Current Diabetes Reports (2019) 19: 84
https://doi.org/10.1007/s11892-019-1190-x

PSYCHOSOCIAL ASPECTS (SS JASER, SECTION EDITOR)

Can the Routine Use of Patient-Reported Outcome Measures Improve the Delivery of Person-Centered Diabetes Care? A Review of Recent Developments and a Case Study

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Published online: 16 August 2019

Abstract

Purpose of Review In recent years, the recommendation for and use of patient-reported outcome measures (PROMs) in routine diabetes care has significantly increased. We review recent evidence and highlight key opportunities and challenges related to the active clinical use of PROMs to support person-centered diabetes care and focus areas for future research in the area.

Recent Findings Recent pragmatic studies support that integration of multi-dimensional PROMs for diabetes in clinical care as part of a care improvement strategy can be acceptable for and valued by people with diabetes (PWD) and healthcare professionals (HCPs) and may improve multiple aspects of quality of care, including screening, medical care monitoring and decision support, individualization of self-management support and goal-setting, and broader benefits related to active patient participation and person-centred diabetes care. We identify multiple intervention, individual, and care setting characteristics, which influence acceptability, feasibility, implementation, and effectiveness of PROMs in routine care. Recent clinical PROM studies highlight the value of mixed methods research and systematic involvement of PWD, clinicians, and other stakeholders in the design and implementation of questionnaires for patient input in routine diabetes care.

Summary We identified a new significant trend towards participatory development of multi-dimensional PROMs with the aim of IT-enabled integration into routine diabetes care to facilitate multiple components of person-centered diabetes care and better clinical, quality of life, and cost outcomes. While results from large-scale randomized controlled studies are still limited, a growing number of pragmatic implementation studies support that user-centric PROM interventions have the potential to facilitate significant improvements in care for PWD.

Keywords Patient-reported outcomes · Person-centered diabetes care · Health-related quality of life · Psychosocial diabetes care · Collaborative diabetes care · Value-based healthcare

This article is part of the Topical Collection on *Psychosocial Aspects*

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Background

Scope and Focus for This Review

In the extant literature, patient-reported outcome (PRO) is typically defined as "data reported directly by the patient about health, quality of life, or functional status associated with a health condition or care or treatment," and patient-reported outcome measures (PROMs) as the self-report instruments used to report the PROs.

PROs represent however only one of multiple types of psychometrically validated patient-reported information typically collected as part of a PROM intervention in diabetes [1•, 2•]. Other important information found clinically relevant to collect from PWD and caregivers includes clinically valid assessments of social support, illness beliefs, self-care behaviors and care preferences and priorities.

For practical purposes, we use the term diabetes PROM in this review to denote an intervention using validated patient questionnaires for routine care which may include multiple types of validated patient questionnaire information such as patient-reported input (PRI) as well as PROs. The main approach to use of PROM in diabetes care we refer to in this review is depicted in Fig. 1.

Introduction

There is a growing recognition in the diabetes community of the urgent need to advance delivery of person-centered and individualized diabetes care in order to improve outcomes, care for vulnerable populations, and overall reduce the burden of disease [3–5].

Diabetes is a demanding chronic condition requiring comprehensive, ongoing individualized multi-disciplinary medical, psychosocial, and self-management care and support. At the same time, healthcare systems face major resource constraints. The development of scalable efficient solutions to help healthcare professionals (HCPs) and people with diabetes (PWD) work together to individualize medical diabetes management and integrate psychosocial and behavioral aspects of diabetes in a humanistic and person-centred way is therefore a critical consideration.

Key elements of person-centered diabetes care found to be associated with better care outcomes and optimized hyperglycemia management include active participation of PWD and caregivers in their care, person-centred communication and therapeutic relationship, a biopsychosocial and "whole-person" care model, and collaborative and shared decision-making [5–7, 8••].

The IDF [9, 10,] and ISPAD [11] guidelines and several national diabetes guidelines including the ADA Medical Care Guidelines [8••] recommend the regular use of PROMs in diabetes management to monitor psychological aspects of diabetes such as well-being, depression, and diabetes-related distress on a regular basis.

The assessment of outcomes of diabetes care include differentiated disease-specific measures of health, functioning, and disease burden which can only be achieved through the combination of clinical data and reliable and valid PRO data [4, 12].

Use of PROMs to improve diabetes care has been identified by the behavioral diabetes research community for decades as an important strategy and more than a hundred psychometrically validated diabetes PROMs have been reported in the literature. The PAID (Problem Areas in Diabetes) and Diabetes Distress Scale (DDS) are some of the most widely used in clinical practice [13], yet no consensus exists regarding which PROMs to use as standard part of clinical practice [14•].

A wide range of constructs only measurable through patient report, such as health, daily functioning, depression, symptom distress, treatment burden, self-care, illness impact, beliefs, and distress, have been shown to predict treatment responsiveness, care utilization, and health outcomes in diabetes [15, 16].

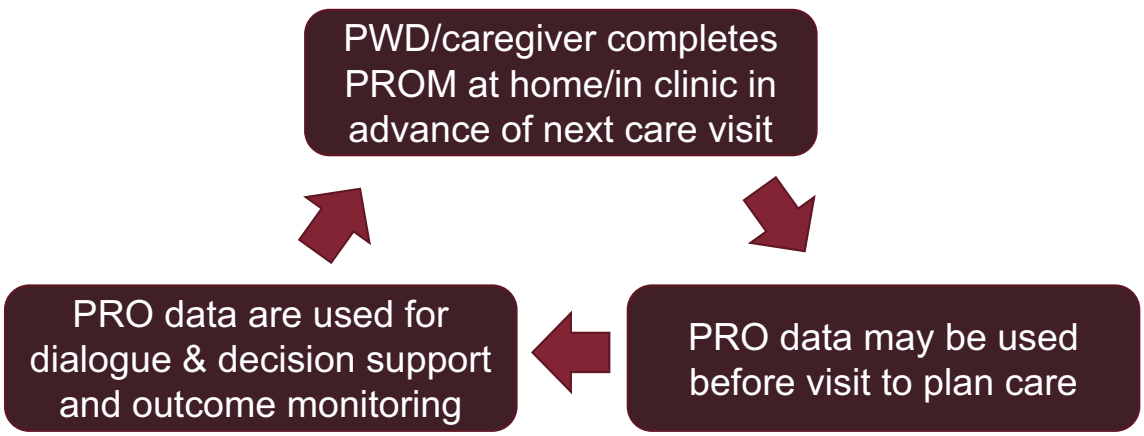


Fig. 1 Simplified diagram of the typical process for use of PRO referred to in this paper

PROs thus provide clinically important and complementary predictive information regarding risk of hospitalization, medication needs, responsiveness to interventions, health promotion, preventative, and telemedicine interventions, and can help quantify individual resources, care, and support needs for decision support and stratification for population health management.

The past lack of efficient IT health infrastructures represents one of several barriers to earlier uptake of PROMs in standard care. The increasing availability of flexible IT, mobile, and electronic health record (EHR) systems which enable seamless and real-time PROM integration represents a significant opportunity for chronic illness care transformation.

In recent years, multi-dimensional PROMs have been designed for use in routine diabetes care to support patient participation, self-management support, dialogue and treatment decision support, and for adding PRO as a "missing link" in clinical care quality monitoring.

New PROM programs utilize IT technology for seamless integration of PRO in the clinical flow [17, 18].

The recent global core outcome standards set from the International Consortium for Outcomes Measurement (ICHOM) for type 1 and 2 diabetes include three PROMs for assessment of well-being (WHO-5), depression (PHQ-9), and diabetes distress (PAID) on an annual basis [19•]. While ICHOM's recommendations focus on use of PRO for outcome assessment at population level, implementation of systematic data collection will result in maturation of diabetes IT PROM systems and reduce practical barriers to use of PROMs in individual care planning. PROMs play an increasing role in IT innovations for collaborative care, coordinated chronic care, telemedicine, digital health, shared decision-making, health risk assessments, and stepped care.

The focus for this review is the use of PROMs by HCPs to improve diabetes care for individual PWD and caregivers. We review the evidence for person-centred care strategies required to integrate PROMs in routine diabetes care to create sustainable and direct value to PWD, their families, and communities.

We believe successful integration of PRO in routine clinical practice is required to enable the use of population-level PRO data for organizational and value-based care improvements.

Aims and Design of PROMs in Routine Diabetes Care

Main Aims

PROMs are applied in diabetes care for multiple purposes depending on care setting, target population, and program objectives. Some initiatives focus on use of PROMs to screen for specific mental health disorders [8••, 20•] or health risk behaviors [15, 21], individual self-management goal setting [22], facilitation of self-management support [2•], enabling focus on patient values and preferences, and integration of diabetes-related quality of life measurement [1•].

The person-centred hyperglycemia management decision cycle proposed by ADA and EASD requires HCPs to individualize therapy based on a multitude of information about factors such as emotional well-being, daily self-management, and treatment burden [5]. PROMs provide an obvious foundation for making this possible in busy practice and more broadly supports the provision of collaborative and coordinated chronic illness care [4, 6, 12, 23–27, 28•].

We propose future design and evaluation of PROMs in diabetes care focus on impact on and interplay with evidence-based components of person-centered diabetes care, including (a) active participation, (b) person-centered communication, (c) a biopsychosocial care model, and (d) shared decision-making.

Table 1 lists key areas proposed to guide design and evaluation of diabetes PROMs for routine care with respect to person-centred diabetes care (Table 1).

The Design of PROMs

The design of a PROM for clinical use requires a comprehensive process which ensures aims, objectives, conceptual model, domains, items, scales, psychometric scoring methods, algorithms, and clinical use are coherent and informed by a truly participatory process involving all the relevant stakeholders, including especially PWD and their caregivers.

First, after the person-centered objectives have been agreed across stakeholders, a conceptual and theoretical measurement model and domains and constructs can be specified and prioritized in accordance with stakeholder input, qualitative and quantitative research, population health and clinical relevance, and known linkage to factors such as cost of care, risk of hospitalization, treatment responsiveness, disparities, and long-term outcomes [16].

Table 2 shows key domains found relevant for inclusion in diabetes PROMs and lists examples of PROMs with documentation of psychometric validation. Most of the listed questionnaires have not yet been specifically assessed for validity or acceptability for use to measure the identified domains in routine diabetes care.

The harmonization of PROMs for use in diabetes care and research has been challenged by a lack of conceptual clarity and consensus regarding the core domains and constructs to be measured such as "diabetes-related quality of life" [29, 30].

Recent multi-stakeholder projects identify priority domains and constructs for clinical use (Fig. 2) [1•, 4, 14, 19•, 31].

Table 1 Aims and outcome evaluation domains for active use of PROM in diabetes

Shared objectives across multiple stakeholders	Evaluation domains for use of PROMs
Improve health and cost outcomes of diabetes care by focusing care on the priorities, preferences, and needs of each PWD.	1. Active participation of PWD in own care and ongoing treatment. 2. Person-centered communication and PWD-HCP therapeutic alliance. 3. Collaborative care and shared decision-making. 4. Alignment of care with PWD values, preferences, and priorities. 5. Individualized self-management and psychosocial care and support. 6. Individualized hyperglycemia management and medical care: risk screening, diagnosis, referrals (preventative, health promotion, medical), medical therapy and technology optimization, coordination, follow-up, safety, and satisfaction. 7. Multi-disciplinary diabetes care coordinated across healthcare sectors. 8. Behavioral outcomes (self-efficacy, self-care, lifestyle, risk behaviors, healthcare utilization). 9. Clinical outcomes (A1c, time in range, blood pressure, cholesterol, hospitalization, ketoacidosis, hypoglycemia, complications). 10. Patient-reported outcomes (diabetes-related quality of life impact). 11. Public health impact potential (RE-AIM indicator assessment: Reach, Effectiveness, Adoption, Implementation, Maintenance) 12. Prioritization of healthcare resources based on optimization of outcomes for PWD.

Recent clinical PRO diabetes initiatives concluded that no single existing PROMs fulfilled the specific requirements for domain coverage, format, and clinical purpose defined by the stakeholders of the project [1•, 14] (see Fig. 2).

As a result, it was deemed necessary to design new items and questionnaires [1•, 32]. A new diabetes PROM solution in Sweden was designed based on qualitative research with PWD under the theme of "live a good life with diabetes" and consisted of two parts: How the PWD feels he/she (1) "is doing in daily life" (PRO) and (2) is supported by the care team (PRE) [1•]. A multi-sector participatory process in Denmark led to somewhat similar conclusions and priority domains related to health, daily life with diabetes, and patient-reported experience of care (PRE) and confidence in self-management [33]. PRO programs for primary care with PWD as a subset of the target population also conclude that new questionnaires are needed to enable sustainable integration of PROMs in routine care [34, 35]. We believe a key step forward for harmonization of use of PROMs for clinical care would be to establish further multi-national and multi-sector consensus on the key priority PRO domains and constructs.

A key need reported by many studies is short PROMs to cover each domain. Main approaches taken include (1) psychometric shortening of longer scales provided sufficient data is available (e.g. PAID-5, DDS-2 [36, 37]) and (2) use of global or individual screening items and (3) use of adaptive testing (e.g. PROMIS-10) and (4) branching methods. Another key consideration is the appropriate combination of generic and diabetes-specific PROMs. Generic instruments are important for use in primary care and populations with multi-morbidity but there is also ample experience that generic instruments alone are not sufficient for use in diabetes care as they tend to be not actionable, relevant, and specific enough [38•].

Traditional psychometric validation parameters are important but insufficient for selection of PROMs for use in routine diabetes care. Specific PROM aims, care setting, and target group characteristics play a crucial role for determining the optimal PROM format and content [39, 40]. We propose therefore to complement traditional psychometric validation criteria with the following selection criteria specific to the use of PROMs in routine care.

Questionnaires and items should be:

1. Be simple, low-literacy friendly, reflective of the lived experience, respectful, non-judgmental, non-paternalistic, balanced (neutral, negative, and positive items), and adhere to recent declarations regarding patient-centred diabetes language [41].
2. Support active engagement of PWD and caregivers in their own diabetes care.
3. Provide information that care team members can act meaningfully on to deliver better quality care and more value to PWD and their caregivers.
4. Help the PWD improve on one or more patient-important diabetes outcomes.
5. Have the required psychometric reliability, validity, sensitivity, and responsiveness to enable the safe and reliable clinical use for the intended purpose (e.g., dialogue,

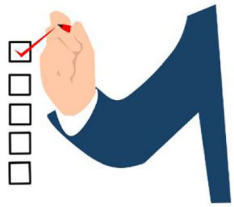
Aims

The DiaProfile PROM solution is intended for use by healthcare professionals across sectors in the care for adults with type 1 and 2 diabetes to improve (1) active participation of PwD in care, (2) care quality, (3) outcomes for PWD and (4) enable value based use of care resources.

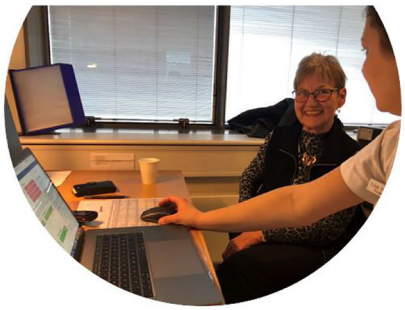
PROM development steps

1. Multi-stakeholder agreement on (1) core person-centred diabetes outcome domains [32] and (2) a clear framework and plan for how to use PRO data to improve outcomes for PWD.
2. Systematic involvement of and collaboration with PWD [101] and caregivers in all project phases using user panels, workshops, focus groups, interviews, surveys and public dialogue.
3. Co-development of criteria to guide the iterative design of the PROM. Iterative process for PROM development and testing with clinicians, PWD, caregivers and researchers.
4. Mixed-methods qualitative research and psychometric validation
5. Co-creation of PROM App and IT solutions for PWD and HCPs.
6. Pilot testing and iplementation: Staff training, quality assurance, data and IT governance.
7. Ongoing implementation monitoring (RE-AIM framework).

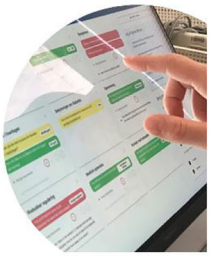
DiaProfile use in routine care



1. PWD fills out DiaProfile at home prior to clinic visit on mobile/tablet/PC (8-12 min).



2. HCP uses DiaProfile as dialogue tool with PWD during clinic visit.



3. One-click acces to local resources and clinical actions relevant for each PRO output.

DiaProfile Questionnaire Domains

1. General health, social support and life situation, 2. Mental health and wellbeing, 3. Daily life with diabetes, 4. Diabetes worries, 5. Self-management and wishes for support, 6. Symptom distress and complication prevention, 7. Blood sugar regulation, 8. Medicine experience, 9. Confidence in access to care, 10. Wishes for topics for next diabetes visit.

DiaProfile Dialogue tool

A single screen overview of input from the PWD on each of the domains, indicated as green (ok), yellow (possible problem area) and red (problem reported that needs to be addressed). Access to tools, care options and ressources relevant for each individual PROM output.

Fig. 2 Case study: The DiaProfile project

decision-support, prevention, health risk screening, symptom and treatment effect monitoring, quality of care improvement, value-based care, and research).

We now review recent literature related to the use of PROMs for diabetes and considerations for implementation, followed by an overview of 6 recent multi-dimensional PROM initiatives for PWD.

Use of PROMs in Different Subsettings

Use of PROMs to Screen and Monitor Depression and Diabetes-Related Distress

Depression and diabetes-related emotional distress are associated with increased risk of impaired self-management, hospitalization, and worse long-term prognosis and are prevalent and underrecognized in most care systems [42–44, 45•]. Improvement of recognition of mental health problems in PWD through the use of PROMs [44] have the potential to improve care outcomes if appropriate psychosocial care and resources are available [8••, 46].

The international guidelines of IDF and ADA recommend the regular assessments of mental health and psychosocial aspects of diabetes [8••, 9] and numerous specific psychosocial screening and assessment questionnaires have been developed for clinical use.

Knowledge gaps remain regarding how to best design and implement acceptable, scalable and sustainable psychosocial screening interventions in diabetes [35].

The multi-national DAWN MIND study [47] evaluated the feasibility of routine use of WHO-5 [48] and PAID [13] and questions about priorities of PWD. It was found to be feasible for most centers to have PROMs completed prior to the clinic visit and for use during the visit [47]. Use of short-form screening questionnaires such as PHQ-9 to screen for depression in PWD in primary care has also recently been reported to be feasible and easier thanks to seamless integration into EHRs [49]. Despite large-scale research and consensus guidelines, institutionalization of these PROM assessments in diabetes care has not progressed in most countries, highlighting the need to address many practical, cultural, and clinical barriers to PROM integration in practice. A few studies have examined the impact of monitoring quality of life and generally report positive impacts on the targeted psychosocial domains [50–52]. One randomized controlled trial found that review of quality of life assessment results in diabetes visits improved psychosocial outcomes in a pediatric population [51]. Discussion of PAID results in clinic visits was associated with improvements in diabetes distress and satisfaction with consultations in a pilot study [52].

While comprehensive depression screening programs can improve outcomes and lower costs of care [53], screening for depression can have inadvertent negative consequences due to false-positives, over-pathologizing what might be normal reactions to living with chronic disease, or due to lack of mental health providers [54–56]. One screening study with minimal resources for follow-up found no outcome benefits for PWD [56] highlighting that merely measuring depressive symptoms by itself does not guarantee better care. Furthermore, many PWD identified as "cases" in practice when using PROMs have been found to either not report an active interest for action or referral on the topic [47, 57] or not be likely to benefit from available treatments. Therefore, the protocol for measurement of mental health problems using PROMs should be carefully designed to align with individual, treatment, and situational risk factors of the PWD and the available psychosocial care and follow-up resources [8••].

A general systematic review of impact of PROMs found that the evidence for use of PROMs for screening was less compelling than for use of PROMs as a management tool [27]. The participatory PROM development projects in Sweden [1•] and Denmark (Fig. 2) both led to a shift away from solely using psychiatric or distress screening questionnaires to inviting input to care from PWD and measuring health experiences and preferences more broadly and neutrally.

Comparative clinical and mixed methods research is warranted to explore and compare PROs and CONs of using psychiatric screening instruments vs various alternative multi-dimensional PROMs in routine practice.

The Impacts of PROMs on Person-Centered Communication Practices

A recent systematic review covering multiple disease areas found 5 robust studies and 21 less robust controlled studies confirming that PROMs can help improve focus on patient values and preferences in the clinical encounter [28•]. Importantly, PROMs by themselves may have a limited impact on HCPs' own communication practices [58], as stated by one author: "PROM feedback to HCPs does not appear to change ingrained care culture and approaches by itself" [12, 59•].

Use of PROMs to Support Active Participation of PWD

Active participation of PWD in care is an important goal with the use of multi-dimensional PROMs in routine care (Table 1). High patient participation and activation is

associated with better health outcomes [6, 60] and qualitative research supports that PROMs likely contribute to better diabetes outcomes through a facilitation of active participation of PWD in care [24, 61••].

The DiaProfile project (Fig. 2) illustrates one potential mechanism by which PWD may be engaged to be more active. Users report that filling out the PROM helps them reflect on their diabetes needs and priorities and what they want to do

Table 2 Domains identified as relevant for use in routine diabetes care

PRO domains with empirical data supporting clinical relevance and importance to PWD and caregivers	Examples of PROMs
General self-reported health	EQ-5D [77], SF-6D [78], SF-12 [79], PROMIS 10/29 [38•], Health Status Global item [34]
General quality of life	WHO-QOL BREF [80]
Mental health (well-being, depression, anxiety, eating disorders) and stress	WHO-5 [48], PHQ-9 [81], PHQ-4 [82]. Further listing see [8••] Distress thermometer [83].
Impact of health or diabetes on quality of life, including emotional distress	DIDP (DAWN Impact of Diabetes Profile) [42, 84], DHP-18 (Diabetes Health Profile) [78] DPM (Diabetes Impact on Productivity) [85] PAID (Problem Areas in Diabetes) [13], PAID-5 [36], DDS/DDS-2/4 [37]. DMQoL (Diabetes Specific Measure for Quality of life) [86] QDIS [87]
Treatment experience and treatment burden	GDST (Global Diabetes Satisfaction Treatment) [88], DTSQ (Diabetes Treatment Satisfaction Questionnaire [89], PETS (Patient Experience with Treatment and Self-Management) [62]
Hypoglycemia burden	TRIM-HYPO (Treatment Related Impact Measure – Non Severe Hypoglycemia) [90] HFS-II (Hypoglycaemia Fear Survey II Short Form) [91]
Symptom distress (e.g., neuropathy, cardiovascular, cognition, sleep, gastro-intestinal, sexual function, vision, hyper and hypo-glycemia)	DSCR (Diabetes Symptom Checklist) DSM (Diabetes Symptom Measure [85] DN-4 (Neuropathic pain questionnaire) [92] GCSI-DD (Gastroparesis Cardinal Symptom Index-Daily Diary [93]
Self-efficacy, confidence in self-management, health competence, action competence, health behaviors, knowledge, disease mastery and active engagement, resilience, empowerment	DSCSA (Diabetes Self-Care Summary of Activities) [94] CIDS (Confidence in Diabetes Self-Management) [16] DSMQ (Diabetes Self-Management Questionnaire) [95] DES-SF (Diabetes Empowerment Short Form). [45•] PAM (Patient Activation Measure) [60] HEIQ (Health Education Impact Questionnaire) [96]
Perceived access to person-centered care, confidence in and support from extended diabetes care team	DSDSP (DAWN Support for Diabetes Self-Management Profile) [45•] HCC-DSF (Health Care Climate - DAWN Short Form [45•] PACIC (Patient Assessment of Chronic Illness Care) [97]
Examples of other patient-reported information relevant for use with PROM	
Social determinants of health, including health literacy, social risks (e.g., food insecurity, housing instability), access to care, social support	Health Literacy Screener [98] Stressful Life Events [51] PRAPARE [99] AHC (Accountable Health Communities Screening tool) [100] ICHOM Access to Care Items for diabetes [19•] DSS (Diabetes Social Support Scale) [88] Barriers to Medication Taking [88]
Health risk behaviors	Tobacco and alcohol screening (e.g., AUDIT-C) MOHR (My Own Health Record) [15, 58]
Motivation towards behavior change	MATCH 9-item scale [101]
Blood sugar unawareness	Hilleroed Blood Glucose Unawareness Screening Item [102] Hypoglycaemia Awareness Questionnaire (HypoA-Q) [103]
Personal priorities, goals, preferences, wishes for support	CTH (Connection to Health) [2•], MOHR (My Own Health Record) [15], DAWN MIND (Monitoring Individual Needs [47], DAWN2 (Diabetes Wishes Attitudes and Needs) [42], DiaProfile (Fig. 2)

themselves to take control and helps them prepare better for their diabetes consultation.

In addition, the expectation raised by the PROM that their HCP will have a focus on their input and their perspective motivates some to be more actively engaged in preparing for the visit.

Prospective, randomized controlled studies are needed to examine how specific PROM procedures and solutions affect different levels of active participation and engagement in PWDs' own health and active participation of caregivers, as well as potential mediators, such as information and navigation support and self-reflection facilitated by PROM completion.

Active engagement may be assessed by use of PROMs such as the Diabetes Empowerment Scale DAWN Short Form [45•] and the Patient Activation Measure (PAM) [62] and through qualitative and behavioral assessments related to, e.g. pre-consultation communication, speak time and concrete participation in care planning, taking part in decision-making, attending visits and educational activities, seeking out resources pro-actively and independently, applying problem-solving techniques, being pro-active in prevention, health promotion, and self-management.

New digital and mobile health capabilities make it relatively easy for IT PROM solutions to generate individualized information and support for PWD which may allow for limited but automated support for PWD without HCP involvement, reducing the need for HCP training and time.

Use of PROMs to Facilitate Collaborative Goal Setting

PROMs in diabetes have been shown to be useful to facilitate setting of goals for diabetes self-management [2•, 63], but evidence that increased goal setting translates into better self-management and better outcomes remains to be fully shown [22]. Some tools for shared decision-making in diabetes integrate PROMs and show promising effects for contributing to greater involvement of the PWD in the decision process [26].

Insights from Research on Use of PROMs Across Diseases

PROMs have been utilized successfully in multiple other health conditions including cancer, epilepsy, and asthma to improve identification of quality of life issues, improve patient-HCP communication, facilitate care focused on individual preferences, values, and needs, decision-support, and facilitate screening and ongoing treatment effect monitoring [28•, 64].

Implementation studies across diseases provide valuable insights for diabetes PROM research regarding the real-world requirements for facilitation and implementation support, HCP training, and data utilization for optimal reach and adoption in practice [28•, 65, 66]. The literature supports the trend toward person-centred use of diabetes PROMs we highlight here regarding the design and development, training, IT systems, dialogue, and decision-support tools and related care initiatives [12, 28•, 64, 67••, 68••].

User Involvement and Resource Requirements

User Involvement in Design, Implementation, and Evaluation

At the heart of the PROM intervention is the expectation that each PWD and/or caregiver completes a PROM as part of receiving their care. Unless the PROM is experienced as a help to improve care or self-management for that PWD, it is unlikely to become an integral part of routine care.

Involvement of PWD in the design and implementation of PROMs is therefore vital and increasingly applied [67••]. Several of the recent PROM studies we identified also adopt participatory research designs, including multi-stakeholder partnerships, internet-based participatory research, town hall meetings, co-creation workshops, focus groups, iterative participatory, and rapid design evaluation processes [31, 40, 58].

While some studies cite benefits of involvement of users, we found very scarce systematic reporting on process quality and outcomes of user involvement in PROM interventions.

In the DiaProfile project (Fig. 2), systematic user involvement was applied using pre-defined quality criteria for user involvement [70]. User involvement facilitated the application of the person-centred item selection criteria previously defined (in section The Design of PROMs), including alignment with position statements regarding patient-centred language [41]. This significantly influenced decisions regarding the design of the national PROM and clinical solution.

The design of PROM projects require a multi-step process with involvement of PWD and HCPs as partners in all phases.

From the outset, PWD and caregivers play a role as partners to (1) define priorities for better care and better lives with diabetes and (2) give input to what key purpose and approach to use of PROMs in diabetes care they prefer.

In respect to design of PROM tools, PWDs are key to ensure PROMs and feedback tools reflect and capture the lived experience.

PWD and caregivers can help as partners in all phases to

1. select or develop items and technologies in line with their lived experience.

2. give feedback to the experience of and perceived value of completing specific PROMs.
3. give input to optimal frequency of assessments and what kind of feedback and reporting is needed.
4. identify cultural and practical barriers and solutions to optimal reach, adoption, and public health impact.
5. ensure broader community engagement, advocacy, uptake, and outreach.
6. enable shared learning and legitimacy for continued development of PROMs as genuine tools for strengthening the voice of PWD and their caregivers in diabetes care.

Involvement of the multi-disciplinary clinical team is equally important across all phases to ensure seamless integration in existing clinical management. Clinically anchored methods such as iterative user design and rapid learning cycles are key to enable the required ongoing learning process and resultant ongoing adjustment and optimization of PROM solutions.

Organizational Readiness and Implementation Support for Use of PROMs in Diabetes Care

The integration of PROM in routine diabetes care requires evaluation of organizational readiness, identification, and mitigation of numerous barriers and a clear plan for how HCPs can act on PRO data to improve care with the available resources [2•, 12, 61••, 67••,].

Key organizational PROM readiness factors include logistical, IT, and real-time data and dashboard functionalities, a patient-centered care culture, organizational leadership and value-based change management, and person-centered care and communication practices.

The effectiveness of PROMs depends on levels of person-centered communication practices and personal care styles of the HCP such as the extent to which HCPs review patients' chart and PROM results prior to visits, use person-centered communication techniques such as active and empathic listening, autonomy support, collaborative care, and shared decision-making, include psychosocial issues, and adopt a multi-disciplinary team care approach [53].

The CTH study found clinical benefits of external structured support to primary care clinics for use of a PROM-based self-management support intervention [63]. Three large-scale programs included successful training of HCPs in using PROs in clinical practice using brief PRO training programs (Table 3) [59•].

Clinics new to PROMs need external resources and support in a transition period which should be planned upfront to avoid breakdown due to resource gaps.

All of the recent multi-dimensional PROM diabetes projects identified (Table 3) utilize or anticipate using health IT technology to enable efficient convenient PRO data collection, visualization, and ongoing communication between PWD and HCPs. Some use very basic presentation of numerical scores by subscale on a PC while other projects use interactive apps and interactive dialogue tools. The integration of mobile text message and app communication and intervention components with PRO functionality represents an important opportunity to facilitate translation of PROM data into concrete actions within existing time constraints.

The use of improved IT systems holds a major potential to facilitate routine collection of information relevant to implementation research and monitoring clinical reach, efficacy, adoption, implementation, and institutionalization [61••].

Readiness assessments, practice facilitation, organizational value-based leadership, and change management and training are key to maximize the benefits of PROMs.

Review of Recent Multi-dimensional PROM Initiatives for PWD

We identified 6 projects from the past 5 years focused on integration of PROMs in routine care which illustrate a significant trend and approach to participatory development of multi-dimensional PROMs in diabetes care (Table 3).

As we identified only few and diverse studies, we review them here as case studies and highlight the Danish DiaProfile project as a new case study.

Aims of the Identified PRO Studies

The selected studies (Table 3) share the aim to develop or evaluate a new PROM solution for use with PWD in routine practice but apply different conceptual and operational models.

Two studies evaluate the use of either a new diabetes-specific PROM [22] or a newly designed questionnaire battery composed of existing separately validated PROMs [2•] to facilitate personal goal setting and self-management support for type 2 diabetes in primary care. Two studies evaluate the use of generic multi-dimensional PROMs in primary care for a general and diverse population [58] and specifically for people with type 2 diabetes [38•]. Two studies describe comprehensive development programs for diabetes-specific multi-dimensional questionnaires for use in routine diabetes care for people with type 1 [20•] and with type 1 and type 2 diabetes [1•] (DiaProfile (Fig. 2)).

Table 3 Selected recent studies involving multi-dimensional PROMs for routine diabetes care

	PROM purpose Study purpose	PROM intervention Domain coverage	Study design/approach	Examples of findings
1) The MOHR My Own Health Record Project [21, 58]	Purpose of PROM use: Assessment of health risks in primary care practice in order to facilitate goal setting and counseling. Study purpose: Evaluate the implementation and public health impact of the MOHR Health Behavior and Psychosocial Assessment in patients in primary care clinics.	Intervention: An electronic or paper-based health behavior and mental health assessment and feedback system paired with counseling and goal setting. Web-based, 20-item, PROM Health Risk Assessment. A brief customized feedback report is used in the clinic. Questionnaire domains: Socio-demographics, 13 specific health risk factors: general health behaviors-diet, exercise, sleep, substance use (tobacco, alcohol, drugs), and mental health (stress, worry, depression).	Design: Pragmatic randomized multi-practice study design to use RE-AIM to evaluate PROM impact.Reach (% patients getting/completing the MOHR assessment), Effectiveness (% patients reporting being asked about topics, setting change goals, and receiving assistance in early vs delayed intervention practices). Contextual factors influencing outcomes and intervention costs. User participation: Iterative user participation for MOHR assessment content, refining study design, input on outcomes measures, designing implementation workflow.	49.6% of patients completed the questionnaires. 60% of practices agreed to use MOHR [58]. No practices were able to sustain the MOHR assessment without adaptations after study completion. Use of MOHR increased staff and clinician time an average of 28 min per visit. Primary care practices can implement health behavior and mental health assessments, but counseling patients effectively requires effort. Implementing routine health risk assessments will identify many behavioral and psychosocial health risks. Authors noted: "By soliciting patient priorities, providers and patients can better manage counseling and behavior change." And "Practices will need more support to implement and sustain assessments."
2) OPTIMA Implementation Study in Primary care Practice [22]	Purpose of PROM use: Promote shared decisions and setup of specific micro-objectives in clinical practice by optimizing communication between PWD (type 2) and their physicians. Study purpose: Assess real-world use and effectiveness of the PROM in adults with type 2 diabetes in primary practice.	Intervention: PWD completes PROM prior to visit. HCP use PROM results to help set up aims and SMART goals. Based on model for PWD-HCP communication focusing on importance of "beliefs" and skills" Questionnaire domains: Beliefs and self-reported behaviors related to (1) physical activity, (2) diet, (3) treatment, (4) knowledge of the disease, (5) self-monitoring of blood glucose, and (5) feelings about DM management.	Design: Cross-sectional survey to examine impact on process parameters and PWD/HCP feedback of use of PROM in primary care. Aims were to 1) Analyze the rate of setup of SMART objectives by physicians in consultations 2) Analyze PWD responses to PROMs and compare to their SMART goals 3) Examine opinions of PWD and HCPS about the use of the PROMS Survey on PROM: Ease of understanding, usefulness, impact on PWD-HCP communication. User participation: Not described	126 doctors recruited 829 PWD. 88–92% of PWD reported ease of understanding, positive effect on PWD-HCP communication, and usefulness. "OPTIMA was found to be a useful and easy tool that could facilitate the communication between PWD and their physicians and promote the set-up of micro-objectives for T2DM management following consultations." Doctors were not trained in advance in the use of goal setting or in the specific PROM in order to make the study realistic. While many PWD set SMART goals as a result of the PROMs, majority of PWD found implementation of goals difficult to perform and, consequently, did not perform them often, especially in relation to physical activity. Authors concluded that guidance is required for HCPs to set up SMART goals.

Table 3 (continued)

	PROM purpose Study purpose	PROM intervention Domain coverage	Study design/approach	Examples of findings
3) PROMIS-29 diabetes project [38•]	Purpose of PROM use: Support communication and goal setting discussion with people with type 2 diabetes in routine clinical practice using a generic quality of life PROM. Study purpose: Evaluate factors influencing participation in PROMs and barriers to implementation of PROMIS-29 in adults with type 2 diabetes in primary care organizations serving diverse and disadvantaged populations.	Intervention: Care manager uses PROM feedback with PWD in primary care clinics for goal setting. Questionnaire domains: Generic PROMIS questionnaire: Physical functioning, anxiety, depression, fatigue, sleep, social functioning, pain interference, and intensity.	Design: 2 primary care sites each set out to recruit app. 200 patients to complete the PROM procedure twice. Semi-structured interviews with 36 PWD completing baseline and follow-up PRO assessments to assess factors influencing participation in PROM's data collection and goal setting in practices serving disadvantaged populations. 13 interviews with HCPs. User participation: Not described	Only 26% of PWD of the target population were reached. At site 2 however, 90% of PWD who were invited accepted to participate. 73% of participants also did PROM follow-up. People with multi-disease were highly overrepresented. At site 1, 40% of PROM completers set a goal vs 90% at site 2. PWD had concerns with item wording and understanding, but some could see insights be of value to their HCPs. It was proposed to consider diabetes-specific items. PWD needed more reassurance that items will be used. HCP reported benefits such as getting PWD into pain management that would otherwise not have been. PWD had doubts about relevance of PROM to care and fear of negative consequences. HCPs able to integrate PROM into existing goal setting workflow gave highest rating. Both PWD and HCPs need training and support about purpose and meaning of the PROM, strategies and best practices for data collection, attention to patient burden.
4) The Connection to Health (CTH) Project [2•, 63]	Purpose of PROM use: Comprehensive support for implementation of tailored diabetes management and self-management support in primary care Study purpose: Evaluate effectiveness and implementation of CTH (PROMs and action planning electronic-based self-management support intervention) in adults with type 2 diabetes in diverse primary care clinic settings	Intervention: PWD receive an immediate summary, along with profiles from prior times to denote change over time. PWD are asked to review the summary and identify areas to discuss with their care team in preparation for making an action plan. A parallel report is prepared for the clinician that also includes decision support tools and options for the clinician for each flagged area. Questionnaire domains: Health behaviors (diet, physical activity, medication, alcohol, tobacco), disease distress, depression, life stress. (Expanded to social risks, health literacy, and motivation towards changing health in later version.)	Design: Cluster randomized trial on reach, effectiveness, adoption, implementation, and maintenance (using RE-AIM principles [35] of CTH for PWD T2DM in primary care practices. To determine benefit of practice facilitation (PF) on PROM and self-management support program (CTH + PF) relative to CTH without practice facilitation (CTH) and self-management support education (SMS-ED) in primary practice and key practice characteristics that affect CTH RE-AIM outcomes. User participation: PWD and clinicians were involved in all phases of development.	A total of 488 patients enrolled in the CTH system (141 CTH, 347 CTH + PF). Patients from practices in the CTH + PF arm who used CTH showed significantly improved HbA1c trajectories over time compared with patients from SMS-ED practices. EHR documented self-management activities (discussing PROM areas, action planning, referrals) were significantly increased in CTH and CTH + PF study arms compared with SMS-ED.

Table 3 (continued)

	PROM purpose Study purpose	PROM intervention Domain coverage	Study design/approach	Examples of findings
5) Mater Young Psychosocial screening and management in young people years with diabetes [20•]	Purpose of PRO use: Individual case identification of psycho-social problems in order to provide comprehensive health service for young adults (18–25) with type 1 diabetes. Study purpose: Assess psychosocial needs and develop short-form psychosocial screening survey for young adults with type 1 diabetes.	Intervention: Recommendation for a brief psychosocial screening assessment for young adult PWD-T1. Questionnaire domains: QoL, mental health (diabetes distress, depression, anxiety, well-being), fears/concerns (hypoglycemia-unawareness, fear of hypoglycemia, eating), barriers to care/support (social support, environment, finances), self-image (weight, shape)	Design: Cross-sectional survey and use of this to develop short-form psychosocial screening survey. Protocol outlining comprehensive screening study with a large range of chronic health conditions, inclusive of medical, mental health, impairment, and quality of life variables. User participation: Not described.	Importance of having psychosocial screening programs which address particular needs and challenges of young adults with diabetes, including transition issues. Psychosocial screening was well accepted in the cross-sectional survey.
6) Sweden National Diabetes Register [1•, 31]	Purpose of PROM use: To implement a standard quality of life measurement as part of clinical care and collect data for use in the national diabetes register. Study purpose: Development and initial testing of new diabetes PROM for standard use with adults with type 1 and 2 diabetes.	Intervention: PWD completes the PROM in advance of visit as part of routine care. HCP uses profile scores from the diabetes PROM as part of dialogue with PWD. Questionnaire domains: General health, diabetes-related worries, limitations, self-care, satisfaction with treatment, access to and support from diabetes team	Design: Participatory development process for IRT-based profile diabetes PROM. Clinically anchored qualitative pilot testing. Qualitative research study led to content and format of the national multi-dimensional PROMS. Qualitative pilot evaluation study value in clinical practice and to PWD ongoing. User participation: Users and patient organization representatives were involved in the design and development of the PROM.	PRO questionnaire model developed with focus on opportunities, prerequisites, and possible barriers. User involvement and qualitative research development process identified the following elements as important for integration of PROM to support person-centered diabetes care: capacity approach: worries, etc.

Methods Used to Evaluate Impact

Pragmatic, qualitative, and mixed methods research designs are the predominant methods used in the identified PROM evaluation studies in order to evaluate process and outcome impacts of PROMs at multiple levels, from individual impact of PROMs on health, self-management, and care delivery benefits to indicators of implementation and population-level impact potential [12, 71]. One recent study applied a cluster-randomized design with 18-month follow-up to evaluate impact of the intervention on clinical outcomes [63].

Interviews with PWD and HCPs and evaluation surveys among PWD and HCP users generally show high acceptance and high perceived value of PROMs [2•, 22, 38•]. In one study, 88–92% of PWD were very satisfied with the PROM assessment and the majority of HCPs also found it useful to some extent but no data on clinical outcomes were reported [22].

While the pragmatic studies yield valuable insights regarding acceptability and perceived value, generalizing these findings requires great caution. Further randomized controlled studies, taking into account challenges of self-selection bias and the need for some element of attention control groups is needed [72].

The RE-AIM framework is applied with some success by several studies to structure the collection of multiple types of evidence regarding reach, effectiveness, adoption, implementation, and sustainability of the PROM intervention in order to estimate public health impact potential [2•, 58]. The operationalization of these dimensions is feasible and important for any PROM solution. Studies show significant variation in reach and adoption but overall evidence supports that reasonable rates can be achieved (Table 3). A recent cluster-randomized study reported that use of a web-based PROM diabetes self-management education intervention in primary practices led to significant improvements in glycemic control (Dickinson et al. 2019). Methodological differences related to PROM intervention scope and care setting however make it difficult to make generalized conclusions regarding the effectiveness of use of diabetes PROMs in clinical practice on clinical outcomes [38•, 73].

Comparison of Multi-dimensional PROMs Applied in Diabetes

While there is overlap in the PRO domains covered by each of the PROMs reported on in Table 3 [1•, 2•, 20•, 58, 74], most of the specific questionnaires and items used are different. This may partly reflect the appropriate use of participatory design processes to ensure questions match the specific needs and preferences of the target population and factors such as care setting and PROM aims.

Differences in choice of PRO items for some domains however, highlight the need for harmonization which can facilitate scalability, consistency, validation, and research.

The projects in Table 3 exemplify different methods for development and design of the PROM used in the recent initiatives. The DiaProfile project (Fig. 2) developed a new PROM using a systematic multi-stakeholder participatory process and mixed methods qualitative research. The deliberate use of a formalized domain structure provides important flexibility for ongoing optimization of the operational, action-orientated psychometric assessment of individual topics within each domain.

The DiaProfile PROM is a questionnaire battery consisting of both previously validated and newly designed items and scales which fit a co-developed national conceptual PRO measurement model and clinical PROM application model.

The MOHR and CTH PROMs and the Mater psychosocial screening questionnaire also combine previously validated with newly designed scales and items [2•, 20•, 21].

In contrast, the Swedish project built a new multidimensional diabetes quality of life questionnaire from qualitative research and using IRT for psychometric validation and design of scoring [1•, 31] and Scholle et al. used a fully prevalidated PROM, the PROMIS-29 [75].

While design approaches differ, the predominant approach is to combine pre-validated items when possible and then add newly developed items as required to meet the practical PROM program objectives [2•, 20•, 58].

The selected pragmatic research studies we reviewed (Table 3) mainly report that PWD and HCPs find PROM solutions to be acceptable and value adding for people with diabetes and corroborate broader PRO research suggesting a major potential for PROM interventions to improve delivery of person-centered diabetes care.

We identified similarities as well as differences in the PROM initiatives (Table 3) in regard to both aims, development method, domain coverage, and actual PRO items which highlight that this field is still in its infancy.

Conclusions

General and diabetes-specific evidence is mounting regarding the potential for new PROM solutions to help facilitate a transition towards IT-facilitated person-centered, coordinated value-based diabetes care [12]. If delivered in appropriate context and with relevant support, PROMs have a potential to harness the voice of PWD, improve focus on individual needs, resources, insights and priorities of each PWD during consultations, help clinicians with treatment decision support and monitoring, and help prioritize use of healthcare resources for optimal public health benefit.

In order to reach a tipping point for institutionalization of PROMs for value-based diabetes care, continued large-scale studies using both pragmatic and randomized controlled research designs are needed to inform design, implementation strategy and demonstrate level of impact.

Successful use of PROMs requires shared commitment of all stakeholders to adopt and apply these in context of person-centered care with sufficient resources for ongoing learning and implementation support as needed to create positive impact [7, 12, 17, 24, 28•, 39, 67••, 76].

While further randomized trials evaluating clinical improvements are underway, we are highly optimistic regarding the new trend we have identified for diabetes PROM initiatives which reflect a move from narrow psychological screening tools to multi-dimensional person-centered assessments co-developed with PWD with focus on raising the voice of PWD in care, enabling active patient participation, supporting prevention and health promotion, self-management, and better collaboration, and securing a whole-person-centered biopsychosocial care practice. The use of new multi-dimensional diabetes PROMs creates new opportunities for ongoing learning and co-creation of novel ways to partner with PWD to support autonomy, resiliency, health promotion, prevention, and care.

Pragmatic and participatory research is needed to inform operationalization of assessments of organizational readiness, practice facilitation, and quality assurance for use of PROMs in practice. Involvement of PWD and clinicians, in co-learning, comprehensive advance implementation planning [12], and training of HCPs [59•] and culture change through leadership are additional key success factors.

We concur with other recent reviews [61••] that merely conducting PROM assessments as a stand-alone intervention will not deliver the desired health benefits. Rather, it is the shared, coordinated multi-disciplinary and cross-sectoral effort to translate the input of PWD and caregivers into better individual care that will improve outcomes.

We have identified a new and promising trend towards multi-dimensional PROM diabetes initiatives guided by systematic user involvement with PWD and clinicians in all phases which harness the opportunities of IT and mobile health technologies. We highlight the potential for shaping innovative PROM initiatives through multi-disciplinary and multi-sectorial collaboration with PWD as equal partners an clearly defined objectives for person-centered value-based diabetes care and prevention.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any intervention studies with human or animal subjects performed by any of the authors. Qualitative research involving people with diabetes and caregivers was undertaken by Soren E. Skovlund for this study. All participants in this research gave informed written consent and study protocol was conducted according to local and national scientific regulations.

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