Cardiovascular Diabetology

COMMENT

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Defining patient-reported outcomes in diabetes, obesity, cardiovascular disease, and chronic kidney disease for clinical practice guidelines - perspectives of the taskforce of the Guideline Workshop

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Abstract

Recent clinical practice guidelines for diabetes, obesity, cardiovascular disease (CVD) and chronic kidney disease (CKD) emphasise a holistic, person-centred approach to care. However, they do not include recommendations for the assessment of patient-reported outcomes (PROs), which would – dependent on the topic of guideline – be important for improving shared decision-making, patients' concordance with guideline recommendations, clinical outcomes and health-related quality of life (HRQoL). The Taskforce of the Guideline Workshop discussed PROs in diabetes, obesity, CVD and CKD as well as the relevance of their inclusion in clinical practice guidelines for the management of these conditions.

Highlights

- Patient engagement in disease management is a topic that is becoming increasingly important, also in terms of improving clinical outcomes
- Person-reported outcome measures (PROMs) are tools to assess person-reported outcomes (PROs) in an efficient and standardized manner
- Validated disease-specific measures for diabetes, obesity, CVD, and CKD as well as generic measures are available

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- Currently underutilised in the routine care of cardio-renal-metabolic diseases, the integration of recommendations on PROs and PROMs into clinical practice guidelines may help to overcome the barriers to their implementation

Keywords Cardiovascular disease, Chronic kidney disease, Diabetes, Obesity, Person-reported outcomes

Introduction

Despite remarkable progress in the pharmacological treatments of diabetes, obesity, CVD, and CKD, and respectively updated recommendations in clinical practice guidelines, the prevalence of these diseases in the global population is still significant and is expected to continue to increase [1–5]. This fact supports the observation of suboptimal implementation of clinical practice guideline recommendations into routine clinical care [6], apart from other factors such as an ageing population, social determinants of health, and the climate change that have also been reported to contribute to the rising global burden of chronic diseases [7–9].

The implementation of clinical practice guidelines in routine care can be influenced by different factors, including poor applicability of the guidelines in real-world practice and person-related factors [10], such as engagement with treatment. Therefore, the management of chronic diseases, which require long-term professional care and individual self-management, has been encouraged to shift away from the traditional healthcare professional-directed care model to a person-centred care model [11].

Person-centred care is a model of care that emphasizes a person's experiences as whole individuals, rather than merely focusing on their symptoms and diagnoses [12].

Person-centred care entails a holistic approach to treatment and shared treatment decision-making, promoting patient empowerment [13]. The holistic approach to treatment addresses physical, emotional and social needs, recognising that health is influenced by many factors beyond medical conditions [14]. Shared decision-making incorporates patients' perspectives about their health and overall well-being, as well as preferences and values into decisions and oversight of care [15]. This ensures that treatment is optimally tailored to each patient's individual circumstances. The person-centred approach can improve patient satisfaction, health behaviour, symptom burden and healthcare utilization and will therefore become increasingly important [16].

International recommendations focus on a holistic patient-centred approach in the care of patients with diabetes with or without CVD [17, 18], CKD [19] and obesity [20, 21]. Implicitly, this means that it is important to gather information not only on disease symptoms and treatment side events, but also on daily functioning, well-being and HRQoL. These data must then be used to evaluate treatment effectiveness, disease management and health outcomes in general. This broader view is supported by regulatory agencies [22, 23].

For the U.S. Food and Drug Administration (FDA) "the individual's perspective about the impact of trying to manage the disease and the burden that self-management confers must be addressed to achieve optimal health outcomes" [22]. For the European Medicines Agency (EMA) "the voice of patients and carers is critical during the whole life cycle of a medicine, from early development to reporting of adverse drug reactions and risk minimization" [23].

The patient perceptions of the impact of an intervention or therapy on their health are referred to as PROs and have been defined by the FDA as "any report of the status of a health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else" [24, 25]. PROs therefore cover domains as diverse as physical health, mental health, unobservable symptoms (e.g. pain, fatigue), HRQoL, social functioning and perceived health status.

PROs can be captured by patient self-report or interviews, but in clinical practice, consultation time is often short, limiting in-depth discussions about well-being. Therefore, collecting PROs in a standardized manner using patient-reported outcome measures (PROMs), which are often questionnaires, rating scales, or single questions, can be helpful in the clinical setting.

Nonetheless, despite the existence of validated PROMs in the areas of diabetes, obesity, CVD, and CKD, they are rarely utilized, and when utilized, they are usually positioned as secondary to a physical outcome. Furthermore, recommendations on the collection of PROs and the use of PROMs are missing from the person-centred clinical guidelines for the management of these conditions, which are comorbidities that often coexist and increase the individual's disease burden.

Having made this observation, the Taskforce of the Guideline Workshop discussed the state-of-the art of PROs in diabetes, obesity, CVD, and CKD, and the pertinence of including recommendations for PRO collection in clinical practice guidelines for their management, depending on the topic of interest.

Given the rapid developments in diabetology, obesity, cardiology and nephrology, a transition in clinical guideline development towards the concept of "Living Guidelines" [26] should be considered and the integration of recommendations for PRO assessment into those guidelines discussed. Hereby, we present a reflection on and

propose recommendations for the incorporation of PROs into future clinical practice guidelines for managing diabetes, obesity, CVD and CKD.

PROs in clinical research and clinical practice

As underlined, the FDA and the EMA recognize the importance of including patient input throughout the life cycle of a medicine or a medical device [27, 28] and expect clinical trials to increasingly incorporate endpoints that are meaningful to patients and responsive to treatment [22, 29, 30]. Data from PRO trials have added value in therapy and health technology assessments as they help determine the risk-benefit ratio of a treatment by giving new information on patient adherence, progress, and satisfaction with care [22, 23]. This will ultimately have an impact on decisions by national healthcare authorities and reimbursement policies.

PRO data, collected during clinical trials, can also be used to inform clinical guidelines and clinical practice [31], and generate real-world PRO data. Thus, the collection and generation of PRO data can be seen as an iterative process that alternates between routine clinical care and clinical research. The challenges inherent in this process are to define the constructs that should be evaluated for each disease or intervention, to establish scientifically rigorous methods for PRO collection, measurement, analysis and reporting, and to implement PRO assessment in clinical practice.

Specific and generic PROs in diabetes, obesity, CVD and CKD

The World Health Organization (WHO) defines health in its Constitution as a "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [32]. Apart from disease symptoms and treatment-related issues, well-being under a specific condition can also be affected by psychological, socioeconomic and financial factors [33]. Thus, when considering assessing PROs, and choosing the constructs and instruments to measure them, it is important to look at both disease-specific and generic PROs, as both provide complementary information on individual's HRQoL, engagement with treatment, satisfaction and communication.

The process of analysing and evaluating PROM results is challenging, and the presence of multiple conditions, such as diabetes, obesity, CVD and CKD, adds to the complexity of the task. It can be difficult for a person with multimorbidity to distinguish the effects of a disease and its treatment from the effects of other comorbidities. On the other hand, the coexistence and combination of two or more chronic diseases can potentiate synergistic, antagonistic or additive effects [34]. Hence, particularly in the context of multimorbidity in diabetes, it is important to identify the specific PROs for each condition and the generic PROs common to all of them.

Diabetes-specific PROs

Diabetes is a disease where those afflicted can be empowered to monitor and control some important outcomes, such as blood glucose and hypo- and hyperglycemia. However, dysglycemia can lead to physical symptoms such as pain or blurred vision [35]. In addition, worries for outcomes of the disease or fear of hypoglycemic episodes can cause emotional and psychological symptoms, such as distress, anxiety, and depression [36] which affect a person's mental well-being, perceived quality of life and the ability to function.

The health outcomes and the HRQoL of a person living with diabetes also depend on the adoption of self-management behaviours. These behaviours are influenced by both individual characteristics (attitude, education, compliance with treatment and lifestyle modifications) [35], and environmental factors (stigma, social support, financial concerns) [35].

Whether some individuals might find self-management behaviors facilitated by diabetes technology, others might encounter difficulties using insulin pumps, glucose sensors and continuous glucose monitoring (CGM) devices or automated insulin delivery (AID) systems. A person living with diabetes can take advantage of the information provided by CGM to take timely decisions on sugar and carbohydrate intake, adequate physical activity, adjustment of insulin, prevention of hypoglycemic episodes, and learn about the impact of its lifestyle in general. But the vast amount of CGM information, frequent audio alerts, and the demand for constant disease monitoring, data interpretation, and action can lead to frustration and distress. Overall, individual differences in skills with CGM systems, insulin pumps, or AID systems, as well as education and understanding about diabetes and its treatment, condition the individual's mental health and success in disease management. This emphasizes the importance of social determinants of health for the success rates of a given intervention in diabetes, and of PRO collection and analysis for the identification of individuals or populations requiring additional support.

Efforts have been made to establish relevant PROs in diabetes that should be assessed in clinical care. In 2020, the Diabetes Working Group of the International Consortium for Health Outcomes Measurement (ICHOM), identified psychological well-being, depression and diabetes-related emotional distress from a core list of standard outcomes for diabetes as PROs that should be prioritized for assessment in routine clinical practice [37], and recommended as PROMs the WHO Well-Being Index (WHO-5), the depression module of the Patient Health Questionnaire-9 (PHQ-9) for depression and the

Problem Areas in Diabetes (PAID) scale for distress [37]. These specific PROMs were chosen because PROMs should be able to be used in any health care setting, regardless of whether it has high or low resources, and because they are freely available in many languages.

The position of the ICHOM Diabetes Working Group is consistent with the recommendations of the American Diabetes Association (ADA), which considers diabetes distress, depression, anxiety, cognitive functioning and chronic pain as constructs to be assessed [38]. Recently, the European Health Outcomes Observatory (H2O) reviewed evidence for 53 identified diabetes specific PROs and 88 PROMs [39]. Numerous PROs and their respective PROMs may cause confusion for health care providers, thereby obstructing the assessment of PROs in diabetes care. In a further refinement to establish a consensual diabetes outcome set for both type 1 and type 2 diabetes in clinical practice, a shorter list of PROs to be measured regularly (Table 1) alongside clinical outcomes has been developed [40]. The proposed outcome set aims to be adaptable to different subgroups and their specific needs, since managing type 1 and type 2 diabetes presents different challenges. For instance, it was observed that only people with type 1 diabetes considered regular screening for depression and eating problems to be important, while only people with type 2 diabetes endorsed screening for sexual health [40]. However, the substantial number of PROs agreed to be included in the outcome set (Table 1) can be a burden on patients and compromise its own feasibility and validity.

It would also be beneficial to consider identical PRO domains in diabetes clinical care and research. This would facilitate the interpretation of therapeutic interventions and observational study results and their application to patient monitoring and daily care. However, PROs are either seldom collected or captured in a non-standardized way [41], which poses a hindrance to comparability of interventions and findings across studies. Based on a systematic review of randomized clinical trials in diabetes including the assessment of one or more PROMs, a consensus statement on the PRO core domains to be assessed in clinical research, endorsed by the ADA and the European Association for the Study of Diabetes (EASD), among other organizations, has been published recently [41] (Table 1).

Comparing the PRO domains recommended for diabetes clinical practice and research (Table 1), we can see that depression, diabetes distress, fear of hypoglycemia, functional health status, well-being and social functioning, sexual health, sleep quality and quantity, and treatment satisfaction overlap, suggesting that these are the PROs that should be primarily assessed in both areas.

Table 1 PRO domains proposed to be assessed in diabetes clinical practice [34] and diabetes research [35]

PRO domains proposed to be assessed	
Diabetes clinical practice [34]	**Diabetes research [35]**
Depression	
Diabetes distress	
Fear of hypoglycemia	
Hypoglycemia unawareness	
Perceived diabetes symptoms	
Functional heath status, well-being* and social functioning	
Eating problems	
Lifestyle behavior**	
Sexual health	
Sleep quality and quantity	
Perceived control of diabetes	
Self-care performance	
Perceived importance of self-care	
Capacity for self-care	
Motivation for self-care	
	Impact of diabetes devices and technology
Treatment satisfaction	
Diabetes-specific QoL	

QoL, quality of life; *including psychological well-being; **including alcohol consumption and smoking

Obesity-specific PROs

Obesity is a complex, chronic condition that remains stigmatized and under-recognized. It has long been seen as the result of irresponsible lifestyle options and behaviours, laziness and lack of self-discipline, although it is recognized that genetic, environmental and socioeconomic factors play a role in its development [42].

People with obesity experience weight stigma and discrimination frequently, even in the healthcare setting [43]. Stigma and prejudice towards obese people have a significant impact on individual self-esteem and cause distress, which can lead to adverse physiological, psychological and behavioral responses.

Weight stigma has been shown to be associated with cortisol and C-reactive protein levels, glycated hemoglobin, oxidative stress, depression, anxiety, body image dissatisfaction and eating disturbances [44]. Binge eating has been associated with internalized weight stigma in adults [45], children, and adolescents [46], contributing to further weight gain, and low self-esteem.

Given the above, it is not surprising that, whereas physical health is perceived as the most important PRO in obesity by healthcare professionals, self-esteem is viewed as the most important PRO by individuals living with the disease [47]. In total, eight PROs to be assessed in obesity treatment research have been identified by the Standardize Quality of life measurement in Obesity Treatment (S.Q.O.T) initiative: self-esteem, physical health/functioning, mental/psychological health, social health,

eating, stigma, body image, and excess skin [47]. Validated PROMs have been identified for all PROs, except for stigma [47]. Impact of Weight on Quality of Life-Lite (IWQOL-Lite) was selected for assessing self-esteem, and BODY-Q was the PROM selected to assess the other six core domains [47]. Recently, normative BODY-Q values have been generated from the general population, which can be used as reference in both research and clinical practice [48].

CVD-specific PROs

Cardiovascular disease is an umbrella term comprising several diseases such as atrial fibrillation, coronary artery disease, heart failure, hypertension, myocardial infarction or stroke. Specific PROMs have been developed for each disease, and an extensive compilation can be found in recently published literature [49, 50]. However, what all of them have in common is the high burden of symptoms on patient's HRQoL. Symptoms such as syncope, palpitations, dyspnea, chest pain, and life-threatening arrhythmias can limit a patient's well-being physically (e.g. fatigue) and induce psychological distress in the form of anxiety or depression [51]. Beyond the symptoms, the prospect of living with a lifelong condition and needing medication to survive can cause general distress. Therefore, multidimensional PROMs, assessing both physical and psychological function have been developed and validated [50], but PRO assessment in CVD primarily has been performed in clinical trials [49], and is used infrequently in clinical practice [50].

The reasons underpinning the poor use of a simplified form of the Kansas City Cardiomyopathy Questionnaire (KCCQ) in routine clinical care have been investigated [52]. The KCCQ is a PROM that captures symptom frequency, symptom burden, physical limitations, social limitations and quality of life in heart failure, and can be used in clinical trials and clinical practice [53]. Both, participants and clinicians deemed this PROM appropriate and beneficial [52], but lack of awareness of the significance and value of PROs and difficulties in streamlining their integration into electronic health records may be factors limiting the use of KCCQ in practice [52].

Associations and Committees of the European Society of Cardiology (ESC), the Heart Failure Association and the ESC Patient Forum have issued a joint statement referring to the importance of including guidance on PROs and PROMs in ESC clinical guidelines, to assess the performance of and adherence to recommendations [50]. The American Heart Association (AHA) emphasizes the importance of PROs in cardiovascular medicine for adults in a recently published scientific statement and sets an example by recommending standardized assessment of PROs using validated questionnaires in people with heart failure (Fig. 1), such as the KCCQ or Minnesota Living with Heart Failure Questionnaire (MLHFQ) [54–56].

CKD-specific PROs

Currently, patients living with CKD can be managed with medication, but this will not restore their kidney function. The main goal of CKD management is to slow down the progression to advanced CKD and prevent end-stage kidney disease.

Although patients in CKD advanced stages exhibit a significant burden of symptoms and impaired HRQoL and may require kidney replacement therapy such as hemodialysis or kidney transplantation for survival, those in the initial stages of the disorder are frequently asymptomatic and remain undiagnosed [57]. Screening for CKD in risk populations by determining the estimated glomerular filtration rate and the urine albumin-creatinine ratio is recommended [19]. Assessment of PROs

2022 ACC/AHA/HFSA Guideline for the Management of Heart Failure

COR	LOE	Recommendation
2a	C-LD	In patients with HF, standardized assessment of patient-reported health status using a validated questionnaire can be useful to provide incremental information for patient functional status, symptom burden, and prognosis.

Fig. 1 Recommendation from the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure on the assessment of PROs [54, 56]. Abbreviations: C-LD, Level C-Limited Data; COR, Class of Recommendation; LOE, Level of Evidence

for CKD patients has not been prioritized but could play an important role not only for monitoring a patient's HRQoL but also for providing complementary information regarding symptom prevalence and severity.

Based on a systematic literature review, the ICHOM CKD Working Group selected six PRO domains relevant for CKD: general HRQoL, pain, fatigue, physical function, depression and daily activity [58]. The working group focused mainly on outcomes relevant to patients with very high-risk CKD [58], but even in this population, patient-reported burden can vary, depending on the intervention. Patients who receive a kidney transplant generally experience fewer and less severe symptoms than patients receiving dialysis and have an improved HRQoL [59]. These symptoms include muscle weakness, fatigue, poor sleep, itching, decreased appetite, depression, dry mouth and poor mobility [59]. In particular, fatigue, pruritus, sleep problems and muscle cramps were found to be associated with reduced work productivity and activity limitation in patients with advanced CKD compared with patients with early CKD [60]. However, many of these symptoms can be mitigated by changes in clinical management [61] which underlines the importance of collecting PROs in CKD in routine clinical care.

As a disease-specific measurement tool, the Kidney Disease Quality of Life 36-item short form survey (KDQOL-36) [62] can be used. Recently, a PRO scale (chronic kidney disease-person-reported outcome, CKD-PRO) has been developed to evaluate the clinical outcomes of CKD patients [63].

Generic PROs

As seen above some of the mentioned disease-specific PROs, such as depression, emotional, physical and sexual health, sleep quality and quantity, social functionality and treatment satisfaction, are more generic, and common to diabetes, obesity, CVD and CKD. There is also evidence that pain, fatigue, depression, anxiety, sleep disturbances, physical, sexual and mental function, participation in social roles and activities and overall health are relevant PROs for patients, irrespective of the disease [35, 64]. Therefore, it has been suggested to assess these PROs for multiple medical conditions using the Patient-Reported Outcomes Measurement Information System (PROMIS) [35], comprising commonly relevant PROs across the domains of physical, mental, and social functioning [64].

Table 2 lists proposed generic and diabetes-, obesity-, CVD-, and CKD-specific PROMs.

Table 2 Proposed PROMs

Disease specificity	Validated PROM(s)
Diabetes	• Diabetes psychosocial assessment tool (DPAT) [65] • WHO Well-Being Index (WHO-5) [66] • Patient Health Questionnaire-9 (PHQ-9) [67] • Problem Areas in Diabetes (PAID) [68]
Obesity	• Impact of Weight on Quality of Life-Lite (IWQOL-Lite) [69] • BODY-Q [70]
CVD	• Kansas City Cardiomyopathy Questionnaire (KCCQ) [71–73] • Minnesota Living with Heart Failure Questionnaire (MLHFQ) [74]
CKD	• Kidney Disease Quality of Life 36-item short form survey (KDQOL-36) [75–77] • Chronic kidney disease-person-reported outcome (CKD-PRO) scale [63]
Generic	• Patient-Reported Outcomes Measurement Information System (PROMIS) [78]

Evidence for the implementation of PRO assessment in clinical care

Investigation of the role of PRO assessment in clinical care suggests PROMs can be useful in the clinical setting by enabling individualization and patient-centred care [79, 80]. Most of the evidence supporting PRO collection in clinical practice has been collected in oncology [33, 81], where the routine use of PROMs has been associated with improved symptom control, increased supportive care measures, and patient satisfaction [81], as well as longer overall survival and reduced hospitalization [82].

There are general recommendations for implementing the assessment and measurement of PROs [80, 83, 84] in clinical practice, and in the areas of cancer, rheumatic disease, and orthopaedics, significant experience in routine assessment of PROs has been reported [85–87].

Recently, a clinical practice guideline on the use of PROMs in cancer clinical care [88] recommended digital symptom monitoring with PROMs in routine clinical care during systemic cancer treatment [88].

Evidence supporting the integration of PRO assessment in clinical practice in diabetes, obesity, CVD and CKD is scarce, probably because clinicians are not routinely assessing PROs for these diseases [89].

However, the use of PROMs in diabetes outpatient care has been investigated in a scoping review [90], which analyzed the outcomes of the Diabetes Flex [91, 92], and DiaProfil [93] trials, assessing multidimensional PRO domains, and the outcomes of the DiaPROM [94–97] and diabetes psychosocial assessment tool (DPAT) [65] trials, assessing diabetes distress, and psychological needs, respectively.

In the DiabetesFlex trial, participants who had filled the multidimensional questionnaire, had increased WHO-5 and decreased PAID scores compared with standard care participants, suggesting that visits combined with PROs improved diabetes-related well-being [91]. Furthermore, participants who enrolled in the PRO-based telehealth intervention DiabetesFlex Care [92] became

more involved in their own care and found conversations with healthcare professionals more relevant [92]. Participants of the DiaProfil trial also found that completing the questionnaire facilitated positive reflection and better preparation for their visits, and would like to continue to use it [93]. On the other hand, the participants of the DiaPROM pilot trial [95], who were only assessed for diabetes distress, found PRO reports of limited value during consultation [94], while participants of the DPAT trial [65] found the PROM easy to use. Furthermore, the DPAT PROM helped to identify anxiety, depression, and significant weight, shape and eating concerns in young people with type 1 diabetes [65].

Interestingly, a cross-sectional study testing the use of PROMIS-10 as a generic tool to measure general health, and an adaptation of PAID as the diabetes-specific questionnaire in patients diagnosed with type 2 diabetes ≤ 4 years [98] found that diabetes-related distress was negatively and significantly correlated with physical and mental health and that the PROMs helped to detect problems with self-confidence in managing diabetes and sexual dysfunction in one third of the participants [98].

These differing views on the usefulness of PROMs for patient care should lead us to consider the following: PROMs will only be useful in clinical practice if patients find them easy to use, if their results are considered effectively, and if appropriate resources are offered in response. This situation is not unique to the diabetes clinical environment.

In stroke clinical practice, PROMs are also used as part of routine follow-up [99]. Interviewed patients have reported the added value of PROMs in gaining insight into their problems, in arranging further care and in ensuring all important topics were discussed during the consultation [99].

Barriers to the implementation of PRO assessment in clinical care

Integrating PRO assessment into the workflow of routine clinical practice may face limitations. In the DiaProfil trial, healthcare professionals reported that it was demanding to address many PRO issues during the allocated time for a visit [93]. On the patient's side, low literacy or high levels of distress may pose obstacles to PRO measurement [100]. Furthermore, for the medical community, the availability of several standardized PROMs for capturing symptom status, HRQoL and physical, psychological and social functioning, has created a practical barrier to accepting the value and routine use of PROs [33]. Moreover, lack of awareness of clinicians about the value of PROs in clinical care and gaps in education on PRO collection and PROM selection are serious limitations to the assessment of PROs in clinical practice.

Barriers also exist in the form of limited resources, lack of administrative and infrastructural requirements for data collection and management, or uncertainty about aspects that truly matter to patients. This means, that goals of PRO collection should be defined prior to implementation of PRO assessment, and selection of PROMs should follow existing guidelines and conceptual models as well as consideration of measurement properties [101], including validity, reliability and responsiveness to change.

In practice, overcoming the barriers to PRO assessment in clinical practice for diabetes, obesity, CVD and CKD could be facilitated either by developing clinical practice guidelines specifically on this topic, as has been done for cancer [88], or, preferably, by including recommendations for PRO assessment in clinical practice guidelines for disease management.

How to implement PROs and PROMs into clinical practice guidelines for diabetes, obesity, CVD and CKD

PROs are dynamic by nature. As healthcare practices evolve and new treatments, interventions, and technologies emerge, PROs or the chosen PROMs to measure them can quickly be outdated or fail to capture relevant aspects of patients' experiences. Consequently, the collected information may not accurately reflect the patient's current health status. Moreover, patient demographics, cultural norms, and preferences change over time. So, PROs need to adapt to these changes and consider diverse patient populations and their unique needs, and the correspondent PROMs need to be regularly updated to ensure they remain relevant. Hence, it can be deemed that PROs and PROMs possess a living characteristic.

The concept of "living guidelines" gained prominence during the COVID-19 pandemic because it combines the integration of novel evidence-based information on the effectiveness and safety of treatments and interventions, with the need to quickly update clinicians with trustworthy guidelines and accelerate knowledge transfer into routine clinical practice. A similar need for a quicker update of disease management guidance is also felt in diabetes, obesity, CVD and CKD, since clinical research in these areas is developing fast and there is a permanent feed of new information about pharmacotherapy available. Moving towards living guidelines would be helpful, and since PROs add value and depth to understanding beyond the clinical outcomes of these novel interventions, it would be advantageous to establish also the health domains and constructs to be assessed in living clinical practical guidelines.

The incorporation of PRO constructs and evidence supporting them into the guidelines' creation process could be facilitated by the Magic App platform for

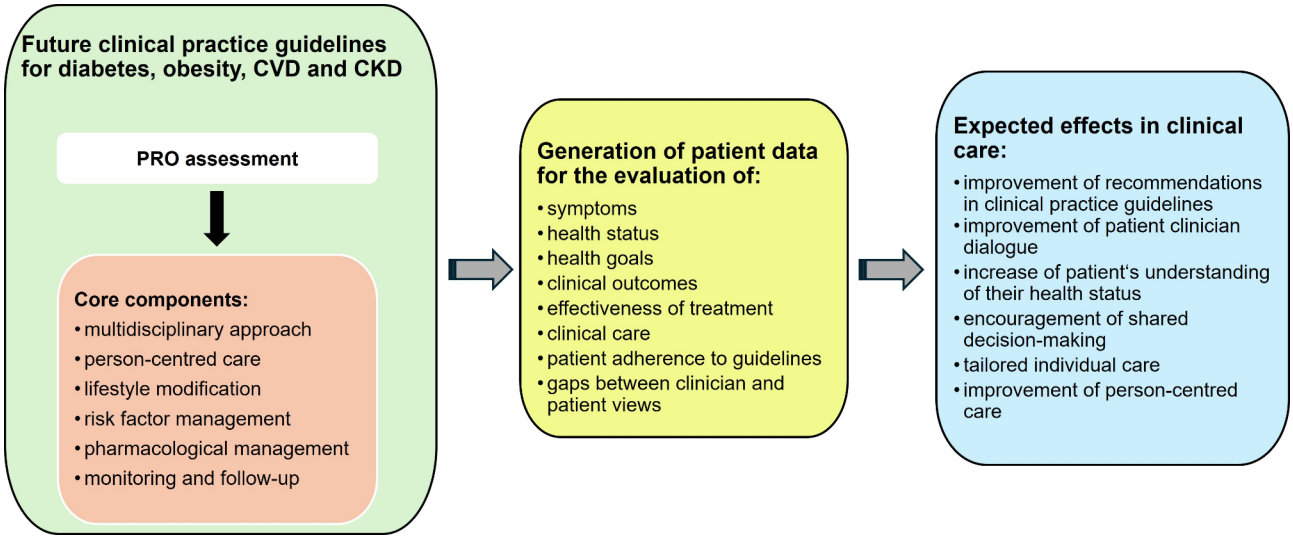

Fig. 2 The impact on clinical care of incorporating PRO assessment into the core components of future clinical practice guidelines for the management of diabetes, obesity, CVD and CKD

guideline development (https://magicevidence.org/magicapp/), which uses Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology [102] and is now being widely applied to the creation of rapid recommendations and living guidelines.

Limitations

A limitation of this article is that a narrative summary of the available literature was applied. Conclusions are based on expert opinions from the discussions of the Taskforce of the Guideline Workshop on this topic, and offer the opportunity to include perspectives derived from the clinical experience of the members.

Summary and conclusions

Diabetes, obesity, CVD and CKD are chronic conditions that require long-term management and a holistic, patient-centred approach. By incorporating PROs into clinical practice, healthcare providers can better understand patients' perspectives, improve communication, and ultimately enhance treatment adherence and clinical outcomes [93, 103]. Despite the benefits, PROs are still rarely used in routine care. Including PRO assessments in clinical practice guidelines could bridge the gap between patient and clinician perspectives and improve person-centred care. Therefore, we recommend that PRO assessment be included into the core components of future clinical practice guidelines for the management of diabetes, obesity, CVD and CKD (Fig. 2).

Abbreviations

ADA	American Diabetes Association
AHA	American Heart Association
CKD-PRO	Chronic kidney disease-person-reported outcome
COR	Class of recommendation
DPAT	Diabetes psychosocial assessment tool
EMA	European Medicines Agency
ESC	European Society of Cardiology
FDA	U.S. Food and Drug administration
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
H2O	Health Outcomes Observatory
HRQoL	Health-related quality of life
ICHOM	International Consortium for Health Outcomes Measurement
IDF	International Diabetes Federation
KCCQ	Kansas City Cardiomyopathy Questionnaire
KDQOL-36	Kidney Disease Quality of Life 36-item
MLHFQ	Minnesota Living with Heart Failure Questionnaire
PAID	Problem Areas in Diabetes
PHQ-9	Patient Health Questionnaire-9
PRO	Patient-reported outcome
PROM	Patient-reported outcomes measure
PROMIS	Patient-Reported Outcomes Measurement Information System
WHO	World Health Organization
WHO-5	WHO Well-Being Index

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Competing interests
Katharine Barnard-Kelly is founder and shareholder at Spotlight-AQ Ltd. KBK has received research support from Dexcom, Embecta, JDRF, Novo Nordisk and Roche Diabetes Care, and honoraria from Sanofi. Tadej Battelino has served on the advisory boards of Abbott, Boehringer Ingelheim, Dreamed Diabetes, Eli Lilly and Company, Indigo Diabetes, Medtronic, Novo Nordisk, and Sanofi. TB has received speaker's bureau honoraria from Abbott, Eli Lilly and Company, Medtronic, Novo Nordisk, Roche, and Sanofi. The University Medical Center has received research grant support from Abbott, GluSense, Medtronic, Novo Nordisk, Sandoz, Sanofi, and Zealand Pharma. Frank C. Brosius is a consultant for MAKSCIENTIFIC. Antonio Ceriello reports consulting and speaking for Bayer, Berlin-Chemie, Eli Lilly and Company, Guidotti, Merck, Novo Nordisk, Roche Diagnostics and Sanofi. Francesco Cosentino has nothing reported. Julian Elliott has nothing reported. James R. Gavin III has served on the advisory boards of Abbott Diabetes Care and Embecta, and on the speaker's bureaus of Boehringer Ingelheim and Eli Lilly and Company. Francesco Giorgino has served on the advisory boards of AstraZeneca, Eli Lilly and Company, Novo Nordisk, Roche Diabetes Care, Sanofi and as a consultant to AstraZeneca, Boehringer Ingelheim, LifeScan, Medimmune, Medtronic, Merck Sharp & Dohme, Roche Diabetes Care and Sanofi. FG has also received research support from Eli Lilly and Company and Roche Diabetes Care. Jennifer Green has nothing reported. Linong Ji declares that he has no competing interests. Monika Kellerer has served on advisory boards of Abbott Diabetes Care, Astra Zeneca, Bayer AG, Boehringer-Ingelheim, Eli Lilly, NovoNordisk and Sanofi. Sue Koob has nothing reported. Mikhail Kosiborod reports consulting or advisory board participation for 35Pharma, Alnylam Pharmaceuticals, Amgen, Applied Therapeutics, AstraZeneca, Bayer, Boehringer Ingelheim, Cytokinetics, Dexcom, Eli Lilly and Company, Esperion Therapeutics, Janssen Pharmaceuticals, Lexicon Pharmaceuticals, Merck (Diabetes and Cardiovascular), Novo Nordisk, Pharmacosmos, Pfizer, scPharmaceuticals, Sanofi, Structure Therapeutics, Vifor Pharma and Youngene Therapeutics. MK has also received honoraria from AstraZeneca, Boehringer Ingelheim and Novo Nordisk, and research grants from AstraZeneca, Boehringer Ingelheim and Pfizer. Nebojsa Lalic declares that he has no competing interests. Nikolaus Marx has received research grants from Boehringer Ingelheim and MSD, speaking fees form Amgen, AstraZeneca, Bayer, BMS, Boehringer Ingelheim, Eli Lilly and Company, MSD, Novo Nordisk, and Sanofi-Aventis and has served or serves on the advisory board of Amgen, Bayer, BMS, Boehringer Ingelheim, MSD, Novo Nordisk, and Sanofi-Aventis. Prashant Nedungadi has nothing reported. Christopher G. Parkin has nothing reported. Helena W. Rodbard declares that she has no competing interests. René D. Rötzer is employee of Sciarc GmbH. Lars Rydén declares that he has no competing interests related to this work. Wayne Sheu has nothing reported. Eberhard Standl declares that he has no competing interests. Britta Tendal Jeppesen declares that she has no competing interests. Pinar Topsever has received honoraria or consulting fees from AstraZeneca, Boehringer Ingelheim, Eli Lilly and Company, and LifeScan, and has served on the speaker's bureau for AstraZeneca. PT received grant/research support from PCDE, made possible by corporate sponsorship from AstraZeneca, Eli Lilly, Novo Nordisk, and Roche Diagnostics; the sponsors had no input into the study protocols. Per Olav Vandvik has nothing reported. Christoph Wanner received honoraria for steering committee and adboard participation as well as lecturing from Alexion, AstraZeneca, Bayer, Boehringer Ingelheim, Eli-Lilly, MSD, Novo Nordisk and Sanofi. Oliver Schnell is founder and CEO at Sciarc GmbH, Baierbrunn, Germany.

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