Table B.1 Description and appraisal of included studies

Description of studies recommending diabetes specific PROs and appraisal of the relevance of the evidence and the patient importance of the recommended outcomes.

**KEY**

| Relevance of the evidence | | Patient importance of the recommended PROs | |
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| ✓✓✓ | Recommendations for PROs that should be included in a core outcome set collected in routine diabetes practice and used to inform care and/or service development (consensus work) | ✓ | Recommendations reflect PROs that are important to people with diabetes |
| ✓✓ | Recommendations for PROs that should be collected in routine diabetes practice and used to inform care and/or service development | ✗ | Recommendations do not reflect PROs that are important to people with diabetes |
| ✓ | Recommendations for PROs based on attributes that would make them clinically useful only | ? | Not clear whether recommendations reflect PROs that are important to people with diabetes |

| Study (population) | Objective/method | Relevance of the evidence | Patient importance of the recommended PROs |
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| **Nano (2020)** [1]<br><br>Type 1 and 2 diabetes mellitus | (International Consortium for Health Outcomes Measurement (ICHOM) study) Consensus work with rigorous consensus methodology employed – literature review (of PROs/PROMs used in diabetes studies and studies reporting on the perspectives of people with diabetes) and (International, Multi-stakeholder) Delphi survey - and a focus on developing a core outcome set. | ✓✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform benchmarking/service development** (i.e. focus on population level outcome assessment). PROs reflect 'key concepts involved in clinical diabetes care'. | ✓<br><br>PROs reflect patient important outcomes; literature review included studies reporting on the perspective of people with diabetes on the 'most relevant outcomes in diabetes care', and expert consensus (incl. people with diabetes) selected 'key domains of perceived importance to people with diabetes' (outcome set is consistent with a value-based approach to care).<br><br>*Expert consensus*<br>**Selection of people with diabetes:**<br>**Recruitment via ICHOM website and social media channels, working group members' professional networks and the patient** |

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| | | | <u>**networks of the JDRF, USA and Imperial College London Diabetes Centre, Abu Dhabi. Demographics for people with diabetes: Working group included 4 'patient members' – no further detail provided. External stakeholders (online survey n=128): Aged 18–65 years (86%); women (59%); Type 1 diabetes (22%) and Type 2 diabetes (78%); treated with insulin or non-insulin therapy (94%) (remainder on lifestyle); living in Mexico, United Arab Emirates, the UK and the USA.**</u> |
| **Marrero (2019)** [2]<br><br>Type 1 and 2 diabetes mellitus | Consensus work with rigorous consensus methodology employed – (Multistakeholder, National; USA) Nominal group process technique - and a focus on developing a core outcome set (no initial literature review). | ✓✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care** (i.e. 'contribute to clinical treatment decisions') and **service improvement** (i.e. they should be 'used by hospital systems'). PROs reflect key insights into diabetes; 'the important PROs to understand the unique experiences and response to treatment by individuals with diabetes'. | ✓<br><br>PROs reflect patient important outcomes; experts (incl. people with diabetes) identified the key domains that should be assessed – no further detail provided. |
| **Association of American Diabetes Educators (AADE) (2003)** [3]<br><br>Type 1 and 2 diabetes mellitus | Consensus work undertaken with less methodological rigor – 'literature review' and (National; USA, Multi-stakeholder) 'expert consensus' (no further detail) – focus on developing a core outcome set.<br><br>*Limited to a focus on 'patient orientated behavioural outcomes' and Diabetes Self-Management Education* | ✓✓✓<br><br>PROs should be measured when evaluating aspects of routine diabetes care; Diabetes Self-Management Education. PROs should be used to **inform individual patient care**; intention that the PROs should be assessed in routine consultations and used to guide Diabetes Self-Management Education, by focussing on important domains identified by people with diabetes, then monitor progress. PROs reflect key outcomes of care. | ?<br><br>Not clear whether patient perspective was considered when deciding on important PROs; expert consensus was based on health care professional opinion but included a 'a customer analysis of AADE membership' – no further detail provided. |
| **Young-Hyman (2016)** [4]<br><br>Type 1 and 2 diabetes mellitus | (American Diabetes Association (ADA) Position Statement) Consensus work undertaken with less methodological rigor – (National; USA) 'expert consensus' (undefined) focus on providing evidence-based guidelines for assessment in diabetes (no initial literature review)<br><br>*Limited to a focus on psycho-social care in diabetes* | ✓✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care.** PROs reflect most common psychological factors affecting people with diabetes, are clinically useful (i.e. 'based on commonly used | ✗<br><br>Stated that outcome assessment should be patient centred, but not apparent that the patient perspective was considered as part of expert consensus deciding on important PROs. |

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| | | clinic models'), key outcomes of care (i.e. 'based on tested interventions'), and reflect those that can be feasibility implemented in clinical practice. ✓✓✓ | |
| **Agiostratidou (2017)** [5]<br><br>Type 1 diabetes mellitus | Consensus work undertaken with less methodological rigor – (National; USA) 'stakeholder survey' (no further detail) to identify clinically meaningful outcomes beyond HbA1c that were 'discussed by steering committee based on published evidence (no further detail), clinical expertise, and with feedback from advisory committees representing important stakeholder groups' - focus on developing a core outcome set (focus on expanded set of clinical outcomes but stated standard PROs must be developed for Type 1 diabetes mellitus; one important PRO noted).<br><br>*Limited to a focus on new Type 1 diabetes mellitus therapies (and PROs not comprehensively considered)* | PROs should be measured when evaluating aspects of routine diabetes care; new Type 1 diabetes mellitus therapies (focus on research/clinical trials rather than clinical practice – but authors acknowledge PROs can be used to **improve service provision** (i.e. they 'can capture helpful information for guiding diabetes care teams on which aspects of their routine delivery they need to improve'). PROs reflect key outcomes of care. | ✗<br><br>Patient perspective was not considered as part of steering committee that discussed PROs. |
| **McColl (1995)** [6]<br><br>Type 1 and 2 diabetes mellitus | Consensus work undertaken with less methodological rigor – (GPs only, National; UK) Delphi survey. Focus on developing core outcome sets for diabetes (Type 1 and Type 2) BUT initial candidate outcomes reflected PROs that are clinically useful beyond diabetes (i.e. also asthma etc.) and was refined by identifying PROMs/sub-scales that adequately captured each outcome and then determining the extent to which these predicted 'general health perceptions'; the outcome set is therefore restricted to PROs aligned with general perceptions of health (intended to reflect a focus on a holistic approach to care rather than on particular aspects of disease) and it is not possible to discern those originally identified as clinically useful specifically in diabetes (literature review but to identify PROMs to capture predetermined PROs). Recommendations also potentially outdated. | ✓✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform service development** (i.e. intended the PROs would be used to judge the effectiveness of care for people with diabetes in ambulatory care settings; the main application was anticipated to be the evaluation of quality assurance initiatives). PROs reflect 'health outcomes that are valuable in the everyday work of primary health care teams (incl. diabetes teams)'. | ✗<br><br>Patient perspective was not considered as part of expert consensus deciding on important PROs. |
| **Skovlund (2019)** [7]<br><br>Type 1 and 2 diabetes mellitus | Informal review of evidence on the use of PROMs in diabetes and considerations for implementation/strategies required to integrate PROs/PROMs into routine diabetes care; included identification of key 'domains' (i.e. PROs) found relevant for use in routine diabetes care/inclusion in multidimensional PROMs to be used in this context (and with empirical data supporting their clinical relevance and importance to people with diabetes). Review methods and evidence upon which these key domains are based is not described. | ✓✓<br><br>PROs should be collected in routine diabetes care to **inform individual patient care**; focus on use of PROs/PROMs by health care professionals to improve diabetes care for individuals with diabetes (albeit it is noted that collecting this data may also **inform service improvement**). PROs reflect 'key domains with empirical data supporting clinical relevance' | ✓<br><br>PROs reflect 'key domains with empirical data supporting importance to people with diabetes' – no further detail provided. |

**Svedbo Engström (2018)** [8]

Type 1 and 2 diabetes mellitus

Multi-phase study to develop a multi-dimensional PROM (for integration into the Swedish National Diabetes Register); item generation based on qualitative data and PROM refined based on expert review/consensus and cognitive interviews (variety of stakeholders). Undertaken in Sweden.

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PROs should be collected in routine diabetes care to **inform individual patient care** (i.e. support clinical consultations; intended PROM would be used as a communication tool in clinical diabetes care). PROs reflect key insights into diabetes, key outcomes of care and key questions for clinical decision making (providers were involved in refining the PROM)

✓

PROs reflect patient important outcomes; initial qualitative study eliciting important aspects of life for adults with diabetes (with a view to developing a PROM that reflects this), PROM refined based on expert consensus including people with diabetes, and cognitive interviews undertaken with people with diabetes to ensure face and content validity.

*Qualitative study*
**Selection of people with diabetes: Purposively sampled to generate heterogeneous sample on demographics, diabetes duration, glycaemic control, presence of late complications, risk factors and treatment. Inclusion criteria: Swedish adults (≥18 years), Type 1 or Type 2 diabetes (duration ≥5 years), able to describe their situation in Swedish.**
**Demographics for people with diabetes: Type 1 diabetes (n=15, 52%): age (years) mean=45.7 (±16.4, 22–64); women (40%); diabetes duration mean=22.7 (±13.9, 6–50); treated with insulin (100%) and insulin pump (47%), HbA1c (average over past 2 years) (mmol/mol) mean=62 (±11, 42–80); BMI (average over past 2 years) mean=26.6 (±5.2, 16.8–35.5); hospital-based outpatient clinic (93%) and primary healthcare clinic (7%). Type 2 diabetes (n=14, 48%): age (years) mean=63.7 (±10.4, 44–81); women (43%); diabetes duration mean=13.4 (±5.0, 5–23); no pharmacological treatment (7%), oral anti-diabetes drugs (29%), insulin (7%), combined treatment (e.g. tablets, insulin, incretine) (57%); HbA1c (average over past 2 years) (mmol/mol) mean=59 (±14, 41–83); BMI (average over past 2 years) mean=29.4 (±19.7, 23.0–38.3); hospital-based outpatient clinic (7%) and primary healthcare clinic) (93%).**

*Expert consensus*
**Selection of people with diabetes:**
**Representative from the Chairperson of the patients' association (the Swedish Diabetes Association), panels of 11 experts including individuals with Type 1 (n = 1) and Type 2 (n = 2) diabetes (purposively sampled from qualitative study), and representatives from the Greater Stockholm Diabetes Association (local patient association) (n=2) – no further detail provided.**
**Demographics not reported*.***

*Cognitive interviews*
**Selection of people with diabetes:**
**Purposive sampling from qualitative study to generate heterogeneous sample on type of diabetes, treatment and demographics (age, sex, socio-economic status, living in a city or a rural area). Inclusion criteria: adult (18 years), Type 1 or Type 2 diabetes, living in Sweden, diabetes duration 5 years and willing to share their experiences.**
**Demographics for people with diabetes:**
**Type 1 diabetes (n = 3) and Type 2 diabetes (n = 3) – no further detail provided.**

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| **Schoenthaler (2020)** [9]<br><br>Type 1 and 2 diabetes mellitus | Multi-phase study to develop a text-based programme for embedding PROs in diabetes clinical practice (primary care; designed to be integrated into electronic records and clinical workflow); item generation based on qualitative data and tool refined based on expert review and user testing (variety of stakeholders). Undertaken in the USA. | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care**; tool intended to focus the clinic visit on what is important to people with diabetes (i.e. patients' receive personalised reports including trends in PRO data over time and providers have access to summary data based on these reports, e.g. informing them of key trends over time). in user testing phase all providers found value in discussing the report with patients during their clinic visit. PROs reflect key insights into diabetes, key outcomes of care and key questions for clinical decision making; initial | ✓<br><br>PROs reflect patient important outcomes; iterative user-centred design approach starting with focus groups with people with diabetes to identify PROs (focus on experience of living with diabetes and barriers and facilitators to achieving goals). List of PROs reduced by people with diabetes who ranked them in order of importance and refined during a design workshop and user testing phase (I.e. during this phase people with diabetes provided feedback on the perceived usefulness of tracking the selected PRO data for diabetes |

interviews/focus groups with providers considered the clinical relevance of PROs initially identified by people with diabetes (and identified any other important PROs) and providers involved in refining tool

self-management/discussing this data with providers to help manage their diabetes).

**Selection of people with diabetes:**
**Potentially eligible patients were identified via a search of the electronic health records of a network of primary care practices serving an ethnically diverse population (New York), using the diagnosis-related group codes indicating the presence of Type 2 diabetes and receiving care at one of the practices. Eligibility was determined from potentially eligible patients' electronic record and patient confirmation. Inclusion criteria: Diagnosis of T2D (≥6 months); HbA1c >7% at least twice in the past year; fluency in English or Spanish; willing to send and receive text messages; and aged ≥18 years. Exclusion criteria: Refusal or unable to provide informed consent; acute renal failure, end-stage renal disease (ESRD) or evidence of dialysis, renal transplantation, or other ESRD-related services; participation in another Type 2 diabetes study; significant psychiatric comorbidity or reports of substance abuse; pregnant or planning to become pregnant within 12 months; or planning to discontinue care at the practice within the next 12 months.**

**Demographics for people with diabetes:**
**Focus groups (n=12): age (years) mean=62.5 (5.6); HbA1c mean=7.95 (0.8), women (67%)**
**Design workshop (n=17 stakeholders including people with diabetes) - no further detail provided.**
**User testing (text messages, n=10) – no further detail provided.**
**User testing (personalised reports, n=9): 4 had participated in user testing (of which 2 were recruited from the focus groups) and 5 were naive to the program – no further detail provided.**

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| **Rubin (2006)** [10] <br><br> Type 1 and 2 diabetes mellitus | (Diabetes Attitudes, Wishes and Needs (DAWN) study) Large cross-sectional survey conducted in 13 countries representing 11 regions; Australia, France, Germany, India, Japan, the Netherlands, Poland, Scandinavia (Sweden, Demark, Norway), Spain, the UK, and the USA. Objective to identify attitudes, wishes and needs of people with diabetes and providers. Planned by a multidisciplinary international advisory group, and questionnaire development based on review of diabetes-related instruments and focus groups (variety of stakeholders). All PROs included were considered recommended. | ✓✓ <br><br> No explicit recommendation to collect PROs in routine diabetes practice, but suggestion that the data should be used to **inform service improvement**; stated the objective was to lay the groundwork for efforts to improve diabetes care nationally and globally. PROs reflect key insights into diabetes; all of those included were considered important by the stakeholders designing the survey. | ✓ <br><br> PROs reflect patient important outcomes; people with diabetes were included in focus groups underpinning questionnaire development – no further detail provided. |
| **Nicolucci (2013)** [11] <br><br> Type 1 and 2 diabetes mellitus | (Diabetes Attitudes, Wishes and Needs (DAWN) 2 study) Large cross-sectional survey conducted in 17 countries representing four continents; Algeria, Canada, China, Denmark, France, Germany, India, Italy, Japan, Mexico, the Netherlands, Poland, Russian Federation, Spain, Turkey, the UK and the USA. Objective was to build on the findings of the original DAWN study (survey included original items and new questions), determine the progress made in achieving the actions identified, and identify new strategies for improving diabetes care (and establish national benchmarks for PROs). Planned by a multi-disciplinary international advisory group (variety of stakeholders). All PROs included were considered recommended. | ✓✓ <br><br> No explicit recommendation to collect PROs in routine diabetes practice, but suggestion that the data should be used to **inform service improvement**; outcomes assessed reflect agreed indicators for person centred care (for cross-national comparison) and stated survey was designed to provide data-driven guidance for all stakeholders in diabetes management regarding how diabetes care may be optimised locally, nationally and internationally (at the micro, meso or macro level). PROs reflect key outcomes of care (and insights into diabetes; all of those included were considered important by the stakeholders designing the survey). | ✓ <br><br> PROs reflect patient important outcomes; 'patient advocacy' was consulted in the development of the questionnaire, and survey design was based on 'a person-centred model for chronic illness care'. Survey was piloted by people with diabetes (n=7) from India, Canada, USA, and the UK to ensure face validity and acceptability, and 'subjected to written reviews' by people with Type 1 and 2 diabetes prior to finalisation. No further detail provided. |
| **Vieta (2011)** [12] <br><br> Type 2 diabetes mellitus | Literature review of PROMs (that assess 'aspects of Type 2 diabetes mellitus') used in published research in terms of their validity and appropriateness for health care decision making (wide variety of study designs included); PROMs were evaluated for six properties (presumed to define important outcomes for decision makers/'quality outcomes'; reliability, validity, sensitivity, feasibility for routine use (i.e. whether data is easy to obtain and the outcome is readily interpretable), and scope (i.e. whether it synthesises the highest number of possible 'aspects' of the outcome) - decisions were based on published psychometric properties and the comparability of these results between studies. Recommended PROMs were those scoring highly on the 'quality as an outcome' as well as on the quality of the evidence from which this was ascertained. | ✓✓ <br><br> PROs should be collected in routine diabetes care and used t**o inform service development**; stated the review helps decision makers determine the relevant PROMs to be measured in Type 2 diabetes mellitus to monitor program performance (i.e. the quality of patient care) and reallocate resources (i.e. improve the quality of care). PROs reflect those with PROMs that are most suitable for informing health care decision making (based on key criteria for this) | ✗ <br><br> Patient perspective was not considered when deciding the outcomes most appropriate for informing health care decision making. |

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| **Speight (2009)** [13]<br><br>Type 1 and 2 diabetes mellitus | Expert opinion piece making recommendations for PROs that should be measured in diabetes based on consideration of the 10 PROMs most frequently used to measure quality of life in diabetes (based on a systematic literature review); authors explain the PROMs measure distinct PROs (i.e. concepts that are not the same as quality of life but are concerned with issues that are important for it) and discuss their unique value for informing on an individuals' quality of life and well-being.<br><br>*Limited to a focus on quality of life and allied outcomes.* | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care**; stated that used together these PROs/PROMs can provide a full detailed picture of the effects of diabetes and its treatment and have potential to identify ways that treatment can be tailored to reduce the burden of diabetes (the authors recommend measuring all of them as part of a questionnaire battery). PROs reflect key (unique) insights into diabetes that are clinically useful. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Hermanns (2013)** [14]<br><br>Type 1 and 2 diabetes mellitus | Expert opinion piece making recommendations about which PROs (related to psychological well-being) should be measured in diabetes and what screening tools should be integrated into routine diabetes care/consultations (primary care) (with a focus on pragmatic solutions for achieving this). The authors discuss the unique value of recommended PROs for informing on an individuals' well-being.<br><br>*Limited to focus on psychological well-being* | ✓✓<br><br>PROs should be collected in routine diabetes care and used **to inform individual patient care**; rationale is provided in terms of the clinical utility of each PRO recommended (e.g. distinguishing whether patient are experiencing diabetes-related emotional distress or depression is required to inform and direct treatment pathways). PROs reflect key (unique) insights into diabetes that are clinically useful. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Kalra (2019)** [15]<br><br>Type 1 and 2 diabetes mellitus | Expert opinion piece (based on an international, multi-disciplinary scientific meeting; 'review of literature/evidence' (no detail provided) and clinical experience managing diabetes) making recommendations on assessing diabetes-related emotional distress and psychological burden in diabetes.<br><br>*Limited to a focus on psychological burden* | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care**; stated that assessment of the recommended PROs is crucial to then provide 'counselling' and achieve optimal outcomes in routine diabetes care (e.g. providers should identify diabetes-related emotional distress, and its cause, and minimise its impact on the affected person (in routine diabetes care rather than referring people to alternative services). PROs reflect common 'problems' in diabetes and key factors associated with diabetes end-points. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Bradley (2018)** [16] | Cross-sectional study reporting on the profile of predictors associated with select PROs/PROMs in diabetes; health status, generic quality of life, diabetes-specific quality of life, treatment satisfaction and worry about hypoglycemia. | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient** | ✗<br><br>Patient perspective on important outcomes not considered. |

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| Type 1 and 2 diabetes mellitus | Recommendations based on the PROs/PROMs considered differing widely and in important ways in terms of the factors (e.g. treatment intensification, HbA1c, hypoglycemia, etc.) that are associated with them (and providing unique insights into an individuals' quality of life and well-being). Undertaken in nine countries: Belgium, France, Germany, Greece, Italy, the Netherlands, Spain, Turkey, and the U.K.<br><br>*Limited to a focus on diabetes-specific quality of life, diabetes treatment satisfaction, worry about hypoglycaemia and health status (stated that these are the PROs that matter most for people with diabetes but this is not substantiated).* | **care**; stated that the study demonstrates the importance of ensuring each of the recommended PROs are considered when 'choosing between diabetes treatments'. PROs reflect key (unique) insights into diabetes that are clinically useful. | |
| **Huang (2008)** [17]<br><br>Type 1 and 2 diabetes mellitus | Cross-sectional study comparing the psychometric properties of a generic (SF-36) versus diabetes-specific (D39) measure of 'health related quality of life'. Recommendations based on the PROs/PROMs considered providing unique insights into an individuals' quality of life. Undertaken in Taiwan.<br><br>*Limited to a focus on diabetes-specific QoL and perceived health status* | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care**; study objective was to guide instrument selection in routine diabetes practice (the authors recommend combined assessment of both PROs). PROs reflect key (unique) insights into diabetes that are clinically useful. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Bott (1998)** [18]<br><br>Type 1 diabetes mellitus | Study reporting on the development and validation of a measure of diabetes-specific QoL (Diabetes-specific Quality of Life Scale; DSQoLs) that quantifies three distinct PROs. Undertaken in Germany.<br><br>*Limited to a focus on diabetes-related burdens and restrictions, diabetes treatment goals and diabetes treatment satisfaction.* | ✓✓<br><br>PROs should be collected in routine diabetes care and used to **inform individual patient care**; the authors describe the advantage of quantifying the recommended PROs in terms of their utility for providing key insights that can inform routine diabetes care (e.g. knowledge of treatment goals can be used with information on treatment satisfaction, and diabetes-related burdens and restrictions, to inform tailoring of treatment strategies). PROs reflect key (unique) insights into diabetes that are clinically useful. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Reaney (2016)** [19]<br><br>Type 2 diabetes mellitus | Literature review of PROMs, and therefore PROs (i.e. the concepts claimed to be elicited and domains assessed by each PROM), used to define endpoints in Phase 3 trials of newer classes of Type 2 diabetes mellitus drugs.<br><br>*Limited to a focus on newer classes of Type 2 diabetes mellitus drugs* | ✓✓<br><br>PROs should be measured when evaluating aspects of routine diabetes care; newer classes of Type 2 diabetes mellitus drugs (focus on research/clinical trials rather than clinical practice). Suggestion that the data should be used to **inform individual patient care**; stated that clinicians should consider the | ✗<br><br>Patient perspective on important outcomes not considered. |

| Harman (2019) [20]

Type 2 diabetes mellitus | (Selecting Core Outcomes for Randomised Effectiveness trials In Type 2 diabetes mellitus (SCORE-IT) study) Consensus work with rigorous consensus methodology employed – literature review (of the outcomes used in registered trials of therapies for Type 2 diabetes) and (Multi-stakeholder, International (but mostly UK)) Delphi survey - and a focus on developing a core outcome set.

*Limited to a focus on non-surgical interventions for hyperglycemia.* |

recommended PROs in addition to clinical data when discussing the available options with their patients (i.e. in addition to measuring this in clinical trials). PROs reflect key outcomes of care that are clinically useful.

✓

PROs should be measured when evaluating an aspect of routine diabetes care; non-surgical interventions for hyperglycemia (focus on research/clinical trials rather than clinical practice). **No recommendations about using PROs to inform individual patient care or service provision.** PROs reflect key outcomes of care.

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PROs reflect patient important outcomes; initial list of outcomes was developed based on rapid review of qualitative literature (focussing on views and experiences of people with Type 2 diabetes on their condition and treatment) and extraction of patient experiences from HealthTalk online (i.e. adults aged 18 years and over with type 2 diabetes). Delphi survey and consensus meeting included people with Type 2 diabetes and their carers (n=116 and 13, respectively).

**Delphi survey and consensus meeting Selection of people with diabetes: Potential participants were contacted via national and international professional bodies and patient organisations including but not limited to: Diabetes UK, International Diabetes Federation (IDF), American Diabetes Association (ADA), and Diabetes Canada. Potential participants were approached via an email to members, an e-newsletter, a link on a website, twitter or Facebook, an online community, and/or a patient magazine. The number of participants in each 10-year age range was monitored to ensure representativeness of the Type 2 diabetes population (which may be older with limited access to an online survey.**

**Demographics for people with diabetes (Delphi survey, n=116): Age (years): 30–39 (3%), 40–49 (7%), 50–59 (16%), 60–69 (47%), 70–79 (25%), >80 (2%) Country of residence: UK (99%), Greece (1%). No further detail provided.**

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| **Byrne (2017)** [21]<br><br>Type 1 diabetes mellitus (15-30 years of age) | (D1 NOW study) Consensus work with rigorous consensus methodology employed – literature review (of interventions to improve clinical, behavioural or psychosocial outcomes for young adults with Type 1 diabetes mellitus) and (Multi-stakeholder, international) Delphi survey - and a focus on developing a core outcome set. | ✓<br><br>PROs should be measured when evaluating aspects of routine diabetes care; interventions (all) (focus on research/clinical trials rather than clinical practice). **No recommendations about using PROs to inform individual patient care or service provision.** PROs reflect key outcomes of care. | ✓<br><br>PROs reflect patient important outcomes; Delphi survey and consensus meeting included (young) people with diabetes.<br><br>*Delphi survey and consensus meeting* **Selection of people with diabetes: Young adults with T1DM (aged 15–30 years) were invited via support groups, diabetes services or through other methods accessible to members of the study team (E.g. in Ireland, the study invite was circulated to Diabetes Ireland, a national charity dedicated to supporting and educating people with diabetes). The study was more also widely announced via social media channels, e.g. invitations were posted on Facebook accounts of online support groups for people with Type 1 diabetes. Snowball sampling was used; participants were invited to convey the study details to other individuals who may have relevant expertise. Demographics - not reported specifically for young people with Type 2 diabetes.** |
| **Ventura (2006)** [22]<br><br>Type 1 and 2 diabetes mellitus | (Diabetes Management and Impact for Long-term Empowerment and Success (MILES) 2 study) Large cross-sectional survey; undertaken in Australia. Objective to identify the impact of Type 1 and 2 diabetes mellitus on psycho-social health and well-being. Generation of survey content is not described. All PROs included were considered recommended. | ✓<br><br>**No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect key insights into diabetes; all of those included were considered important by the stakeholders designing the survey. | ?<br><br>Not apparent that the patient perspective was considered in determining the content of the survey (method not described). |
| **Donald (2012)** [23]<br><br>Type 1 and 2 diabetes mellitus | Large prospective survey; undertaken in Australia. Objective to contribute to holistic understanding of psycho-social aspects of diabetes by examining the natural trajectory of diabetes and its treatment. Generation of survey content is not described. All PROs included were considered recommended. | ✓<br><br>**No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect key insights into diabetes; all of those included were considered important by the stakeholders designing the survey. | ?<br><br>Not apparent that the patient perspective was considered in determining the content of the survey (method not described). |

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| **Chen (2019)** [24]<br><br>Type 2 diabetes mellitus | Literature review of the range of PROMs that have been used in studies involving registries that focus on and/or include people with Type 2 diabetes (mellitus and the associations between these PROMs, Type 2 diabetes mellitus and its complications); the findings reflect outcomes used in registries in a range of countries (Europe, Japan, USA, Germany, China, Canada, and Denmark) and hence the international uptake of PROMs in registries/routine diabetes care (e.g. ICOHM recommendations). All PROs identified were considered recommended (data on associations with other variables is limited owing to the focus of the review and not sufficient to suggest recommendations). | ✓<br><br>PROs are currently collected in routine diabetes care. **No explicit recommendations about using PROs to inform individual patient care or service provision.** PROs reflect key insights into diabetes and key outcomes of care; the PROs identified reflect those considered important to collect and integrate into routine diabetes practice. | ✗<br><br>Not apparent that the patient perspective was considered in determining the content of the registries. |
| **Glasgow (1999)** [25]<br><br>Type 1 and 2 diabetes mellitus | Literature review (updated) of PROMs used to evaluate Diabetes Self-Management Education and recommendations for future research (incl. what can and should be measured).<br><br>*Limited to a focus on Diabetes Self-Management Education.* | ✓<br><br>PROs should be measured when evaluating aspects of routine diabetes care; Diabetes Self-Management Education (focus on research/clinical trials rather than clinical practice). **No explicit recommendations about using PROs to inform individual patient care or service provision.** PROs reflect key outcomes of care. | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Eigenmann (2009)** [26]<br><br>Type 1 and 2 diabetes mellitus | Literature review of PROMs available to evaluate Diabetes Self-Management Education. Recommendations based on psychometric properties (i.e. validity and reliability), **relevance**, feasibility, burden/acceptability, and sensitivity to change.<br><br>*Limited to a focus on Diabetes Self-Management Education.* | ✓<br><br>PROs should be measured when evaluating aspects of routine diabetes care; Diabetes Self-Management Education (focus on research/clinical trials rather than clinical practice). **No explicit recommendations about using PROs to inform individual patient care or service provision.** PROs reflect key outcomes of care (and those that can be measured most accurately, feasibly, acceptably, and with tools that are most responsive to change) | ✗<br><br>Patient perspective on important outcomes not considered. |
| **Moffet (2009)** [27]<br><br>Type 1 and 2 diabetes mellitus | Large prospective survey (register based); undertaken in USA. Objective to identify a wide range of social and behavioural variables hypothesised to be potentially confounding, moderating or mediating factors associated with social differences on diabetes outcomes. All PROs included were considered recommended. | ✓<br><br>**No explicit recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect key insights into diabetes that are clinically useful; the PROs identified reflect those considered important to | ✗<br><br>Not apparent that the patient perspective was considered in determining the content of the survey/registry. |

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| collect and integrate into routine diabetes practice. |

**Primary and additional papers reporting on the above studies**

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