Patient Education and Counseling 116 (2023) 107933

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.journals.elsevier.com/patient-education-and-counseling

Which diabetes specific patient reported outcomes should be measured in routine care? A systematic review to inform a core outcome set for adults with Type 1 and 2 diabetes mellitus: The European Health Outcomes Observatory (H2O) programme

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ARTICLE INFO

Keywords:
Diabetes mellitus
Type 1
Type 2
Patient reported outcome measures

ABSTRACT

Objectives: The objective was to identify candidate patient reported outcomes with potential to inform individual patient care and service development for inclusion in a digital outcome set to be collected in routine care, as part of an international project to enhance care outcomes for people with diabetes.
Methods: PubMed, COSMIN and COMET databases were searched. Published studies were included if they recommended patient reported outcomes that were clinically useful and/or important to people with diabetes. To aid selection decisions, recommended outcomes were considered in terms of the evidence endorsing them and their importance to people with diabetes.
Results: Twenty-seven studies recommending 53 diabetes specific outcomes, and patient reported outcome measures, were included. The outcomes reflected the experience of living with diabetes (e.g. psychological well-being, symptom experience, health beliefs and stigma) and behaviours (e.g. self-management). Diabetes distress and self-management behaviours were most endorsed by the evidence.
Conclusions: The review provides a comprehensive list of candidate outcomes endorsed by international evidence and informed by existing outcome sets, and suggestions for measures.
Practice implications: The review offers evidence to guide clinical application. Integrated measurement of these outcomes in care settings holds enormous potential to improve provision of care and outcomes in diabetes.

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https://doi.org/10.1016/j.pec.2023.107933
Received 11 June 2023; Received in revised form 21 July 2023; Accepted 2 August 2023
Available online 16 August 2023
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1. Introduction

The risk of complications for people with Type 1 or Type 2 diabetes mellitus, can be significantly reduced by maintaining blood glucose, blood pressure and serum lipids close to target parameters [1,2]. While there are multiple clinical guidelines [3,4], technologies and pharmacological therapies to facilitate metabolic control, clinical outcomes critically depend on the activation of patient level self-management behaviours, such as diet, exercise, taking medications and health monitoring. Engagement with self-management behaviours is positively associated with metabolic outcomes and reduced risk of diabetes complications [5].

There are, however, multiple factors that can mediate the adoption of diabetes self-management behaviours in people with diabetes. Examples of intrinsic factors with a demonstrated impact include: the person's psychological orientation to their diabetes (e.g. acceptance, motivation, self-efficacy); physical factors (e.g. comorbidity, functional capacity, sensory deficits); psychiatric morbidity (e.g. depression, eating disorders, anxiety disorders, personality disorder); diabetes specific psychological issues (e.g. fear of complications, hypoglycaemia or adverse treatment effects, diabetes distress); and cognitive function [6–12]. Similarly, examples of extrinsic factors include: exposure to effective diabetes self-management education and support; interaction with healthcare services; social support; stigma; socioeconomic circumstances/resources; and cultural factors [13–16]. These sorts of variables are broadly distributed within and across diabetes settings and populations, with the variation likely explained by individual and contextual moderating and mediating variables [17]. This contributes to variation in the performance of diabetes care in achieving metabolic targets. Currently that level of performance is often suboptimal and inconsistent, exposing large numbers of people with diabetes to the risk of costly complications [18,19].

To address these shortcomings, large integrated diabetes data collection systems (regional and national) have been developed in some countries to allow more systematic monitoring and analysis of outcome data, inform service development, and improve performance of care [20,21]. These systems are utilised to enhance care provision at both the individual patient and population levels. They provide feedback for people with diabetes and healthcare professionals on care performance and facilitate communication between them [22,23]. For healthcare professionals such information can populate clinical dashboards highlighting areas of deficit in achieving metabolic targets in their populations, enabling risk stratification and service development [19]. For people with diabetes the information can be used to: highlight psychosocial problems affecting their diabetes that need support; support individualised treatment and care plans [22,23]; enable insightful comparisons with peers; and empower them by providing access to their own health data.

Patient reported outcomes (PROs) are aspects of health status captured directly from a patient without amendment or interpretation of their response by a healthcare professional [24], and a patient reported outcome measure (PROM) is the self-report instrument used to report a PRO [25]. PROMs are distinguished from patient reported experience measure(s) (PREMs), which capture patients' experience or evaluation of treatment satisfaction and care quality [26]. Whilst PROs are often only loosely associated with clinical outcomes [8], they have long been recognized as important outcomes themselves [17]. For integrated data management systems to be effective, they must include PROs such as diabetes self-management behaviours and the factors that may influence them. This makes it possible to identify, explain and address deficits in outcomes, and identify individuals or groups of people requiring more support [27]. In keeping with the principles of value-based healthcare it is also critical that the data collected are relevant and important to people with diabetes [28].

While there are many diabetes specific and generic PROMs of relevance to the diabetes population, optimal strategies for incorporating these into self-completed digital applications, integrated with clinical data, are yet to be identified. This knowledge deficit requires, in the first instance, identification of what to measure and how best to measure it. Numerous outcome sets exist for research, for example in gestational diabetes [29], polycystic ovary syndrome [30]; kidney transplantation [31], chronic obstructive pulmonary disease [32] and diabetes [33,34]. Previous attempts to identify outcome sets for routine diabetes care have typically been developed nationally (e.g. in the USA, UK, or Denmark), or they are outdated or limited in focus and/or methodology [35–39]. The Diabetes Working Group of the International Consortium for Health Outcomes Measurement (ICHOM) sought to identify a standard outcome set for routine application in diabetes care via a systemic literature review of outcomes used in diabetes research and/or important to people with diabetes, and a consensus driven, international and multidisciplinary Delphi panel [40]. The set was pragmatically restricted to three predominantly generic PROs; psychological well-being, depressive symptoms and diabetes distress, and the objective was to provide population level outcome data to inform benchmarking and service improvement. In addition, while there has been uptake of clinical outcomes from the ICHOM set in international diabetes registries [20], uptake of the recommended PROMs has been limited [20,41]. Key factors explaining this poor uptake likely reflect practical barriers, such as time constraints, limited manpower, and a lack of clinical champions, appropriate infrastructure, policies and governance mechanisms [38,40,42,43]. Low perceived clinical relevance and utility of the PROs and PROMs included in existing outcome sets amongst healthcare professionals may also play a role.

Hence, in this project we sought to learn from the work undertaken by the ICHOM group, and identify a more global set of clinically relevant PROs with high relevance and importance to people with diabetes that could be implemented digitally and internationally in routine diabetes care to inform individual patient care and assess and improve system level performance. This paper describes a systematic literature review to identify candidate PROs, and PROMs, to be considered for inclusion in such a set. Many PROs that relate to long-term conditions generally, such as depression, anxiety and quality of life, are commonly endorsed by people with diabetes. Nonetheless this paper focuses on PROs that are specifically experienced by people with diabetes, for example diabetes distress and diabetes specific QoL, to ensure that the factors of highest relevance to people living with diabetes are additionally captured. The review forms part of a wider project, the European Union Innovative Medicines Initiative funded Health Outcomes Observatory (H2O) programme [43], which aims to advance previous endeavours and move beyond the definition of an outcome set to develop an integrated, digital diabetes dataset and implementation model that will be trialled in health care settings across Europe.

2. Methods

2.1. Search strategy

A systematic literature search was conducted in February 2021 to identify published evidence on PROs and/or PROMs in diabetes. PubMed, COMET, and COSMIN databases were searched without date or language limitations; using a combination of keywords and Medical Subject Heading (MeSH) terms recommended by topic experts and identified from papers of known relevance retrieved during a scoping search.

The PubMed search strategy had two facets: population terms (diabetes; Type 1 or Type 2 diabetes mellitus) AND outcome terms (patient reported outcome(s), patient reported outcome measure(s), outcome

set, psychometric, or general measurement instrument e.g. questionnaires[4]). Following guidance, MeSH terms were used to search records that had been indexed in Medline whilst keywords were used to search records not yet indexed [44]. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and the Core Outcome Measures in Effectiveness Trials (COMET) databases were searched using 'diabetes' as a keyword (ongoing studies were not retrieved). The citations were transferred to Endnote v8 and exported to Covidence. The PubMed search syntax is available in Appendix A [45].

2.2. Selection criteria

Studies were included if they recommended PRO(s) that could be collected in routine diabetes care and used to inform care at the individual patient and/or service level, and/or facilitate person centred care. The recommendations made about PROs were assessed and studies were included if the PROs were endorsed in relation to at least one of the following criteria:

- Utility for monitoring care performance, improving communication and/or informing clinical decision making/care (e.g. key questions for clinical decision making, outcomes associated with diabetes self-management behaviours/endpoints, key insights into diabetes, common psycho-social problems, etc.)
- Utility for informing health care decision making at the service level (e.g. key indicators/outcomes of care, outcomes that meet criteria defining utility for this, etc.)
- Utility for facilitating person centered care (i.e. patient important outcomes)

The full inclusion and exclusion criteria are described in Table 1. There was no restriction based on study design, and those making explicit and implicit recommendations were included (e.g. consensus work developing an outcome set for routine diabetes care and epidemiological surveys including variables considered to provide key insights into diabetes respectively). Studies reporting on PROs in a relevant diabetes population but not making any recommendations were excluded. A PRO was defined following the Food and Drug Administration definition [24].

Table 1
Selection criteria. The inclusion and exclusion criteria against which search results were appraised.

	Included	Excluded
Population focus of recommendations	Adults (≥18 years) People with Type 1 or Type 2 diabetes mellitus, or a diabetes complication subpopulation (e.g. individuals experiencing Diabetic Peripheral Neuropathy)	Adults <18 years Uncertainty over diabetes status; pre-diabetes or gestational diabetes; Maturity-Onset Diabetes of the Young (MODY); long-term conditions including diabetes but where recommendations for diabetes are not reported separately
Type of outcomes recommended	Both diabetes specific and generic patient reported outcomes: relevant to all people with diabetes; either Type 1 or Type 2 diabetes mellitus specifically; a diabetes complication sub-population; or living with a long-term condition (including diabetes)	Outcomes reflecting clinical parameters that would be objectively determined or patient reported experience measure(s).

2.3. Screening process

Titles and abstracts were screened independently by two researchers, with conflicts resolved by discussion and consensus. The selection criteria were piloted on the first 100 titles and abstracts. The reviewers met to discuss and resolve differences in interpreting the criteria, and the criteria were refined. The revised criteria were then piloted again in relation to an additional 100 titles and abstracts, to ensure consistency had been achieved. Interrater agreement for title and abstract then full paper screening was assessed using Cohen's kappa coefficient. The agreement using the revised criteria was 0.99.

2.4. Data extraction

Data were extracted independently by at least two researchers on the following variables:

- Author (year)
- Type of study (objective(s) and method)
- Study population or population focus (i.e. Type of diabetes or diabetes complication sub-population)
- Recommended PRO(s)
- PROM(s) recommended to measure the PROs.

Conflicts were resolved by discussion and consensus. Data extraction required some interpretation. There was variability in the PROs that the recommended PROMs were understood to measure in different studies (e.g. some authors mis-interpreted the Diabetes Distress Scale as a measure of diabetes specific quality of life rather than diabetes distress). Some PROMs incorporated multiple constructs aligned to distinct PROs and were given generic descriptors (e.g. diabetes specific quality of life) which did not reflect the PROs measured. Recommended PROMs, and their development work, were analysed to determine which PRO(s) were actually measured, and hence recommended, and these were extracted.[5] PROMs that were too heterogeneous to be linked to a single PRO and which could not be deconstructed to do so at the subscale level, were excluded. Some outcomes related to clinical parameters that are primarily expressed as a patient experience were included as PROs (e.g. hypoglycaemia unawareness, pain, depression). Outcomes that reflect clinically related patient reports not defined by patient experience (e.g. self-reported history of a diabetes complication) were not considered PROs. Uncertainty about how outcomes should be classified was resolved through discussion with diabetes specialist clinicians in the research team.

2.5. Appraisal of study relevance

The included studies varied, and were therefore appraised, in terms of:

- The 'relevance of the evidence', defined as the extent to which studies made explicit recommendations, that had been agreed by relevant stakeholders, for PROs that should be included in an outcome set to be collected in routine diabetes care and used to inform care at the individual and/or population levels. This was

[4] Papers identified by the diabetes and 'psychometric' or 'general measurement instrument' terms were restricted to reviews, because this otherwise yielded an unmanageable number of citations.

[5] Unless study authors explicitly stated that the recommended PRO was the concept to be measured and that the PROMs were merely suggestions of what might be suitable to measure it.

determined based on the study objective, methods, and the recommendations made. We identified three levels of relevance (listed from highest to lowest):

1. Consensus studies recommending PROs for an outcome set to be used in routine diabetes care to inform care and/or service development
2. Studies that did not use a consensus approach but did recommended PROs for use in routine diabetes care to inform care and/or service development
3. Studies that did not use a consensus approach or explicitly recommend PROs for use in routine diabetes care, but which did implicitly recommend PROs based on attributes that would make them clinically useful (e.g. epidemiological surveys implicitly recommending variables that provide key insights into diabetes).

Studies were assigned one of these three levels of relevance.

- The 'patient importance of the recommended PROs', defined as whether there was evidence reported in the paper that the recommended PROs are important to people with diabetes. This was rated as yes, no, or unclear.

This approach meant that the recommended PROs could be appraised in terms of the relevance of the studies endorsing them and their importance to people with diabetes, rather than simply the number of studies endorsing them. This was critical because PROs that were established some time ago (e.g. diabetes distress in 1995) are likely to be more widely cited, known and used. The PROs were categorised according to the highest level of relevance of the evidence endorsing them and whether there was evidence to suggest importance to people with diabetes.

2.6. Data synthesis

The extracted data were synthesised across studies using a biopsychosocial model of health that differentiates three core (interlinked) domains that are impacted by diabetes and its treatment: Physical and Functional (e.g. symptom burden, sleep, sexual health) Psychological (e.g. cognitive, emotional, behavioural) and Social (e.g. support, stigma). Within each domain, we iteratively built a framework of conceptually distinct PROs. The process, described in Fig. 1, was informed by frameworks used in other outcome sets (i.e. ICHOM), reviews and expert opinion pieces distinguishing PROs and PROMs that are particularly difficult to conceptualise and operationalise (i.e. depression, diabetes specific quality of life, diabetes distress) [46–51], and any psychological theories relevant to the PROs identified (usually noted in the paper), namely Social Cognitive Theory [52], Self Determination Theory [53] and Modified Social Learning Theory [54]. Definitions describing each PRO were based on this literature, the development work for the recommended PROM(s), or definitions used by the World Health Organisation (WHO) or American Psychological Association (APA). The synthesis was undertaken in parallel by two researchers; a psychologist with experience in diabetes research and an experienced diabetes clinician and researcher. Disagreements were resolved by discussion and consensus. Once half of the studies had been included in the synthesis a workshop was held with the wider team (including clinical academics, psychologists and researchers) to: agree the definitions and conceptual distinctions; organise the PROs within each domain into higher order categories; and consider whether any important PROs were omitted or any included PROs should be excluded (e.g. a PRO related to redundant treatment, inhaled insulin treatment, was excluded).

3. Results

3.1. Description of study flow

The database search yielded n = 2125 papers. Eleven additional papers (n = 6 studies) identified in the scoping search were also included. Titles and abstracts were screened for 2121 papers; 222 accessible papers were identified as eligible for full screening. Sixty-four papers, reporting on 36 studies, were included; 27 studies (75 %) made recommendations about PROs that were specific to people with diabetes. Around half of the studies were excluded because they were restricted to PROMs measuring one particular PRO or they reported exclusively on the digital implementation of PROMs. The latter studies were collated to identify implementation strategies that might be relevant to the H2O project. The search results are summarized in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram in Fig. 2.

3.2. Description of included studies

The types of studies that made recommendations about PROs varied (Table 2). Twenty (74 %) made recommendations for adults with diabetes regardless of type [25,35–37,39,40,48,50,55–66], while four focussed on T2DM [34,41,67,68] and three on T1DM [33,69,70] (with one restricted to young adults [33]). Some studies focussed on a select group of outcomes (n = 6), aspect of diabetes care (n = 6) or both (n = 1), rather than considering all diabetes specific PROs: patient oriented behavioural outcomes, quality of life, psychological well-being, health status, treatment goals and/or satisfaction [35,48,50,59,60,66,69], and PROs in the context of a diabetes therapies [34,68,70], psychosocial care [39], or Diabetes Self-Management Education [35,57,58]. Recommendations for PROs were based on international stakeholder perspectives (n = 6) [33,34,40,62,63,66] and national perspectives (n = 12): USA (n = 6) [35,36,39,61,64,70]; Australia (n = 2) [56,65]; UK (n = 1) [37]; Sweden (n = 1) [55]; Germany (n = 1) [69]; and Taiwan (n = 1) [59], whilst the remaining nine studies were literature reviews [25,41,48,50,57,58,60,67,68]. For each study, the objective, design, method, appraised relevance of the evidence, and patient importance of the recommended PROs are described in Appendix B [45].

In terms of the appraised relevance of the evidence, six consensus studies recommended PROs for an outcome set to inform individual patient care and/or service development [35–37,39,40,70], whilst 13 did not use a consensus approach but did recommend their use in this context [25,48,50,55,59,60,62–64,66–69]. Of these studies, 11 recommended PROs to inform individual patient care [35,39,44,50,55,59,60,64,66,68,69], six recommended PROs to inform service improvement [37,40,62,63,67,70], and two recommended PROs for either of these contexts [25,36]. Eight studies did not use a consensus approach or recommend PROs for use in routine diabetes care, rather they implicitly recommended PRO based on attributes that would make them clinically useful [33,34,41,56–58,61,65].

Nine studies included evidence that the recommended PROs are important to people with diabetes [25,33,34,36,40,55,62–64]. Information about how people with diabetes endorsed PRO(s), how they were selected, and their demographic information was variably reported (see Appendix B [45]). Two studies undertook literature reviews to identify the experiences of people with diabetes [34] or their perspective on the most important outcomes for diabetes care [40]. Three undertook focus groups or interviews with people with diabetes [55,63,64], for example eliciting their experiences and important aspects of life with diabetes, and one extracted patient experiences from an online forum [34]. Five studies undertook a consensus process including people with diabetes [33,34,36,40,55]. Two studies established face and content validity of the PROs captured by a multidimensional PROM or survey via cognitive interviewing [55] and piloting [62] with people with diabetes, respectively. One refined the PROs included in a multi-dimensional PROM via a design workshop and user testing with people with diabetes [64].

3.3. Description of PROs

The conceptual framework comprised 53 diabetes specific PROs

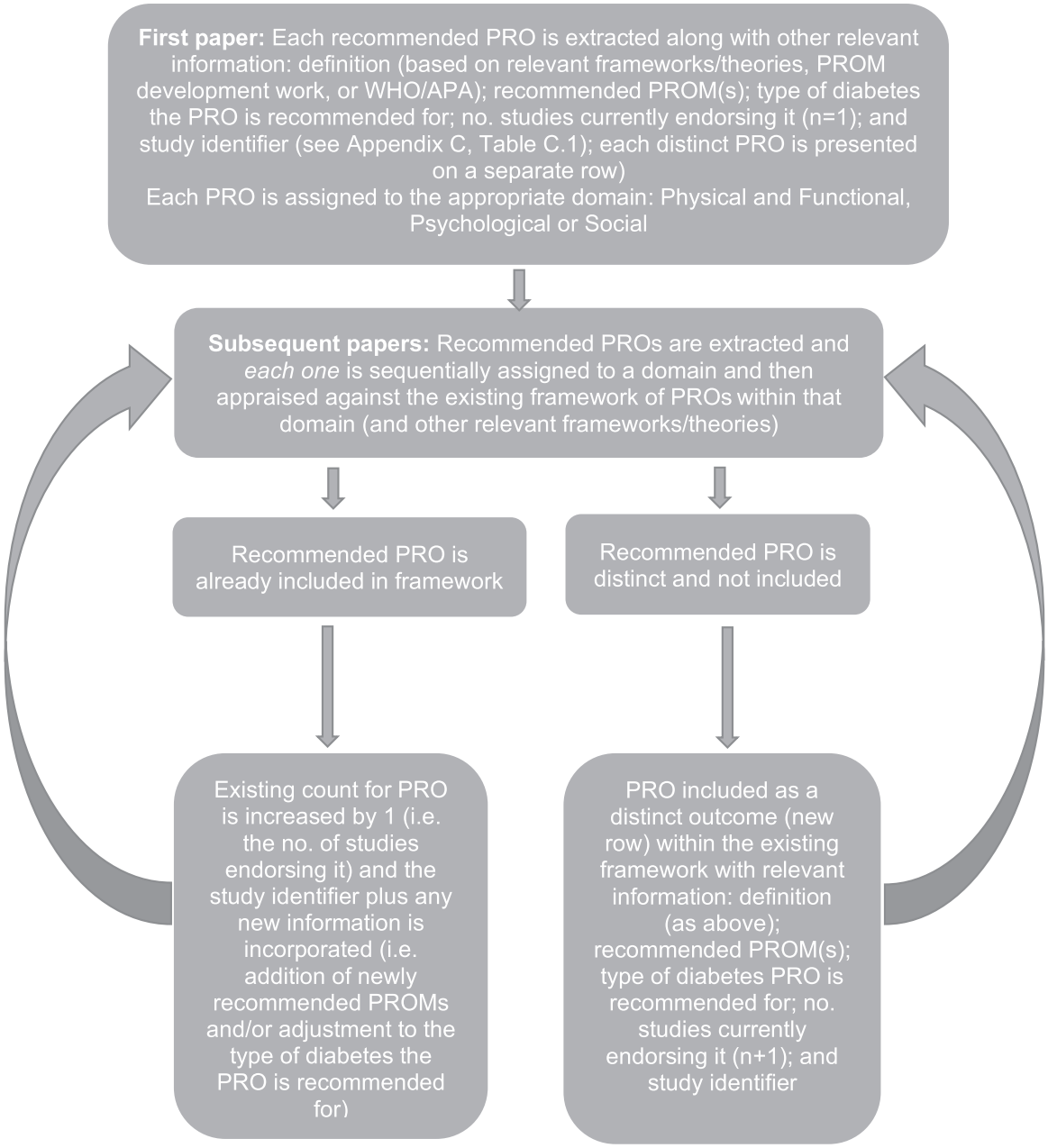

Fig. 1. Approach to data synthesis. Process for building framework of conceptually distinct PROs.

organised into 23 categories[6] (see Appendix C [45]). Forty PROs were psychological, 10 were physical or functional, two were social and one mapped to all three domains. The PROs included both singular (e.g. hypoglycaemia unawareness) and multidimensional constructs (e.g. diabetes symptoms). Two PROs were added in the intermediate review workshop, rather than identified in the studies: fear of complications and perceived autonomy in diabetes care. The categorisation of the PROs is presented in Table 3. The two PROs most endorsed were: diabetes distress and performance of diabetes self-management behaviours, in particular physical activity and diet related behaviour. Most PROs were recommended for both Type 1 and Type 2 diabetes mellitus (n = 46), whereas some were recommended specifically for Type 1 diabetes mellitus (n = 1): treatment goals, or Type 2 diabetes mellitus (n = 6): motivation for performing diabetes self-management behaviours; satisfaction living with diabetes; restrictions caused by diabetes symptoms; attitude to insulin initiation; diabetes specific health beliefs; and diabetes treatment side effects. Eight PROs were recommended exclusively in the context of informing individual patient care; diabetes related numeracy skills; diabetes related problem solving and decision-making; diabetes specific psychological well-being; diabetes self-management behaviour (multi-dimensional); subjective perception of capacity for performing individualised recommendations for physical activity and diet (rather than tracking performance of these behaviours); treatment goals; and the presence of symptoms of sexual dysfunction. Four PROs were recommended exclusively in the context of informing service improvement; side effects of insulin injection (lipodystrophy);

[6] Five diabetes specific PROs/PROMs identified were excluded from the synthesis because they were too heterogeneous to be considered a single PRO and could not be meaningfully deconstructed at the subscale level: The Diabetes Health Profile (DHP), The Diabetes Care Profile (DCP), The Diabetes Therapy-Related QOL Questionnaire (DTR-QoL), The Treatment Related Impact Measure for Diabetes (TRIM-D), and The Appraisal of Diabetes Scale (ADS).

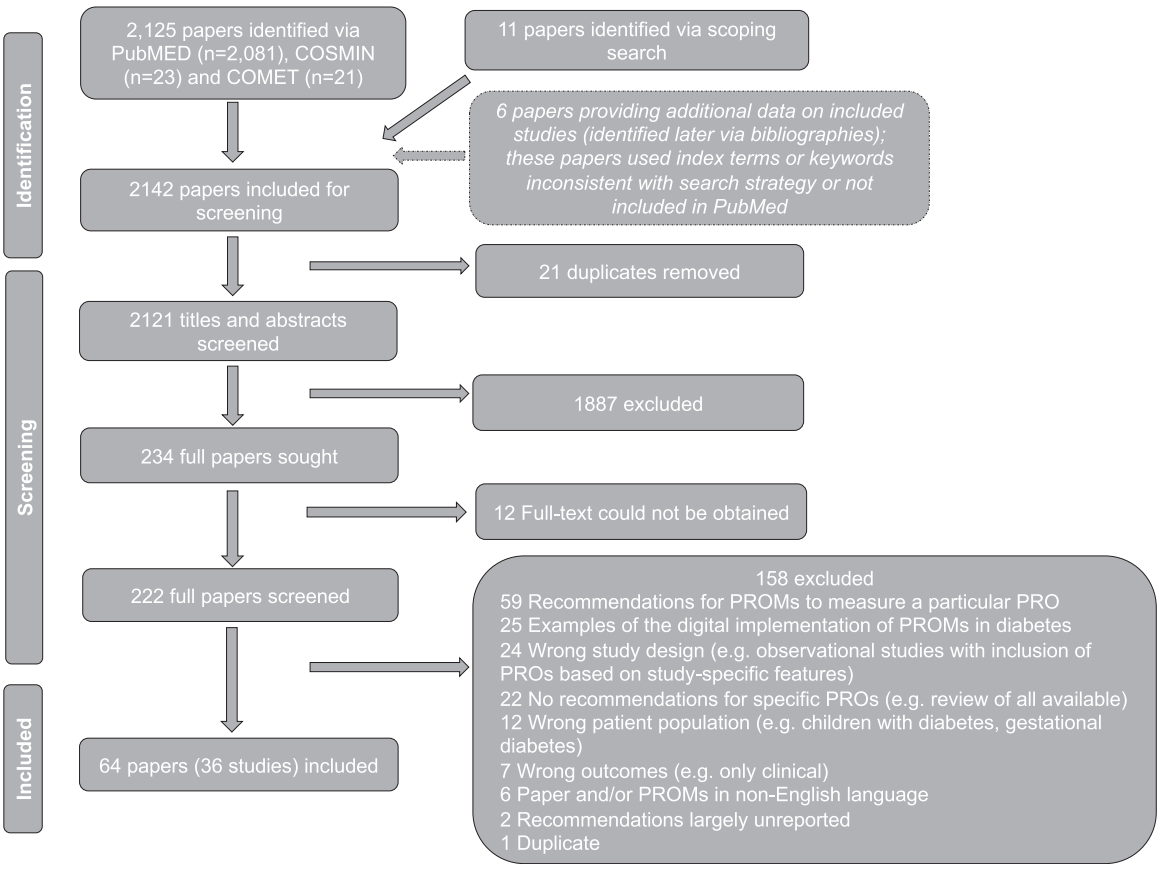

Fig. 2. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram. Visual representation of the search results and study flow.

attitude to insulin initiation; diabetes related stigma; and the presence of symptoms of hyperglycaemia. The remaining PROs were recommended in both contexts.

3.4. Recommended PROMs

Fifty-two psychometrically evaluated PROMs were recommended to measure 72 % (n = 38) of the PROs (listed in Table 3 with citations provided in Appendix D [45]). Another 36 PROMs were recommended to measure 47 % (n = 25) of the PROs but were not validated; these were multifaceted questionnaires used for large scale surveys or single/short-item measures (documented in Appendix E [45]).

3.5. Generic PROs and clinically related patient reports

A number of PROs relating to long-term conditions generally (n = 45) or outcomes reflecting clinically related patient reports not defined by patient experience (n = 7) were identified but omitted from the synthesis presented in this paper (reported in Appendix F and G [45][7]).

3.6. Other useful recommendations

Five literature reviews designed to consider the psychometric properties of PROMs in measuring select groups of diabetes specific PROs were additionally identified. While these reviews did not recommend PROs, they did indicate the sensitivity, reliability and validity of PROMs for measuring the PROs considered. These reviews focussed on diabetes specific quality of life and allied constructs, or the psychosocial impact of Diabetes Peripheral Neuropathy. The studies and the PROMs they recommended are described in Appendix H [45].

4. Discussion and conclusion

4.1. Discussion

This review identified over 50 candidate diabetes specific PROs to be considered for inclusion in an outcome set to be integrated into electronic patient record systems and tested in clinical practice across Europe. The PROs identified were predominantly psychological, far fewer reflected the physical or functional and social domains. They reflect a wide range of constructs: self-management behaviour; psychological well-being; quality of life; treatment satisfaction and goals, symptom experience; health beliefs; social support; stigma; cognitive capacity; and psychological morbidity. Each PRO is supported by evidence suggesting clinical utility and/or importance to people with diabetes. The set is intended to inform: individual patient care, by highlighting issues important to people with diabetes and/or factors that may influence their self-management engagement; and service development, by highlighting issues that can be addressed systemically. It could also be used at an aggregate level to support research in diabetes populations, e.g. on the prevalence and progression of psychosocial problems and the association with clinical outcomes [23]. The candidate PROs have now been shortlisted, alongside other outcomes such as clinical and case mix variables and generic PROs, in a multi-stakeholder, international consensus process and Delphi exercise to agree a scalable dataset (manuscript under review).

The review also identified PROMs recommended for three quarters of the included PROs. We recommend an appraisal of the evidence supporting each PROM when making selection decisions, such as

[7] With a description of four studies excluded as they made recommendations for generic PROs only.

Table 2
Description of included studies. Overview of the types of studies recommending diabetes specific patient reported outcomes.

Type of study	No. studies	Studies
Consensus study identifying outcome sets for collection in routine diabetes practice to inform care and/or service development	6	s1; s2; s14; s15; s17; s27
Literature review of patient reported outcomes and patient reported outcome measures to be used to inform diabetes care	1	s22
Study focussed on developing a composite, multidimensional PROM for routine diabetes care	2	s21; s24
Review of patient reported outcomes and patient reported outcome measures used in diabetes registers	1	s6
Review of outcomes that meet key criteria for informing health care decision making	1	s26
Expert opinion piece on patient reported outcomes that should be assessed in routine diabetes care and used to inform care	3	s13; s11; s23
Consensus study identifying outcome sets for research on core aspects of diabetes care (i.e. diabetes therapies or interventions to improve clinical, behavioural or psychosocial outcomes)	2	s5; s10
Reviews of patient reported outcome measures used in research on core aspects of diabetes care (i.e. diabetes therapies or Diabetes Self-Management Education)	3	s8; s9; s19
Epidemiological surveys including patient reported outcomes	5	s7; s16; s18; s20; s25
Observational study considering distinctions between patient reported outcomes (and patient reported outcome measures) in diabetes (including consideration of clinical utility)	2	s4; s12
Development study reporting a composite, multidimensional patient reported outcome measure (including consideration of clinical utility)	1	s3

development and validation work and reviews of PROMs used to measure each PRO (e.g. Speight et al. [51]). Despite some use in clinical settings, many PROMs are designed for research purposes and a second consensus process is now considering which are acceptable and suitable for routine clinical use. The challenge will be to compress the shortlisted PROMs into a practical outcome set that will enhance diabetes care. It is also important to consider how to balance the relevance of the outcome set to people with Type 1 and Type 2 diabetes mellitus. While most of the PROs were recommended for either type of diabetes, the relevance of some may vary by the type of diabetes, treatment modalities, and other factors such as duration of diabetes, gender and age. We must be mindful of whether PROs are relevant to all people with diabetes or are more relevant to, and hence should be collected for, specific groups of people with diabetes.

While the amount and relevance of the evidence endorsing a PRO may not necessarily indicate their importance, some PROs were particularly endorsed namely diabetes distress and physical activity and diet related behaviour. The significance of these PROs is also reflected in their inclusion or intended inclusion in established diabetes registries [41,55]. It is important to recognise, however, that as diabetes care changes how people experience living with diabetes will change too. Diabetes therapies and technologies continue to rapidly evolve and as we increasingly move toward a more digitalised health care environment existing PROs may need to be adapted and new PROs may emerge. This reflects a general limitation of reviews of PROs; they emphasise what is important now over what will be important. The set may need to evolve over time to reflect these changes. PROMs related to use of current technologies, for example technology acceptance and satisfaction with specific diabetes technologies (e.g. CGM, insulin injection devices), are still in a relatively early stage of development with limited application but will become increasingly important to include. Indeed, we

Table 3
Categorisation of outcomes. Categorisation of the recommended PROs in terms of the relevance of the evidence endorsing them and importance to people with diabetes.

Relevance of evidence	Patient reported outcomes	Patient reported outcome measures	No. studies endorsing each outcome (No. consensus studies)
Endorsed by ≥ 1 consensus study recommending patient reported outcomes for an outcome set to be used in routine diabetes care to inform care and/or service development (and usually endorsed by evidence that they are important to people with diabetes, see exception†)	Diabetes distress: The emotional response to aspects of living with and managing diabetes	PAID; PAID-1; PAID-5; PAID-11; DDS; DDS2; DDS4; T1-DDS; Diabetes Questionnaire (Free of worries subscale; items 6–8); D-SMART tool	17 (4)
	Performance of physical activity behaviour	SDSCA; DSMQ; IPAQ-SF; D-SMART tool	11 (2)
	Performance of diet related behaviour	SDSCA; DSMQ; BDHQ; D-SMART tool	11 (2)
	Performance of self-monitoring of blood glucose behaviour	SDSCA; DSMQ; D-SMART tool	9 (2)
	Performance of diabetes related medication taking behaviour (i.e. taking and refilling)	ARMS-D; SDSCA; D-SMART tool	8 (2)
	Self-efficacy: Perceived capability to perform diabetes self-management behaviours	PCDS; CIDS (insulin using); CIDS (non-insulin using); DSES; D-SMART tool	6 (2)
	Perceived burdens and restrictions related to diabetes and its management	DSQoLs (Burdens and restrictions subscale); Diabetes Questionnaire (Abilities to manage diabetes - not limited by diabetes/blood sugar subscales; items 14–18)	5 (1)
	Perceived support received from others in relation to diabetes (including peer support)	Diabetes Questionnaire (Abilities to manage diabetes - support from others subscale; items 19–21); DSS; D-SMART tool	5 (1)
	Experience of physical and psychological symptoms related to diabetes and its possible complications (presence and/or burden)	DSC-R; DSC-2; DSM	5 (1)
	Patient empowerment: Perceived ability to manage psychosocial issues related to diabetes	DES-SF; D-SMART tool	5 (1)
	Performance of foot care behaviour (i.e. self-foot exam)	SDSCA	5 (1)
	Diabetes related problem solving and decision making: The	Diabetes Questionnaire (Abilities to	3 (1)

(continued on next page)

Table 3 (*continued*)

Relevance of evidence	Patient reported outcomes	Patient reported outcome measures	No. studies endorsing each outcome (No. consensus studies)
	cognitive aspect of diabetes self-management behaviour[i]	manage diabetes - capabilities to manage diabetes subscale; item 9–11); D-SMART tool	
	Fear and worry related to hypoglycemia	HFS-II; HSF (worry subscale); HFS-II SF	3 (1)
	Engagement with and optimal use of diabetes services	DSMQ; D-SMART tool	3 (1)
	Diabetes related eating problems/ disorders (e.g. intentional medication omission to produce weight loss)	None suggested	2 (1)
	Perceived restrictions related to diabetes symptoms (T2D)	None suggested	1 (1)
	Side effect of insulin injection (lipodystrophy)[ii]	None suggested	1 (1)
	Diabetes related numeracy skills[i]†	DNT	1 (1)
Endorsed by ≥ 1 study that did not use a consensus approach but did recommending PROs for use in routine diabetes care to inform care and/or service development (and usually endorsed by evidence that they are important to people with diabetes, see exceptions†)	Diabetes specific quality of life: The perceived impact of diabetes on one's life in ways that are important to the individual	ADDQoL; D-39; DQoL; DIDP; WHOQOL-BREF DMQoL	11
	Satisfaction with diabetes treatment (both process and outcomes)	DTSQ; DSQoLs; GDST	6
	Diabetes specific psychological well-being: Aspects of mental health related to diabetes including but not limited to negative well-being (e.g. feeling depressed because of diabetes: also diabetes distress, diabetes related positive well-being, etc.)[i]	Well-Being Questionnaire 28 (W-BQ28), Diabetes Questionnaire (Mood and energy subscale; items 3–5)	3
	Diabetes knowledge (general and related to one's clinical outcome measurements)	CHES-Q	3
	Diabetes self-management behaviour (multi-dimensional): Performance of health behaviours specifically prescribed for managing diabetes[i]	DSMQ	3
	Patient activation: Believing that the patients' role is important and possessing the knowledge, skills/ competencies, and confidence to take action and maintain this in terms of managing one's own health and well-being	PAM; heiQ	2
	Perceived control over diabetes and blood glucose levels (comprising self-efficacy and locus of control; internal versus external)	None suggested	2
	Skills and techniques for managing diabetes (knowledge-based)	heiQ; Diabetes Questionnaire (Abilities to manage diabetes - capabilities to manage diabetes subscale; items 9–11)	2
	Diabetes-related stigma: Feeling disqualified from full social acceptance related to having diabetes (felt versus enacted)[ii]	DSAS-1; DSAS-2	2
	Attitude to initiating insulin treatment (including psychological insulin resistance) (T2D)[ii]	ITAS	2
	Perceived burdens and restrictions related to non-severe hypoglycemia	Treatment-Related Impact Measure-Non-severe Hypoglycemic Events (TRIM-HYPO)	1
	Behaviours aimed at avoiding hypoglycemia (fear driven) (increasing risk of hyperglycemia)	HFS-II SF	1
	Symptoms of hyperglycaemia (presence)[ii]	None suggested	1
	Physical symptoms of gastroparesis (presence)	GCSI-DD	1
	Neuropathic pain (identified via bedside sensory examination)	DN-4	1
	Impact of diabetes on life/work productivity	DPM	1
	Subjective perception of one's current *capacity* in terms of performing individualised recommendations for physical activity (rather than tracking performance of this behaviour)[i]	Diabetes Questionnaire (Abilities to manage diabetes - diet and exercise subscale; items 12 +13;)	1

(*continued on next page*)

Table 3 (*continued*)

Relevance of evidence	Patient reported outcomes	Patient reported outcome measures	No. studies endorsing each outcome (No. consensus studies)
	Subjective perception of one's current *capacity* in terms of performing individualised recommendations for diet (rather than tracking performance of this behaviour)[i]	Diabetes Questionnaire (Abilities to manage diabetes - diet and exercise subscale; items 12 +13;)	1
	Symptoms of sexual dysfunction (presence)[i]†	None suggested	2
	Diabetes treatment goals[i]† (T1D)	DSQoLs	1
Endorsed by studies that did not use a consensus approach or explicitly recommend PROs for use in routine diabetes care, but which did implicitly recommend PROs based on attributes that would make them clinically useful (but with no evidence that they are important to people with diabetes, see exception‡)	Diabetes treatment side effects‡ (T2D)	None suggested	1
	Perceived importance of physical activity	None suggested	1
	Perceived importance of diet related behaviour	None suggested	1
	Perceived importance of self-monitoring of blood glucose	None suggested	1
	Symptoms of hypoglycemia (presence and intensity)	Edinburgh Hypoglycaemia Survey (EHS)	1
	Behaviours aimed at avoiding hyperglycemia (fear driven) (increasing risk of hypoglycaemia)	None suggested	1
	Hypoglycemia unawareness: The failure to sense a fall in blood glucose below normal levels	Gold score	1
	Performance of oral self-care behaviour	None suggested	1
	Symptoms of female urinary incontinence (presence)	None suggested	1
	Motivational orientation to performing diabetes self-management behaviours ('autonomous' versus 'controlled') (T2D)	TSRQ-diabetes	1
	Satisfaction with living with diabetes: Satisfaction with aspects of physical or emotional health related to diabetes (T2D)	CHES-Q	1
	Diabetes specific health beliefs (multi-dimensional): Attitudes and beliefs about diabetes	None suggested	1
	Diabetes specific health beliefs (theoretical model): Attitudes and beliefs about diabetes based on a theoretical model of health behaviour (e.g. The Health Belief Model) (T2D)	None suggested	1

[i]PROs recommended only in the context of informing individual patient care; [ii] PROs recommended only in the context of informing service improvement
T1D=outcome recommended exclusively for Type 1 diabetes mellitus; T2D=outcome recommended exclusively for Type 2 diabetes mellitus
ADDQoL=Audit of Diabetes-Dependent Quality of Life; ARMS-D=Adherence to Refills and Medications Scale; BDHQ=Brief-type self-administered diet history questionnaire; CHES-Q=Current Health Satisfaction Questionnaire; CIDS=Confidence In Diabetes Self-Care; DDS=Diabetes Distress Scale; DDS-2 =Diabetes Distress Scale-2; DDS-4 =Diabetes Distress Scale-4; T1-DDS=Type 1 Diabetes Distress Scale; DES-SF=Diabetes Empowerment Scale-Short Form (DAWN); Diabetes Questionnaire=Diabetes Questionnaire (Swedish National Diabetes Register); DIDP=DAWN Impact of Diabetes Profile; DNT=Diabetes Numeracy Test; DN-4 =Douleur Neuropathique 4 Questions; DPM=Diabetes Impact on Productivity
DQoL=Diabetes Quality of Life measure (DCCT); DSAS-1 =Type 1 Diabetes Stigma Assessment Scale; DSAS-2 = Type 2 Diabetes Stigma Assessment Scale; DSC-R=Diabetes Symptom Checklist-Revised; DSC-2 =Type 2 Diabetes Symptom Checklist; DSES=Diabetes Self-efficacy Scale; DSM=Diabetes Symptom Measure; D-SMART tool=D-SMART tool (American Association of Diabetes Educators); DSMQ=Diabetes Self-Management Questionnaire; DSQoLs=Diabetes-Specific Quality of Life Scale; DSS=Diabetes Support Scale; DTSQ=Diabetes Treatement Satisfaction Questionnaire; D-39 =Diabetes-39; EHS=Edinburgh Hypoglycaemia Survey; GDST=Global Diabetes Satisfaction Treatment; GCSI-DD=Gastroparesis Cardinal Symptom Index Daily Diary; heiQ=Health Education Impact Questionnaire; HFS-II=Hypoglycemia Fear Survey-II; HFS-II SF=Hypoglycemia Fear Survey-II Short Form; IPAQ-SF=International Physical Activity Questionnaire, short form; ITAS=Insulin Treatment Appraisal Scale; PAID=Problem Areas in Diabetes (PAID); PAID-1 =Problem Areas in Diabetes-1; PAID= 5 =Problem Areas in Diabetes-5; PAID-11 =Problem Areas in Diabetes-11; PAM=Patient Activation Measure; PCDS=Perceived Competence for Diabetes Scale; SDSCA=Summary of Diabetes Self-Care Activities; TFS=Treatment Flexibility Scale; TRIM-HYPO=Treatment-Related Impact Measure-Non-severe Hypoglycemic Events; TSRQ-diabetes=-Treatment Self-Regulation Questionnaire-diabetes; W-BQ28 =Well-Being Questionnaire 28; WHOQOL-BREF DMQoL=World Health Organization quality of life scale (diabetes module)

identified a recommendation for a PROM that elicits device function and bother (I.e. the Treatment Related Impact Measure for Diabetes) albeit this PROM was excluded because it could not be aligned with single PROs.

Previous reviews of PROs and PROMs for inclusion in diabetes outcome sets [25,40] were considered in relation to the current review. While there are overlaps with our work, these reviews were undertaken for different purposes and provide findings that are not fully aligned with the aim of this review. The ICHOM set was focussed on providing population level data to inform benchmarking and service development and includes only three PROs one of which is diabetes specific: diabetes distress. The PROs identified by the initial literature review are not described. Skovlund at al [25] recently published a review of the use of PROMs for diabetes considering how these might be integrated into routine diabetes practice, primarily to enhance provision of care at the individual patient level. They similarly identified PROs with empirical data supporting clinical relevance and importance to people with diabetes, though the methods used and evidence supporting each PRO are not well described. Twenty-one diabetes specific PROs were common to both reviews; our review identified an additional 33 PROs and associated PROMs. Eleven (52 %) of the PROs identified by Skovlund et al.

were aligned with the PROs we considered to have the strongest evidence of clinical utility and importance to people with diabetes: diabetes distress; PROs related to diabetes self-management behaviours; self-efficacy; patient empowerment; diabetes symptoms; and diabetes related eating problems/disorders. Our review extends previous endeavours by identifying a broad range of internationally endorsed diabetes specific PROs and PROMs suitable for informing both individual patient care and service development. We report the amount and relevance of the evidence endorsing each PRO and indicate whether there is evidence suggesting their importance to people with diabetes, so that readers are able make informed decisions about their suitability.

Perhaps the most important limitation of our review was the omission of studies examining associations between diabetes specific PROs and clinical outcomes. Unfortunately, we did not identify any studies recommending PROs on this basis. An additional review to specifically consider these associations would be useful. A further limitation is that we did not have the capacity to search the citations of the included studies. Moreover, some studies of known relevance were not identified because they were retrieved by terms that were not consistent with our search (e.g. 'diabetes' AND 'quality of life'); these terms were considered but retrieved an unmanageable number of results. None of these studies had an explicit focus on identifying the important PROs/PROMs in diabetes though (i.e. most reported on epidemiological studies in diabetes). While it is possible that these limitations meant a few PROs were overlooked, given the comprehensive range of PROs identified we are confident that the majority of relevant constructs were identified. Indeed, the PROs recommended in a paper reporting on the development of a national diabetes outcome set to enhance care provision that was published after we had conducted our search were all identified in our review [38]. Therefore, despite these limitations we are confident that for the parameters set for this review a comprehensive representation of the recommended PROs was achieved to inform the next stages of the H2O project.

4.2. Conclusion

Integrating PROs that have potential to inform both patient care and service development, by identifying individual and service level needs, into routine diabetes care is an important objective. The comprehensive list of diabetes specific PROs identified in this review, which builds on existing diabetes outcome sets, represents an important step towards achieving this.

4.3. Practice implications

The categorisation of PROs according to the relevance of the evidence endorsing them and their patient importance, and the information about which PROs are recommended for clinical care, service development or both (and which are recommended for Type 1 and 2 diabetes mellitus or both) (Table 3) provides information to guide decisions about which diabetes specific PROs should be collected in a specific context. For instance, diet and exercise behaviour and diabetes specific QoL are each recommended by 11 studies for informing care and service improvement, but the former is endorsed by more relevant evidence including consensus studies. Similarly neuropathic pain and diabetes treatment goals are recommended by a single study considered equally 'relevant' but only the former is supported by evidence suggesting it is important to people with diabetes. Finally, diabetes related numeracy skills, diabetes related problem solving and decision-making, and diabetes treatment goals are recommended exclusively for informing individual patient care. Validated tools are also suggested for measuring most of the outcomes recommended.

The PROs identified reflect issues that are important to people with diabetes, the performance of diabetes self-management behaviours, and/or factors that might mediate these behaviours. Integrated measurement of these PROs in care settings will hopefully highlight patient related problems, that would otherwise reduce diabetes self-management activation and increase the risk of complications, to clinicians so that they can work collaboratively with people with diabetes to address them. In addition, having datasets integrating PROs and clinical outcomes will enhance the performance of care systems by identifying: care performance deficits; the associations between PROs and clinical outcomes; the relationship between PROs and care inequalities; and areas where care delivery systems require improvement or additional resources. It is important to recognise, though, that if PROs are going to be digitally integrated into care systems, a shift in care culture will be required to ensure clinicians are equipped to deliver person centred management plans that incorporate the problems highlighted by the PROMs.

CRediT authorship contribution statement

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Declaration of Competing Interest

None.

Acknowledgments

We thank the wider H2O project team who provided valuable advice on the design and conduct of this review. H2O has received funding from the Innovative Medicines Initiative (IMI) 2 Joint Undertaking under grant agreement No 945345-2. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme, EFPIA, Trial Nation and JDRF International. The funding source was not involved in the study design; the collection, analysis, and interpretation of data; the writing of the report, or the decision to submit the article for publication. The manuscript reflects only the author's view. The IMI, the European Union, EFPIA, or any Associated Partners are not responsible for any use that may be made of the information it contains.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2023.107933.

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