliminary results. The first consultation exercise involved the research team undertaking this review when the data extraction was completed. The second consultation exercise involved healthcare personnel and researchers at a diabetes specialist outpatient clinic when the last search and data extraction were completed. The results are presented as a narrative summary.

RESULTS

The scoping searches

The search yielded 35 197 citations. After removing duplicate records ($n=11\,201$) and screening titles and abstracts, the full texts of 137 reports were assessed. Finally, seven reports^{27–34} were included, reporting on four studies (figure 1). Many reports were excluded because the PRO measures were not applied for clinical purposes, without consequences for patient care in a 'here and now' perspective.

General characteristics

There was a limited spread in terms of geography, with two reports from Denmark,^{27 28} one from Australia²⁹ and one from Norway.^{30 31} The included reports were published between 2019 and 2022 (table 1). Among the seven reports, there were two randomized controlled trials,^{27 28} two mixed-method feasibility studies,^{28 32} two qualitative evaluations^{30 31} and one experimental cross-sectional study.²⁹ The reports included experiences of patients ($n=659$),^{27–29 31–34} and healthcare personnel ($n=18$).^{30 32}

The identified PRO measures

Three of the PRO measure interventions used previously validated tools, in addition to single items.^{28 29 34} The

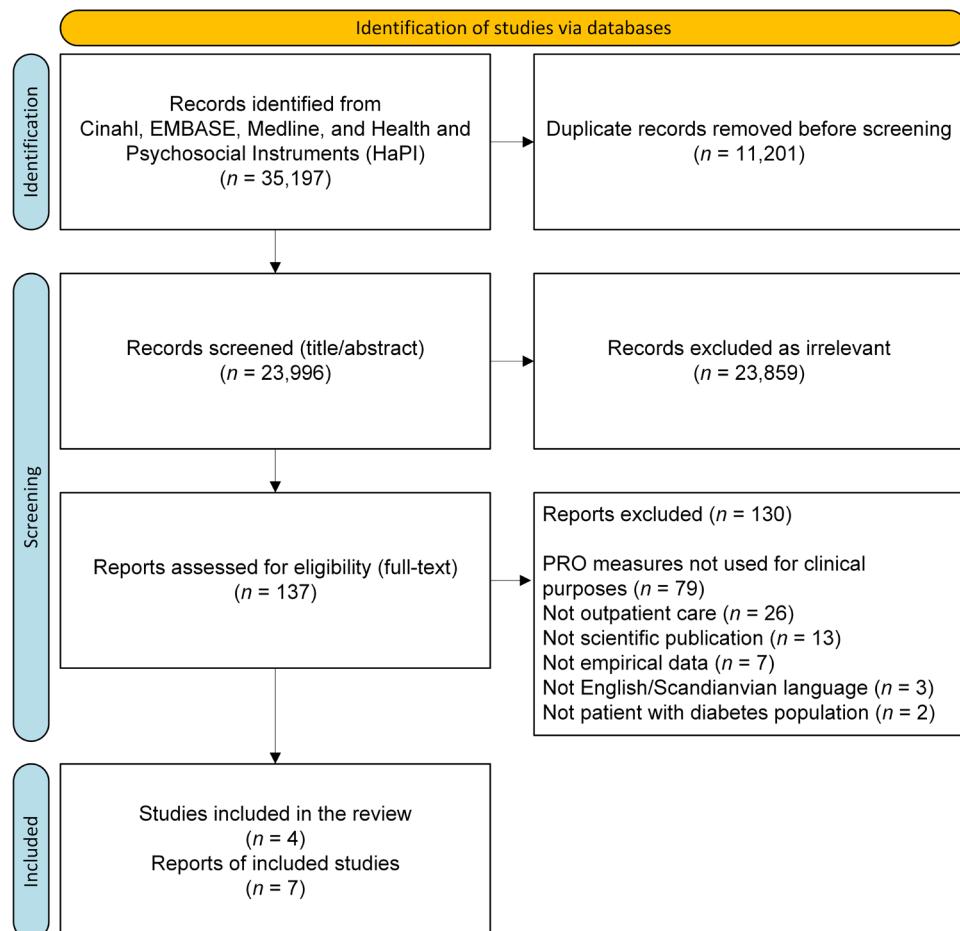


Figure 1 Flow chart. PRO, patient-reported outcome.

Norwegian DiaPROM pilot trial and study^{28 32} was based solely on PAID to assess diabetes distress (table 2). The focus of the PRO measures in both Danish studies was multidimensional and included various themes, such as general health, well-being, self-management, symptoms, complications and patients' concerns,^{28 32} similar to the psychosocial focus in the Australian study.²⁹ Except for one study,³⁰ all the PRO measure interventions included some or all items of PAID. Two studies included WHO-5 to assess emotional well-being in the PRO measure intervention.^{28 32} One study applied the Patient Health Questionnaire-4 measuring symptoms of anxiety and depression,²⁹ and one used one item of 36-Item Short Form Health Survey for overall health.^{28 32} Single items complement the previously validated PRO measures in three interventions.^{28 29 32} Figure 2 illustrates the various PRO measure focus in the interventions.

The PRO measure interventions were all administrated using digital solutions, either in the waiting area of an outpatient clinic or prior to an appointment. Similarly, all the interventions aimed for a preconsultation review of the PRO measure reports by healthcare personnel, thus, aiming to address essential issues and discussing these in the consecutive consultation. In addition, the PRO measure reports could lead to a joint health plan or extra follow-up. In the DiabetesFlex intervention, the participants could choose either digital or physical consultations at the end of their PRO measure report.²⁸

Findings and experiences on the use of PRO measures in the clinic

Patients were satisfied with the digital solutions used to report the PRO measures, as they were easy to use (table 3).^{28 29 32 33} However, there were mixed results regarding the value of the PRO reports on patient follow-up. In the DiaPROM study, patients said that the PRO reports were of limited value during consultations.^{27 31} In contrast, in the study by Bachmeier *et al*,²⁹ the patients stated that the PRO reports were of value in identifying important issues otherwise not addressed. Furthermore, the focus on living with diabetes,^{28 29 31 32} the opportunity to be more open-minded in consultations³¹ and the ability to choose digital consultations were regarded as positive.²⁸

From the healthcare personnel perspective, the time constraints and opportunity to secure intervention fidelity were challenges found in the DiaPROM study.^{27 30} In contrast, Skovlund *et al*³² found that healthcare personnel managed to provide the intervention as intended. Notably, one healthcare worker in the qualitative study by Haugstvedt *et al*³⁰ considered it paradoxical that a PRO measure was required to shed light on a patient's problems rather than acquiring this information during dialogue with the patient in the consultation. However, if a patient reported multiple problems, it became more complex for healthcare personnel to assess the patient's care needs. Only the healthcare personnel in the study by Skovlund *et al*³² were asked whether they

would like to continue using the PRO measures and the healthcare personnel responded positively.

Results of the consultation exercises

The first consultation exercise involved the five researchers who conducted the review, as only the first and last author screened and extracted the data for this scoping review. All the remaining researchers had a nursing background, one with an MSc in an advisory position at the hospital, one with an MSc in a management position, and one a PhD in a research position. They all read the eligible studies and provided a new perspective on the extracted material. Topics discussed included distinguishing between PRO measures applied in the clinic as part of a research project and those applied to directly inform and affect patient care during consultations with the patient.

The second consultation exercise involved all members of the research team and two diabetes specialist nurses in an outpatient clinic. All extracted data from the review and a narrative summary were verbally and visually presented to the group using a presentation tool. Feedback from the participants was given based on the individuals' perspectives. Those in clinical positions had experience using digital PRO measures in their current posts. The presentation contained the scoping review process until the final included studies, a narrative summary of the studies' characteristics, the included reports' use of PRO measures in the clinic, patients' experiences and healthcare personnel's experiences. The participants were invited to share any immediate reflections before they were asked to discuss their interpretation of PRO measures in clinical consultation, the balance between patients' needs and the clinics' resources, whether they experienced more skepticism among healthcare personnel than among patients regarding PRO measures and a more open discussion regarding what a clinical PRO measure should assess considering the identified studies in the review. All the participants found that the narrative summary of the reviewed studies reflected their experiences. Clinical PRO measures can include data from various sources, and it can be cumbersome and time consuming to assess and interpret these data, especially when they are derived from different platforms. Thus, training is crucial to ascertain both confidence and efficiency in using PRO measures. The need for training for patients was also raised, as they are left with more responsibility for their self-management and an increased expectation of being prepared for the consultations. The participants in the consultation exercise specifically raised a concern about whether this increased responsibility was too much for patients with complex conditions. The patients' responses to PRO measurement instruments affected how the consultations were structured. In particular, if patients reported emotional difficulties, diabetes specialist nurses found these challenging to handle due to a lack of time and referral opportunities. On the other hand, they were somewhat confident they would identify

**Table 2** Details of the PRO measure interventions (n=7)

| Study, country | Intervention name | PRO measure focus | Elements, items and domains of the PRO measures in the interventions | Intervention mode and practicalities |
|--|-------------------|--------------------|--|---|
| Bachmeier et al, ²⁹ Australia | DPAT | Psychosocial needs | DPAT comprises three questionnaires, an agenda-setting tool and additional questions: PAID-20 to identify diabetes-related distress PHQ-4 assessing potential anxiety and depression and WHO-5 assessing emotional well-being Social support, financial, weight, shape and eating concerns Hypoglycemia concerns Agenda-setting tool | Participants were given the DPAT form by the clinic staff and completed it independently prior to their clinic appointment. It was unclear whether it was paper-based or web-based or how much time was spent completing it. Predefined referral pathways: a PAID-20 score ≥ 30 prompted diabetes educator review, a PHQ-4 score ≥ 3 for questions 1 and 2 or questions 3 and 4 was the cut-off for referral to a psychologist or activation of a mental healthcare plan with the participant's general practitioner. WHO-5 score ≤ 50 led to a referral to a diabetes educator and ≤ 28 to a psychologist or a general practitioner for activation of a mental health plan. Scoring 1 or 2 items for weight, shape or eating, concerns prompted a dietitian review. Positive scores on social support concerns or finances prompted a review of social work. |
| Haugstvedt et al, ^{*30} Norway | DiAPROM | Diabetes distress | PAID | Electronic PAID before annual consultation. A score of 3 (somewhat serious) or 4 (serious) for items on the PAID scale or a total score ≥ 30 led to follow-up to prevent worsening of diabetes distress. |
| Hernar et al, ^{*33} Norway | DiAPROM | Diabetes distress | PAID | A touchscreen computer (17" screen) in the outpatient clinic's waiting area to ensure visibility for the patients. Patients could go back or change their responses. Patients were not required to log in using personal identification; instead, the application generated a four-character code with a mix of letters and numbers for each session. The patient gave this code during the consultation. The healthcare provider downloaded the PRO measures data from the secure data repository to store in the patients' records. |
| Hernar et al, ^{*27} Norway A | DiAPROM | Diabetes distress | PAID | Electronic PRO measures prior to annual diabetes consultation. Physicians reviewed diabetes PAID scores and referred individuals with scores ≥ 30 or ≥ 3 for single items to at least two diabetes nurse consultations where reported problems were reviewed and discussed. |
| Hernar et al, ^{*31} Norway B | DiAPROM | Diabetes distress | PAID | Participants completed the PAID on an in-clinic touchscreen computer. Physicians reviewed and discussed the PAID results with the participants, guided by a manual. To lessen or prevent severe distress, the nurses reviewed and discussed reported problem areas with the participants, guided by a study manual with specific person-centred communication techniques (active listening, asking open questions, responding, summing up and agreeing on goals and actions to take). |

Continued

**Table 2** Continued

| Study, country | Intervention name | PRO measure focus | Elements, items and domains of the PRO measures in the interventions | Intervention mode and practicalities |
|--|-------------------|------------------------------------|--|--|
| Jensen et al, ^{†34} Denmark | DiabetesFlex | Multidimensional diabetes specific | Well-being (SF-36 general health question, WHO-5), HbA1c, blood pressure, weight, incidents of hypoglycemia, diabetes-related complications, diabetes distress (PAID), topics for the consultation, need for diabetes care, choice of a healthcare professional | Two weeks prior to each consultation, participants completed the internet-based AmbuFlex diabetes-specific, patient-reported outcome questionnaire. A more extensive questionnaire was used for the annual visit (45 items) and a shorter form (17 items) for optional visits. Based on their responses to the AmbuFlex questionnaire, a specialist diabetes nurse evaluated whether it was clinically safe to change or cancel a consultation in accordance with the participant's request. The first consultation in DiabetesFlex care was face-to-face with an endocrinologist and a specialist diabetes nurse. The last two consultations in the annual cycle were optional, and participants could choose to have a face-to-face consultation, change to a telephone consultation or cancel the visit. |
| Laurberg et al, ^{†28} Denmark | DiabetesFlex | Multidimensional diabetes specific | The questionnaire consisted of items on general health perceptions (one item from SF-36) and well-being (WHO-5), self-monitoring, diabetes complications, diabetes distress (PAID), topics individuals may wish to discuss and the individual's preferences in relation to diabetes care and type of healthcare provider | Same mode and practicalities as reported in the study by Jensen et al. ³⁴ |
| Skovlund et al, ³² Denmark | Diaprofil | Multidimensional diabetes specific | The diabetes questionnaire consisted of 33–71 items (depending on the activation of branch logic) that measured health, life situation, social support, psychological well-being, depression, symptom distress, worries about diabetes, confidence in diabetes self-management, blood sugar regulation, medical experience and satisfaction, access to healthcare personnel, priority issues for support and preferred topics to discuss | Participants completed the digital PRO questionnaire 2–10 days prior to the consultation through an email link. During the visit, the healthcare personnel used the PRO dashboard in DiaProfil to review the patient's priorities and issues of concern and collaboratively draw up a plan. The healthcare personnel were advised to review the PRO dashboard in advance, share the screen for mutual viewing, explain the PRO dashboard and the color coding, maintain non-verbal communication and eye contact, use open-ended questions and active listening to prompt more information and confirm findings and cover all flagged PRO issues. |

*Reports from the same project intervention.

†Reports from the same project intervention.

DiaPROM, Diabetes Patient-Related Outcome Measures; DPAT, Diabetes Psychosocial Assessment Tool; HbA1c, hemoglobin A1c; PAID, Problem Areas in Diabetes; PHQ-4, Patient Health Questionnaire-4; SF-36, 36-Item Short Form Health Survey.



| | Bachmeier et al. (29) | Haugstvedt et al. (30) | Hernar et al. (33) | Hernar et al. (27) | Hernar et al. (31) | Jensen et al. (34) | Laurberg et al. (28) | Skovlund et al. (32) |
|--------------------|-----------------------|------------------------|--------------------|--------------------|--------------------|--------------------|----------------------|----------------------|
| Diabetes distress | | DiaPROM | DiaPROM | DiaPROM | DiaPROM | | | |
| Psychosocial needs | DPAT | | | | | | | |
| Multidimensional | | | | | | DiabetesFlex | DiabetesFlex | DiaProfil |

Figure 2 Patient-reported outcome measure focus. DiaPROM, Diabetes Patient-Related Outcome Measures; DPAT, Diabetes Psychosocial Assessment Tool.

patients' needs, regardless of PRO measures. They added that PRO measures allow for a task shift from physicians to nurses on a larger scale than prior and that a more systematic approach to patients' reports can enable the identification of previously undetected problems. Lastly, the diabetes specialist nurses confirmed and highlighted the need for clinical personnel to develop, implement and evaluate tools, such as PRO measures in the clinic to succeed.

DISCUSSION

This scoping review identified and described PRO measures used in clinical settings for patients with diabetes where PRO reports had consequences for current or future consultations. We identified seven reports from four studies presenting unique PRO measures, all covering psychosocial aspects of living with diabetes and using an electronic system to collect PRO data.

Based on the limited number of studies identified in our scoping search and the limited number of PRO measures used in clinical diabetes care, research in this area appears scarce. The heterogeneity among clinics and in healthcare personnel needs might provide some explanation. The use of PRO measures depends on practice goals and priorities, such as prioritizing patients' concerns, involving the patients more directly in their care, better communication, aiming for more effective treatment plans or providing a more positive overall patient experience.³⁵ As a result, different clinics may take different approaches to selecting which PRO measures are most useful for their clinical practice, with each clinic's specific needs and priorities and their patient population influencing their choice of measures. Although the use of PRO measures increasing,^{36 37} research suggests that the potential benefits of these measures increase in line with healthcare personnel's and patients' understanding of why and how these measures are used.³⁸

Among the four identified studies and seven reports in this scoping review, all the PRO measures aimed to identify challenges that the patients faced to better tailor diabetes care. PRO measures allow for an increased focus on psychosocial aspects of living with a chronic condition, which both the patients and healthcare personnel valued in our included studies. Often, PRO measures on psychosocial aspects are collected at the same time as clinical measures, such as HbA1c or time-in-range/time-out-of-range. While multidimensional PRO measures provide a broader perspective on various aspects of diabetes and patient well-being, the questionnaires can

be long and time consuming, thus representing a burden for the patient. Among the four identified studies, the Norwegian study used only the PAID, and the remaining three studies used multidimensional PRO measures. Previous research found a trend in diabetes care towards the use of multidimensional PRO measures.¹² It seems that both the patients and the clinicians were satisfied in the studies that used both unidimensional and multidimensional PRO measures and that it is more important whether the questions are meaningful to answer. In terms of the clinical versus the scientific value of PRO measures, disease-specific measures are often more sensitive to disease-related change in the individual outcomes compared with generic measures, supporting the relevance of disease-specific measures. Choosing the most appropriate PRO measures to collect pertinent patient data, together with relevant clinical measures, is important to ensure both the relevance and quality of service provision. However, if each clinic were to identify and select PRO measures, this would result in a lack of standardization, increased use of resources and ultimately increased costs. Using at least some standardized PRO measures is often practical if these are relevant.³⁷ The use of standardized PRO measures will also enable comparisons between clinics and even between countries if the PRO measure is translated into different languages. One example we identified in this scoping review was the PAID questionnaire used in both the Norwegian study,^{27 30 31 33} one of the Danish studies²⁸ and the Australian study.²⁹ In Norway, PAID is integrated into the national Norwegian Diabetes Register for Adults.³⁹ Thus, there is an opportunity to compare the PAID scores from with those from the national register, which contributes to improving the quality of health services. In addition, PAID is used in healthcare settings in many countries.⁴⁰

Choosing the right PRO measure is of the utmost importance, yet challenging for clinicians.³⁷ Our scoping review shed light on the lack of available PRO measures meeting the requirements of being a practical, reliable, valid and relevant tool. It also suggested that the most valuable clinical PRO measures might not be those developed for scientific research purposes according to scientific standards but those developed for use in a clinical setting. Clinical PRO measures serve a different purpose of being short, to the point, easy to answer and interpret, dynamic and valuable from a clinical perspective. This is opposite to the criteria set for scientific PRO measures used in traditional evaluation of research. Thus, there remains a balance between the clinical need to adapt

Table 3 Findings and experiences on the use of PRO measure interventions (n=7)

| Study, country | Main findings | Experiences of the PRO measure interventions |
|--|--|---|
| Bachmeier et al, ²⁹ Australia | The PRO measure may help identify depression, anxiety, diabetes-related stressors, social, financial and dietary concerns and highlight clinical care needs. PRO measures may also help streamline referrals to relevant members of a multidisciplinary team. | The Diabetes Psychosocial Assessment Tool was easy to use and was accepted by the young adults who completed the form. |
| Haugstvedt et al, ^{*30} Norway | Three themes, each with two subthemes: <ol style="list-style-type: none"> 1. Conflicting demands and priorities: (i) balancing guideline recommendations with patients' main concerns and (ii) experiencing that patients need more support to disclose their emotional concerns. 2. Insights into using dialogue tools: (i) the benefits and challenges of using the PAID questionnaire as a dialogue tool and (ii) the usefulness of communication techniques. 3. Challenges associated with facilitating new interventions: (i) unclear roles and responsibilities in multidisciplinary teams and (ii) the capacity sets the limit, not the willingness. | Physicians and nurses experienced substantial challenges related to time and resources in using dialogue tools to support patients' emotional concerns in clinical diabetes consultations. |
| Hernar et al, ^{*31} Norway | Generally, the touchscreen computer functioned well technically. The median time spent completing the PRO measures was 8min, 19s. Twenty-nine (42.0%) participants completed the PRO measures without missing items, with an 81.4% average instrument completion rate. Participants reported that the PRO measures were comprehensible (n=62) and relevant (n=46) to a large or very large degree, with an acceptable number of items (n=51). Moreover, 54 participants were willing to complete PRO measures annually. Participants commented that the focus of the PRO measures on living with diabetes was valuable. | Capturing PRO measures on a touchscreen computer in an outpatient clinic was technically and practically feasible. The participants found the PRO measures to be relevant and acceptable with a manageable number of items and reported willingness to complete PRO measures annually. |
| Hernar et al, ^{*27} Norway | Throughout the study, 23/39 intervention arm participants qualified for additional consultations, of which 17 attended. Sixty-seven of 79 participants attended the 12-month follow-up (15.2% attrition), and 5/17 referred to additional consultations were lost to follow-up (29.4% attrition). Participants reported PRO measures as relevant (84.6%) and acceptable (97.4%) but rated the usefulness of consultations as moderate to low. | Completing electronic PRO measures was generally accepted and technically feasible. Implementation fidelity and difficulties in delivering the intervention as designed appeared challenging for the clinic. |
| Hernar et al, ^{*31} Norway | Three themes, each with two subthemes: <ol style="list-style-type: none"> 1. Follow-up with limitations: (i) marginal dialogue about everyday challenges and (ii) the value of supportive relationships and continuity. 2. New insights and raised awareness: (i) more life-oriented insights and (ii) moving out of the comfort zone. 3. Addressing problem areas with an open mind: (i) need for elaboration and (ii) preparedness for dialogue. | Completing and using the PAID questionnaire was somewhat uncomfortable yet worthwhile. By using diabetes distress data, together with health and biomedical data, consultations became more attuned to the young adults' wishes and needs, mainly because the dialogue was more focused and direct. Hence, the PAID questionnaire has the potential to facilitate person centeredness and improve patient-provider relationships. |
| Jensen et al, ^{†34} Denmark | Three themes with no subthemes: (1) increased reflection on living with diabetes; (2) involvement brings more flexibility and a strengthened sense of responsibility and (3) changed conditions for diabetes care. | The DiabetesFlex Care could enable patients to take responsibility for their diabetes management and help healthcare professionals to support user involvement and self-management. In addition, it could reduce how healthcare services disrupt patients' daily lives. |
| Laurberg et al, ^{†28} Denmark | Mean difference in hemoglobin A1c between standard care and DiabetesFlex was similar. No intergroup mean changes in lipid profiles or blood pressure were observed. Conversely, DiabetesFlex participants had increased mean WHO-5 and decreased PAID scores compared with standard care participants. DiabetesFlex participants changed 23% of face-to-face visits to telephone consultations, canceled more visits (17% vs 9%) than standard care participants and failed to turn up without canceling their appointment less often than standard care participants (2% vs 8%). | Flexible patient-controlled visits, combined with PROs, improved diabetes-related well-being and decreased face-to-face visits while maintaining safe diabetes management among participants with type 1 diabetes. |

Continued

**Table 3** Continued

| Study, country | Main findings | Experiences of the PRO measure interventions |
|---|---|---|
| Skovlund <i>et al</i> , ³² Denmark | People with diabetes found the PRO diabetes questionnaire to be relevant, acceptable and feasible to complete from home. People with diabetes and healthcare personnel found the digital PRO tool to be feasible and acceptable for use during diabetes-related visits and would like to continue using it. Healthcare personnel could use the tool in a person-centred manner, as intended. For several people with diabetes, completing the questionnaire facilitated positive reflection and better preparation for their visits. The PRO tool primarily improved the quality of dialogue by improving the identification of issues and focusing on the issues most important to the person with diabetes. People with diabetes did not report any negative aspects of the PRO tool. In contrast, healthcare personnel highlighted that it was demanding when the person with diabetes had many PRO issues that required attention within the predefined time allocated for a visit. | The Danish PRO diabetes questionnaire and the digital tool, DiaProfil, are feasible and acceptable solutions for routine diabetes visits. |

*Reports from the same project intervention.

†Reports from the same project intervention.

PAID, Problem Areas in Diabetes; PRO, patient-reported outcome.

specific items from validated PRO measures into new, comprised PRO measures where individual patient responses are of interest, compared with the need for validated, scientifically rigorous instruments measuring concepts in larger samples of patients.

Some core prerequisites are necessary for PRO measures to be relevant for clinical purposes. Similar to the implementation of other new tools, the implementation of PRO measures used for clinical purposes can alter the workflow and add to clinicians' workloads.^{37–41} There must be a continuous focus on training to ensure that healthcare personnel have the required skills to interpret multidimensional PRO measures. All the studies included in our review used electronic methods to administer the PRO measures and collect patient-specific data, allowing for even greater patient individualization.³⁷ Digital solutions can also aid the interpretation of PRO measure scores through colors or thresholds.⁴² Information on a range of self-reported issues is often needed for patients with complex conditions using multiple PRO measures. Such information must then be interpreted in the context of clinical parameters. As each patient is unique, particularly those with complex conditions, it remains challenging to standardize healthcare.³⁵ Data collection using multiple tools and subsequent interpretation of the data are easier using a digital system. However, the implementation of digital PRO measures has been unsuccessful in some healthcare settings.²¹ Thus, thorough identification of the intended users and adaptation of the digital PRO measure remain crucial.¹⁷

Among the identified studies, although all the patients expressed satisfaction with the PRO measures, healthcare personnel showed both skepticism and high satisfaction. In the Norwegian study reported by Hernar *et al*³³ and discussed by the diabetes specialist nurses in our consultation exercise, some healthcare personnel felt that the use

of standardized questions, such as those in PRO measures, to shed light on the patient experience seemed unnecessary, believing that the consultation between the patient and healthcare provider should fulfill this purpose. Thus, some healthcare workers viewed PRO measures as somewhat redundant, as the patients' concerns would have been picked up on and addressed by asking questions during the consultations. Such views might explain some of the skepticism expressed by healthcare personnel towards PRO measures. Interprofessional collaboration is essential to maximize the benefits of PRO measures in the clinic,¹² which could be a challenge. However, by clarifying the rationale underlying PRO measures and their relevance to patient care, PRO measures may be accepted over time and increase the efficiency and quality of health services. To ensure the relevance of PRO measures, the involvement of users at all levels can be valuable, particularly to identify the items most appreciated and regarded as most useful by patients compared with those considered most useful by healthcare personnel.¹⁷ Through the systematic evaluation of patient-specific concerns, healthcare personnel can provide more timely care.³⁸ This systematic evaluation includes balancing the clinics' resources and patients' needs, as PRO measures can identify problems not identified previously, thus, demanding more resources if these problems have a clinical rationale and must be acted on.

The nurses presented with the preliminary results of our scoping review as the patients' concerns would have been picked up on and addressed might make it easier to identify patients that are clinically stable and not in need of a consultation at a particular time, thus, allowing for a more flexible schedule where consultations can be redistributed to those patients with a higher need. The implementation of PRO measures might ultimately increase the quality of healthcare services. PRO measures might

also shift the focus too much over to the systematic collection of PRO measures as discussed by Campbell *et al.*³⁵ A balance between when PRO measures are just numbers and the focus on a personified meeting between a patient and a provider must be maintained and tailored to the individual. PRO measures will not be suited to all settings and all patients.³⁴ Barriers to the use of PRO measures include individuals with high levels of distress or low literacy.³⁵

Implications for further research

Although some PRO measure interventions measure only a single phenomenon, they can be complex and multifaceted. Evaluating complex interventions can benefit from employing various methodological perspectives to document the impact of these interventions on practice, thereby providing a more robust understanding of their effectiveness.³⁷ The studies included in this review employed mixed methodical approaches, including qualitative and quantitative. The diversity of evaluation methods used in these studies and limited number of studies makes it challenging to draw conclusive findings from the results. Given the complexity of PRO measure interventions and their potential impact on clinical practice, future evaluations should involve a range of methodological approaches to ensure a robust evaluation of PRO measures capture various dimensions of their effects and obtain a more nuanced understanding of diabetes care in outpatient clinics.

Limitations and strengths

The search strategy in this study might have needed to be more thorough to identify relevant studies to answer the aims, as we found few studies. However, we used a comprehensive search strategy and generated many results for screening. We carefully defined the inclusion criteria as the term PRO measure is used in numerous ways, and we had a narrow scope of use in clinical practice. Although this made the process of study selection demanding, such an approach was necessary to ensure that the review was comprehensive. There is a risk of language and geographical bias, as we limited our search to English and Scandinavian languages. This could restrict the generalizability of our review, as we could have missed important research. However, we aimed to avoid misinterpretations and reduce irrelevant studies, identifying research directly relevant to our aim and context.

Conclusions

Overall, a limited number of PRO measures used in a clinical setting for patients with diabetes was identified. PAID was the most frequently applied PRO measure, and all studies shared a focus on psychosocial aspects of diabetes. Data were generally collected via electronic methods. Based on the included studies, patients appeared to be satisfied with PRO measures overall, whereas the level of satisfaction among healthcare personnel with PRO measures use varied. More research is needed to address

the development of PRO measures serving a clinical purpose and to shed light on how PRO measures can be used to alter diabetes outpatient services.

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