

BMJ Open What is important for you? A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register

Maria Svedbo Engström,^{1,2} Janeth Leksell,^{2,3} Unn-Britt Johansson,^{4,5} Soffia Gudbjörnsdóttir^{1,6}

To cite: Svedbo Engström M, Leksell J, Johansson U-B, *et al.* What is important for you? A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register. *BMJ Open* 2016;**6**: e010249. doi:10.1136/bmjopen-2015-010249

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2015-010249>).

Received 12 October 2015

Revised 1 February 2016

Accepted 7 March 2016



CrossMark

For numbered affiliations see end of article.

Correspondence to

Maria Svedbo Engström;
msd@du.se

ABSTRACT

Objectives: There is a growing emphasis on the perspective of individuals living with diabetes and the need for a more person-centred diabetes care. At present, the Swedish National Diabetes Register (NDR) lacks patient-reported outcome measures (PROMs) based on the perspective of the patient. As a basis for a new PROM, the aim of this study was to describe important aspects in life for adult individuals with diabetes.

Design: Semistructured qualitative interviews analysed using content analysis.

Setting: Hospital-based outpatient clinics and primary healthcare clinics in Sweden.

Participants: 29 adults with type 1 diabetes mellitus (DM) (n=15) and type 2 DM (n=14). Inclusion criteria: Swedish adults (≥18 years) living with type 1 DM or type 2 DM (duration ≥5 years) able to describe their situation in Swedish. Purposive sampling generated heterogeneous characteristics.

Results: To live a good life with diabetes is demanding for the individual, but experienced barriers can be eased by support from others in the personal sphere, and by professional support from diabetes care. Diabetes care was a crucial resource to nurture the individual's ability and knowledge to manage diabetes, and to facilitate life with diabetes by supplying support, guidance, medical treatment and technical devices tailored to individual needs. The analysis resulted in the overarching theme 'To live a good life with diabetes' constituting the two main categories 'How I feel and how things are going with my diabetes' and 'Support from diabetes care in managing diabetes' including five different categories.

Conclusions: Common aspects were identified including the experience of living with diabetes and support from diabetes care. These will be used to establish a basis for a tailored PROM for the NDR.

Strengths and limitations of this study

- The main strength of this project is that we have chosen to base our patient-reported outcome measures development on the very perspective of the patients.
- We have strengthened the credibility of this study by interviewing individuals with different characteristics to shed light on the research questions from different perspectives.
- A limitation is that the inclusion criteria did not account for the high number of individuals born in another country.

INTRODUCTION

Diabetes is a common¹ and serious lifelong condition associated with an increased risk of microvascular and macrovascular diseases, death^{2 3} and depression.⁴ Unmet blood glucose targets are still a major concern.⁵ The experiences and challenges of living with type 1 diabetes mellitus (DM) or type 2 DM and its self-management have increasingly been illuminated^{6–17} with a number of qualitative publications in recent years.^{18–37} There has also been an increased emphasis on person-centred diabetes care^{12 38 39} and the benefits of including the patient perspective in the outcomes of both research and clinical diabetes care.^{14 40–42}

The Swedish National Diabetes Register (NDR), which is among the largest diabetes registers in the world, is a clinical tool and a means for quality improvement and the assessment of diabetes care on local, regional

and national levels and for epidemiological research.⁴³ Patient-reported outcome measures (PROMs) are patient assessments of daily life and experiences of care⁴⁴ and are an important way forward for the NDR to further improve diabetes care. There are several existing questionnaires^{45–55} focusing on different aspects of patient-reported outcomes such as health-related quality of life, functional status, treatment satisfaction, fear of hypoglycaemia and late complications. However, none was considered fully suitable as a comprehensive and feasible clinical and longitudinal assessment tool for use within the scope of the NDR. Following the example in the DAWN2 study,⁵⁶ combining several questionnaires with study-specific items was not judged as feasible due to the high number of items used.

In a previous methodological study, the implementation of PROMs in the NDR was tested using a PROM based on literature, established questionnaires and clinical experience, and this showed PROMs to be an important complement to medical outcomes.⁵⁷ However, when assessing the patient perspective, by definition, the measure should be based on the identification of what is expressed as important in life for the target group.⁵⁸ In addition to existing research, dedicated qualitative research is especially important in building evidence on content validity and to reflect the verbal phrasing of the target group as the basis for item wording.^{59 60}

Sen's⁶¹ capability approach, which was used as a framework in this study, provides a general frame of thought⁶² and urges that context and specific purpose need to be taken into account when selecting what aspects to evaluate.^{63–65} According to Sen,⁶¹ evaluation of the quality of life should focus on what individuals can do (capabilities) in relation to what they value as important in life rather than what they in fact do (functionings). Important elements are the person's opportunities, prerequisites and possible barriers.⁶¹

We would like to develop a valid and reliable diabetes-specific PROM inspired by the capability approach, which includes important aspects for adults living with diabetes today and is feasible both as a clinical tool and longitudinal measure within the scope of the NDR. To inform the development of the PROM, the specific aim of this study was to describe important aspects in life for adults with diabetes.

METHODS

Design

A qualitative interview study.

Participants and sampling

Purposive sampling (n=29) continued parallel during data collection. Inclusion criteria: a heterogeneous group⁶⁶ (demographics, diabetes duration, glycaemic control, presence of late complications, risk factors and treatment) of Swedish adults (≥ 18 years) living with type 1 DM or type 2 DM (duration ≥ 5 years; [table 1](#)) able to

describe their situation in Swedish. There is a balance between recruiting an adequate number of participants to be able to draw conclusions and stopping recruitment when it is likely that no further data will add substance to the analysis.⁶⁶ The interviews were monitored in terms of repetitive information along with heterogeneity in the sample characteristics. After 25 interviews the answers were repetitive, but the sample was lacking younger individuals. This resulted in the intentional complementary inclusion of four younger participants. After 29 interviews, it was deemed that no further data would add substance to the analysis. Recruitment was assisted by diabetes nurses who distributed the study information to patients meeting the inclusion criteria at four hospital-based outpatient clinics and four primary healthcare clinics participating in the NDR in two regions of Sweden. Four participants were invited to

Table 1 Characteristics of participants

Characteristic	Type 1 DM (n=15)	Type 2 DM (n=14)
Men/women	6/9	8/6
Age, years	Mean 45.7 (± 16.4), range 22–64	Mean 63.7 (± 10.4), range 44–81
18–30	4	0
31–40	1	0
41–50	3	2
51–60	3	3
61–70	4	6
>70	0	3
Diabetes duration years	Mean 22.7 (± 13.9), range 6–50	Mean 13.4 (± 5.0), range 5–23
No pharmacological treatment for diabetes	0	1
Oral antidiabetes drugs	0	4
Insulin	15	1
Whereof insulin pump	7	0
Combined treatment (eg, tablets, insulin, incretine)	0	8
HbA1c average over the past 2 years: mmol/mol	Mean 62 (± 11), range 42–80	Mean 59 (± 14), range 41–83
<53	2	5
53–65	4	7
>65	6	5
BMI average over the past 2 years	Mean 26.6 (± 5.2), range 16.8–35.5	Mean 29.4 (± 19.7), range 23.0–38.3
<18.5	1	0
18.5–24.9	5	4
25.0–29.9	4	5
>29.9	4	6
Hospital-based outpatient clinic	14	1
Primary healthcare clinic	1	13

BMI, body mass index; DM, diabetes mellitus; HbA1c, glycated haemoglobin.

Table 2 Examples of the analysis process from meaning units to condensed meaning units and codes

Meaning unit	Condensed meaning unit	Code
I: What is important for you to be able to live as good a life as possible with diabetes? P: (...) if I can come here [to the diabetes clinic] for visits often. (...)	To be able to live a good life with diabetes, it is important to be able to come to the diabetes clinic often.	It is important to come to the diabetes clinic often
I: Do you get the opportunity to ask questions to your doctor? P: Yes, but... you try... you don't really want to because it is so stressful. It's like this: Do you have any questions? [Mimicking, speaking very quickly] It doesn't feel like he wants to answer any questions.	Can ask the doctor questions but would rather not as it is so stressful. Thinks that it feels like he doesn't want to answer questions.	Feels like the doctor doesn't want questions, it is so stressful
I: What is important in everyday life so you can manage your diabetes well? P: Hmm, fixed routines. Yes, that I have fixed routines, that I eat regularly and eat good food. Or what I think is good food and that I exercise. And that I check my blood glucose levels. This makes me ... Yes it is these kinds of everyday things.	Having fixed routines is important; eating regularly and eating good food, checking blood glucose levels and exercising.	Fixed routines are important

I, interviewer, P, participant.

participate by the authors: two for pilot interviews and two to complement the sample with younger individuals. In total, 47 invitation letters were handed out to potential participants. One individual was excluded for not meeting the criteria for diabetes duration and one could not be reached.

Data collection

Audio recorded semistructured face-to-face individual interviews were held in privacy between late 2012 and mid-2013 (MSE) and lasted 30–120 min (mean: 90 min). The interview guide was based on the literature on diabetes and the capability approach, clinical and research experience, and guidance from experts in qualitative research methodology. The participants were asked to describe their experiences of living with diabetes, important aspects and barriers for a good life with diabetes, and thoughts about diabetes care. Situation-bound probes (eg, what do you mean by..., tell me more about...) confirmed and deepened understanding. Two pilot interviews resulted in a minor revision of the order in which the questions were presented. Both pilot interviews were included in the study as it was deemed that they provided useful information. The majority of the interviews (n=26) were conducted at the outpatient clinics. Owing to the long travelling distances and participant preference, two of the interviews were conducted in the

participants' homes and one at a university. Background data were collected at each interview session. Medical data were collected from the NDR, complemented with data from patient records when information was lacking.

Analysis

The verbatim transcripts (1275 pages or 355 996 words) were analysed using qualitative content analysis (MSE).⁶⁷ With Sen's capability approach used as a frame of thought, we sought to identify resources and barriers important to the achievement of what was considered important in life. To generate a basis for a PROM, the analysis approach was close to the text maintaining the verbal phrasing. Going back and forth, each transcript (ie, the unit of analysis) was read several times and relevant parts were extracted and coded preliminarily (ie, given descriptive labels). Using a word-processing program, parts of similar content were assembled as meaning units, condensed (ie, shortened while still keeping the meaning), coded (table 2), grouped into subcategories according to similarities and differences, and aggregated into categories, main categories and the overarching theme (table 3). Researcher triangulation was used throughout the analysis process. Cross-checking the first 10 interviews (MSE and JL) revealed almost identical extraction of meaning units. Differences were

Table 3 Theme, main categories and categories

Theme	To live a good life with diabetes				
Main categories	How I feel and how things are going with my diabetes		Support from diabetes care in managing diabetes		
Categories	Mastering management to be able to feel good in the present as well as the future.	Barriers related to diabetes	Support from others	Support from diabetes care tailored to individual needs.	Technical devices and medical treatment tailored to individual needs.

discussed and easily resolved. The process of coding, categorising, describing the categories, and choosing representative quotations was discussed until consensus was met within the group.

Ethical considerations

The participants were informed orally and in writing about the study's purpose, confidentiality, voluntary participation and their right to end their involvement at any point. They were also informed that the nurse conducting the interviews was not employed at the clinic. Written informed consent was collected by the research group.

RESULTS

The analysis resulted in the overarching theme 'To live a good life with diabetes' constituting two main categories (table 3). In the following section, the two main categories with accompanying categories are described followed by exemplifying quotes.

How I feel and how things are going with my diabetes

Mastering management to be able to feel good in the present as well as the future

The most central aspect was to feel good, in the present and in the future, and not to be affected too much by diabetes and the workload of its management. These two time perspectives were sometimes described as going hand-in-hand but sometimes not, and therefore needed to be balanced. Good management of diabetes was described as a prerequisite for feeling good in the short and long term. At the same time, living with diabetes and the associated management demands every single day, year after year, could be experienced as tough and overwhelming.

It is exhausting, both physically and mentally. Over the years it sort of wears you down. (...) It's constantly on your mind. (...) You never get a break from it. (#12; Man, 63 years old, Type 1 DM)

A desire to be normal and hope for a cure was expressed. Despite this, most individuals expressed optimism in the future. One aspect brought up was the importance of accepting having diabetes to be able to manage it.

Having diabetes was experienced both as an incentive and as a constraint for a healthy lifestyle. For some, healthy lifestyle changes came naturally, but developing regular habits such as physical activity, healthy eating and monitoring and balancing blood glucose levels could also be challenging and difficult.

The greatest challenge for me is to get a working daily routine when it comes to food. (...) It's a constant struggle. (#7; Woman, 66 years old, Type 2 DM)

Management was described as requiring a lot of knowledge of various sorts and at different levels: from

theoretical and technical knowledge to more advanced knowledge and knowing how to apply and adjust it to different and new situations. Being able to manage diabetes in different situations could be related to feeling proud and a sense of trusting one's own ability. Knowledge was challenged when, for example, facing a new or unfamiliar situation, a changed activity level or time for eating, eating out, going to a party, getting a fever or stomach flu, travelling and having an irregular or changed timetable or tasks in connection to work or education.

It's not easy, it's an endless struggle to try to maintain good blood glucose levels. (...) It's like walking a line. (#24; Woman, 64 years old, Type 1 DM)

The ability to manage diabetes was described as being influenced by how the person feels and events in the person's life and social sphere. In good times, management was easier to deal with than when facing both minor and major undermining factors.

If you feel mentally good and feel that everything is going well, then you have more energy to take care of your diabetes. You, like, want to feel good physically too. (#29; Woman, 22 years old, Type 1 DM)

Undermining factors could be stress, a heavy workload at home or in connection with work or education, menstruation, climacteric symptoms, not feeling well, feeling down or depressed, lacking the necessary strength to manage, experiencing troublesome events, being affected by the poor well-being of family and friends or the need to help and support others. Some of the consequences included unhealthy eating, infrequent physical exercise and less focus on blood glucose levels, as well as feelings of anxiety, guilt, disappointment, shame and worrying about not meeting management demands.

If people around you don't feel good, then you think about them all the time (...) then you neglect your own issues, like food and so on. (#13; man, 57 years old, Type 2 DM)

Barriers related to diabetes

The extent to which diabetes was experienced as a barrier varied over time, in different situations and between participants. Some felt constrained, others not at all: experiencing diabetes as being well integrated in their life and that management came naturally without any special effort. A need to always plan and live according to a strict daily routine could be a natural part of personalities and everyday life but could also be experienced as difficult, imposing, limiting and feeling unable to relax because of constantly having to take blood glucose levels into account and the effort required to keep it in balance. There were also descriptions of, occasionally or continuously, refusing to be constrained

by diabetes, expressing possibly taking too many risks and neglecting management requirements. Diabetes could be seen as something to be ashamed of and needing to be concealed. It could also be experienced as something that ruins lives and impairs relationships with others. For example, there were descriptions of abstaining from social activities and refusing invitations to events because of not wanting to eat, having difficulties doing things spontaneously or finding it bothersome to steer others and to be dependent on support from others.

The negative thing with diabetes is when people at work ask if you can join them for something after work. No, I can't, I'm going home to take my injection and have dinner. You get a little tied up, you know. (#17; Woman, 60 years old, Type 2 DM)

Hyperglycaemia, hypoglycaemia and fluctuating blood glucose levels were experienced as barriers to daily activities such as physical activity, work or educational activities, and were described as frustrating and draining.

It [fluctuating blood glucose levels] takes a lot of energy... It takes a lot, it's a great strain... I'd say, it wears me down. It really wears me down. (#2; Woman, 58 years old, Type 1 DM)

Another barrier was fear and worries of hypoglycaemia or hyperglycaemia, which required courage to handle. These worries could lead to intentionally keeping blood glucose levels too high to avoid the risk of hypoglycaemia, abstaining from activities, difficulties being alone and dependence on others.

It's sad not daring to go [on a trip]. (...) Since it [hypoglycaemia] is a threat, it feels like a lower quality of life. (...) You get a little scared of exposing yourself to situations other than what you are used to. (#17; Woman, 60 years old, Type 2 DM)

The risk of developing late complications due to diabetes such as microvascular and macrovascular diseases could be a source of anxiety. Experiences ranged from not being worried at all to being afraid of losing tactual sensation in the feet, amputation of the feet, cancer and negative effects on the heart, vessels, kidneys and eyes. When late complications were a fact, they were expressed as potential barriers in life, but also as something possible to live with and not necessarily as something diminishing the quality of life.

It is a constant sadness, that I've lost my sight... (...) But it's nothing I get hung up on in my everyday life. (...) I consider myself as having a good quality of life. (#1; Man, 49 years old, Type 1 DM)

Support from others

The support the participants needed and received from others (eg, family, friends, others with diabetes, colleagues, managers, acquaintances or others) varied, both between participants and also for the individual, depending on the situation and over time. The support needed could be related to keeping a healthy lifestyle, understanding of management needs and a possibility to adjust to them, or the risk of hypoglycaemia. If attuned to individual needs and wishes, support from others could be related to feelings of togetherness and help with management, which in turn reduces the extent to which diabetes was experienced as a barrier.

I have many close friends and acquaintances who support me, which means a lot. Above all, in tough periods when it's difficult to manage my blood glucose levels and so on, it's a great support for me. (#28; Man, 31 years old, Type 1 DM)

Lack of support could be related to feelings of disappointment, of being all alone and increase the burden of diabetes. Support from others could also be overwhelming: to constantly be watched over. Despite good intentions, others making comments regarding what to eat and drink could be disturbing and related to shame and the feeling of becoming common goods. To be in need of support from others could be related to a feeling of disliking being dependent on others or feeling like a burden.

Going away and doing something by myself is almost unthinkable. (...) Sometimes you feel like a burden. (#2; Woman, 58 years old, Type 1 DM)

Support from diabetes care in managing diabetes

Support from diabetes care tailored to individual needs

Diabetes care was described as a crucial resource in dealing with diabetes emotionally and practically. Participants wanted to be listened to and that caregivers acknowledge their experiences, knowledge and desire for shared decision-making.

They [the diabetes nurse and physician] are very knowledgeable, but they don't have first-hand experience of what it is like to have this condition, to live with it every minute of every day. Therefore, there has to be cooperation (...) I also need to be part of the process... (#2; Woman, 58 years old, Type 1 DM)

Diabetes care was wanted to target individual needs with regard to access, content, timing, personal treatment, current individual situation and the emotional aspects of living with diabetes. Support was requested in how to handle diabetes in different everyday situations and also in situations faced less regularly, such as travelling, taking part in festivities or being sick. Continuity—being able to meet with the same professional over time—was expressed as a prerequisite for a good and open

discussion. The quality of support experienced varied, both between participants and also for the same person between different professionals and professional groups supplying diabetes care. There were descriptions of being very pleased with and feeling strengthened by the support from diabetes care, as well as descriptions of being disappointed due to not receiving the support they needed or due to being mistreated in some way.

Undergoing medical examinations was considered important and gratitude for this possibility was expressed. Medical examinations could provide confirmation of a good job or motivation to make more of an effort. However, medical examinations alone were experienced as inadequate and were compared to vehicle tests.

There's a lot of focus on numbers and values. They don't always say that much, they are just figures on a piece of paper. And that is absolutely not everything. A lot of it is about how you feel, too. And this is where care is lacking somehow, like talking about how you feel and what you are experiencing. (#28; Man, 31 years old, Type 1 DM)

Some participants experienced that they learnt something every time they visited the diabetes clinic. At the other end of the continuum, there were descriptions of not getting any useful information and of not understanding the information provided due to the use of professional jargon. Participants wanted information to be tailored to individual needs, repeated to refresh memory and kept updated to keep up with changing needs and/or progress in diabetes research. It was also expressed as important for different healthcare groups to supply consistent advice and information and not contradict each other, as this could lead to confusion and uncertainty. Information for family and friends was also asked for, as this might make it easier for the person with diabetes and make family and friends feel more secure and less worried. Being able to pose questions and get them answered was emphasised as another important aspect. Some described having this opportunity, but others were afraid to ask questions and sensed that there was no time for questions.

There is not much time for questions and answers. The diabetes nurse does what she has planned, what she needs to do. And when she is done, we are done talking. (#8, Man, type 2 DM, 81 years old)

Participants expressed a desire for access to diabetes care to be more flexible and better adapted to individual needs regarding timing, frequency, form of contact and being able to make contact when facing a problem. More modern and flexible solutions were asked after; fixed and limited phone times on weekdays or complicated electronic systems were considered an obstacle. Frequent contact with diabetes care was seen as especially important when newly diagnosed and when

making changes: for assessment, guidance and the acknowledgement of efforts made.

...if I could come here [to the clinic] a little more often, then I could keep better habits [eating habits] all the time... (#7, Woman, type 2 DM, 66 years old)

Participants also expressed that individual consultations were most important. However, when in need of more frequent contact, for some it could be satisfactory just to take their weight or glycated haemoglobin, or send an email or make a phone call.

The opportunity to meet and share experiences with others who have diabetes in group-based education was called for. Those who had taken part in such programmes were very satisfied and considered them very educational and adding another dimension to diabetes care. There was a desire for them to be expanded and offered as more than one-off events.

It was excellent, it was probably the best diabetes care I've received. (...) we learned so much from each other. (#17, Woman, 60 years old, type 2 DM)

Technical devices and medical treatment tailored to individual needs

Technical devices and medical treatment well matched to individual needs to facilitate everyday life was experienced as very important. Self-monitoring of blood glucose was carried out in different ways, for example, to learn how different aspects influence blood glucose and to adjust insulin to be able to keep blood glucose at a good level. There were descriptions of how technical devices, such as blood glucose devices, continuous glucose monitoring (CGM), insulin pens with memory functions and insulin pumps really have made life easier. In particular, CGM and insulin pumps were described as giving greater freedom and a better quality of life by allowing the user to be one step ahead and able to act earlier, possibly decreasing the amount of problems experienced with, for example, fluctuating blood glucose levels.

I think the insulin pump is fantastic. Because it gives me freedom. (#24; Woman, 64 years old, Type 1 DM)

On the negative side, it was difficult to get hold of medical products or supplements to technical devices from the pharmacies, in particular for individuals using CGM or insulin pumps. The participants described always needing to carry an extra set and having to pre-order days in advance. Another problem expressed was that technical devices are not always subsidised, potentially resulting in extra costs for the individual and unequal opportunities for management.

I would be so pleased if I didn't have to pay for the CGM myself (...) If I couldn't afford to pay for it, I wouldn't have such a good blood count [HbA1c] (#22, Woman, type 1 DM, 44 years old)

DISCUSSION

In this qualitative study, interviews have given us personal accounts of unique experiences of living with diabetes. Despite this uniqueness, we could identify common aspects in these accounts that can be used as the basis for the subsequent development of a PROM for the NDR. Our results show that living with diabetes is a challenge for the individual that can be characterised by an always present condition, a constant struggle and feelings of being tied up, fear, shame and being alone, as well as of courage, a sense of trusting one's own abilities and togetherness with family, friends and others with diabetes. 'To live a good life with diabetes' is possible, but demanding for the individual. Experienced barriers can be eased by support from the personal sphere, and by support from diabetes care. Diabetes care is a crucial resource to nurture the individual's ability to, and knowledge of how to, manage diabetes, and to facilitate this by supplying support, guidance, medical treatment and technical devices tailored to individual needs.

Our findings add to and show a lot of similarities to the growing body of research on the experience of living with diabetes^{6 7 9 11–13 15–17 38} and the importance of support from diabetes care.^{6 10 11 13 16 39 68} Recent qualitative research has, for example, focused on experiences of being newly diagnosed with diabetes,^{35–37} hypoglycaemia,^{21 34} self-management,^{20 29–33} technical devices^{27 28} and social support,^{18 26} and the need for diabetes care to be tailored to individual needs.^{19 22–25} Aspects identified in this study, such as well-being, balancing self-management demands, barriers and the support needed, have previously been emphasised as important outcomes in diabetes-related research and diabetes care^{14 40–42} and can in part be traced in existing questionnaires.^{45–55} However, to the best of our knowledge, no existing questionnaire covers all aspects.

The use of PROMs in clinical practice is suggested to have a positive effect on, for example, patient–clinician communication, symptom management and supporting clinical decision-making.⁶⁹ Similar to the core of person-centred care: patient narratives, extended dialogue, relationship and partnership with the patient,⁷⁰ our results show that individuals with diabetes have a need to be listened to and want cooperation and shared decision-making. Moreover, they have a lot of knowledge and an ability to reflect on and express in words their weak points and resources, their problems and possible solutions. In a clinic, a PROM can be used as a signalling system and as a reference for further dialogue and thereby enable support from diabetes caregivers to be tailored to meet individual needs. A PROM cannot solve everything and is not the only means for person-centred diabetes care, but it can be one step in that direction.

Audit and feedback to professionals is a widely used strategy in quality improvement with generally small to moderate, but potentially clinically meaningful, effects on professional practice.⁷¹ Including PROMs in the NDR will contribute to a more comprehensive base for

the assessment and for the quality improvement process in Swedish diabetes care. The clinical use and routine collection of PROMs have also been assumed to have an impact on outcomes. However, this complex relationship has yet to be clarified and more high-quality research is needed.^{69 72 73} The implementation should be studied, accounting for enablers and barriers, implementation strategies⁶⁹ and cost benefits.⁷³

By tradition, many questionnaires are developed on the basis of the expertise of professionals, with the risk of not targeting what is important from a patient perspective.⁷⁴ Consequently, what this study contributes and the main strength of this project is that we have chosen to base our PROM development on the very perspective of the patients. Also, we have gathered material for item generation based on the verbal phrasing of the target group. The expertise of professionals is important and should be acknowledged, not in the least to gain support for future use and will be accounted for in future research.

The use of Sen's⁶¹ capability approach has helped us to focus on what is considered important in life to the individual, know that there are individual variations and that what is important cannot be dictated by healthcare personnel irrespective of clinical experience. Moreover, a focus on capabilities rather than functions highlights the individual's freedom of choice,^{61 75} which has helped us to focus on the pre-requisites and resources needed as well as barriers to achieve what is considered important in life to each individual. The choice of the capability approach is by no means exclusive, as its interdisciplinary nature encourages it being used in combination with other approaches, models or theories and measures.⁷⁵

We have strengthened the credibility of this study by interviewing individuals with different characteristics to shed light on the research questions from different perspectives.⁶⁷ We chose to include both individuals with type 1 DM and with type 2 DM, as we aim for a PROM suitable for use irrespective of diabetes diagnosis, to make it easy to handle for diabetes care and for the NDR. Therefore, it was not our intention to analyse differences between type 1 DM and type 2 DM, but rather, similar to Campbell *et al*,⁶⁸ to focus on the experience of living with diabetes. For such different types of diagnosis, our ambition may well be challenging. However, it is strengthened by the fact that the measurement model in the DAWN2 study⁵⁶ and many earlier questionnaires were developed and tested for both type 1 and type 2 DM.^{47–50 52} The future development and testing process will show whether or not this will succeed.

A limitation is that the inclusion criteria did not account for the high number of individuals born in another country.⁷⁶ Of the 29 participants, two individuals originated from another Scandinavian country and one from a non-European country. To gain satisfactory breadth and depth, accounting for cultural aspects was considered beyond the scope of this study. Naturally, cultural aspects need to be considered in the prolongation of this project.

Credibility is also strengthened by different perspectives being represented in the research group,⁶⁷ which consists of both registered nurses and a physician (all females). Furthermore, the group consists of two professors (SG and U-BJ), one assistant professor (JL) and one PhD student (MSE), representing a vast joint experience of research within diabetes care. SG is the head of the Swedish National Diabetes Register and has extensive experience of register-based research and U-BJ and JL have vast experience in qualitative research within the diabetes area. The main author (MSE), who conducted the interviews, is a registered nurse with training in diabetes care and was trained in interview techniques by an expert. She does not work as a diabetes nurse and had no established relationship with the participants prior to the study. Her lack of extensive experience of diabetes care might be a disadvantage; however, it is an advantage in terms of her having less preconceived ideas and because the participants could speak freely about their situation and experiences of diabetes care without being in a state of dependence.

CONCLUSIONS

This study has identified aspects including the experience of living with diabetes and support from diabetes care that will be used as the basis for a tailored PROM for the NDR. By building PROMs into the NDR, we want to offer a clinical tool that, in addition to the still very important medical outcomes, puts emphasis on the perspective of the individual with diabetes.

Author affiliations

¹University of Gothenburg, Sahlgrenska Academy, Institute of Medicine, Gothenburg, Sweden

²Dalarna University, School of Education, Health and Social Studies, Falun, Sweden

³Uppsala University, Department of Medical Sciences, Uppsala, Sweden

⁴Sophiahemmet University, Stockholm, Sweden

⁵Karolinska Institutet, Department of Clinical Sciences and Education, Stockholm, Sweden

⁶Register Center Västra Götaland, Gothenburg, Sweden

Acknowledgements The authors are grateful to all participants and to the professionals facilitating the data collection. Thanks also to Pär Samuelsson for facilitating data extraction from the NDR and colleagues for valuable input.

Contributors MSE conducted data collection, analysis and manuscript preparation, and revision, supported by intellectual contributions from JL, U-BJ and SG. All authors contributed to the study design and approved the final manuscript.

Funding This work was supported by Dalarna University, Uppsala University, and included unrestricted grants to the NDR from MSD, Novo Nordisk and the Swedish Association of Local Authorities and Regions. None of the fund providers have influenced the study, manuscript preparation or publication decisions at any stage.

Competing interests SG had financial support from MSD, Novo Nordisk for the submitted work.

Ethics approval The Regional Ethical Review Board in Gothenburg, Sweden reference number 265–12.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

REFERENCES

- International Diabetes Federation. IDF DIABETES ATLAS 2014 update poster. Secondary IDF DIABETES ATLAS 2014 update poster 2014. http://www.idf.org/sites/default/files/Atlas-poster-2014_EN.pdf
- Eeg-Olofsson K, Cederholm J, Nilsson PM, *et al*. New aspects of HbA1c as a risk factor for cardiovascular diseases in type 2 diabetes: an observational study from the Swedish National Diabetes Register (NDR). *J Intern Med* 2010;268:471–82.
- Lind M, Svensson AM, Kosiborod M, *et al*. Glycemic control and excess mortality in type 1 diabetes. *N Engl J Med* 2014;371:1972–82.
- Roy T, Lloyd CE. Epidemiology of depression and diabetes: a systematic review. *J Affect Disord* 2012;142(Suppl):S8–21.
- McKnight JA, Wild SH, Lamb MJ, *et al*. Glycaemic control of type 1 diabetes in clinical practice early in the 21st century: an international comparison. *Diabet Med* 2015;32:1036–50.
- Ahola AJ, Groop PH. Barriers to self-management of diabetes. *Diabet Med* 2013;30:413–20.
- Barendse S, Singh H, Frier BM, *et al*. The impact of hypoglycaemia on quality of life and related patient-reported outcomes in type 2 diabetes: a narrative review. *Diabet Med* 2012;29:293–302.
- Barnard KD, Peyrot M, Holt RI. Psychosocial support for people with diabetes: past, present and future. *Diabet Med* 2012;29:1358–60.
- Chen CM, Chang Yeh M. The experiences of diabetics on self-monitoring of blood glucose: a qualitative metasynthesis. *J Clin Nurs* 2015;24:614–26.
- Frost J, Garside R, Cooper C, *et al*. A qualitative synthesis of diabetes self-management strategies for long term medical outcomes and quality of life in the UK. *BMC Health Serv Res* 2014;14:348.
- Gask L, Macdonald W, Bower P. What is the relationship between diabetes and depression? A qualitative meta-synthesis of patient experience of co-morbidity. *Chronic Illn* 2011;7:239–52.
- Gomersall T, Madill A, Summers LK. A metasynthesis of the self-management of type 2 diabetes. *Qual Health Res* 2011;21:853–71.
- Ho AY, Berggren I, Dahlborg-Lyckhage E. Diabetes empowerment related to Pender's Health Promotion Model: a meta-synthesis. *Nurs Health Sci* 2010;12:259–67.
- IDF Clinical Guidelines Task Force. *Global guideline for type 2: diabetes*. Brussels: International Diabetes Federation, 2005.
- Nicolucci A, Kovacs Burns K, Holt RI, *et al*. Diabetes Attitudes, Wishes and Needs second study (DAWN2): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabet Med* 2013;30:767–77.
- Paterson BL, Thorne S, Dewis M. Adapting to and managing diabetes. *Image J Nurs Sch* 1998;30:57–62.
- Wilkinson A, Whitehead L, Ritchie L. Factors influencing the ability to self-manage diabetes for adults living with type 1 or 2 diabetes. *Int J Nurs Stud* 2014;51:111–22.
- Rankin D, Barnard K, Elliott J, *et al*. Type 1 diabetes patients' experiences of, and need for, social support after attending a structured education programme: a qualitative longitudinal investigation. *J Clin Nurs* 2014;23:2919–27.
- Rankin D, Cooke DD, Elliott J, *et al*. Supporting self-management after attending a structured education programme: a qualitative longitudinal investigation of type 1 diabetes patients' experiences and views. *BMC Public Health* 2012;12:652.
- Rankin D, Cooke DD, Heller S, *et al*. Experiences of using blood glucose targets when following an intensive insulin regimen: a qualitative longitudinal investigation involving patients with type 1 diabetes. *Diabet Med* 2012;29:1079–84.
- Rankin D, Elliott J, Heller S, *et al*. Experiences of hypoglycaemia unawareness amongst people with type 1 diabetes: a qualitative investigation. *Chronic Illn* 2014;10:180–91.
- Rankin D, Heller S, Lawton J. Understanding information and education gaps among people with type 1 diabetes: a qualitative investigation. *Patient Educ Couns* 2011;83:87–91.
- Bramberg EB, Dahlborg-Lyckhage E, Maatta S. Lack of individualized perspective: a qualitative study of diabetes care for immigrants in Sweden. *Nurs Health Sci* 2012;14:244–9.

24. Oftedal B, Karlsen B, Bru E. Perceived support from healthcare practitioners among adults with type 2 diabetes. *J Adv Nurs* 2010;66:1500–9.
25. Svenningsson I, Gedda B, Marklund B. Experiences of the encounter with the diabetes team—a comparison between obese and normal-weight type 2 diabetic patients. *Patient Educ Couns* 2011;82:58–62.
26. Gunn KL, Seers K, Posner N, *et al.* 'Somebody there to watch over you': the role of the family in everyday and emergency diabetes care. *Health Soc Care Community* 2012;20:591–8.
27. Garmo A, Hornsten A, Leksell J. 'The pump was a saviour for me.' Patients' experiences of insulin pump therapy. *Diabet Med* 2013;30:717–23.
28. Lawton J, Kirkham J, Rankin D, *et al.* Perceptions and experiences of using automated bolus advisors amongst people with type 1 diabetes: a longitudinal qualitative investigation. *Diabetes Res Clin Pract* 2014;106:443–50.
29. Lawton J, Rankin D, Cooke D, *et al.* Patients' experiences of adjusting insulin doses when implementing flexible intensive insulin therapy: a longitudinal, qualitative investigation. *Diabetes Res Clin Pract* 2012;98:236–42.
30. Lawton J, Rankin D, Cooke DD, *et al.* Self-treating hypoglycaemia: a longitudinal qualitative investigation of the experiences and views of people with type 1 diabetes. *Diabet Med* 2013;30:209–15.
31. Peel E, Douglas M, Parry O, *et al.* Type 2 diabetes and dog walking: patients' longitudinal perspectives about implementing and sustaining physical activity. *Br J Gen Pract* 2010;60:570–7.
32. Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *BMJ* 2007;335:493.
33. Mathew R, Gucciardi E, De Melo M, *et al.* Self-management experiences among men and women with type 2 diabetes mellitus: a qualitative analysis. *BMC Fam Pract* 2012;13:122.
34. Brod M, Pohlman B, Wolden M, *et al.* Non-severe nocturnal hypoglycemic events: experience and impacts on patient functioning and well-being. *Qual Life Res* 2013;22:997–1004.
35. Kneck A, Klang B, Fagerberg I. Learning to live with illness: experiences of persons with recent diagnoses of diabetes mellitus. *Scand J Caring Sci* 2011;25:558–66.
36. Kneck A, Klang B, Fagerberg I. Learning to live with diabetes—integrating an illness or objectifying a disease. *J Adv Nurs* 2012;68:2486–95.
37. Kneck A, Fagerberg I, Eriksson LE, *et al.* Living with diabetes—development of learning patterns over a 3-year period. *Int J Qual Stud Health Well-being* 2014;9:24375.
38. Barnard KD, Lloyd CE, Dyson PA, *et al.* Kaleidoscope model of diabetes care: time for a rethink? *Diabet Med* 2014;31:522–30.
39. Coulter A, Entwistle VA, Eccles A, *et al.* Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database Syst Rev* 2015;3:CD010523.
40. American Diabetes Association. Standards of medical care in diabetes—2015: summary of revisions. *Diabetes Care* 2015;38 (Suppl):S4.
41. Glasgow RE, Peeples M, Skovlund SE. Where is the patient in diabetes performance measures? The case for including patient-centered and self-management measures. *Diabetes Care* 2008;31:1046–50.
42. Jones A, Vallis M, Pouwer F. If it does not significantly change HbA1c levels why should we waste time on it? A plea for the prioritization of psychological well-being in people with diabetes. *Diabet Med* 2015;32:155–63.
43. Eliasson B, Gudbjornsdottir S. Diabetes care—improvement through measurement. *Diabetes Res Clin Pract* 2014;106(Suppl 2):S291–4.
44. Calvert M, Blazeby J, Altman DG, *et al.* Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. *JAMA* 2013;309:814–22.
45. Amsberg S, Wredling R, Lins PE, *et al.* The psychometric properties of the Swedish version of the Problem Areas in Diabetes Scale (Swe-PAID-20): scale development. *Int J Nurs Stud* 2008;45:1319–28.
46. Anderbro T, Amsberg S, Wredling R, *et al.* Psychometric evaluation of the Swedish version of the Hypoglycaemia Fear Survey. *Patient Educ Couns* 2008;73:127–31.
47. Eigenmann CA, Colagiuri R, Skinner TC, *et al.* Are current psychometric tools suitable for measuring outcomes of diabetes education? *Diabet Med* 2009;26:425–36.
48. El Achhab Y, Nejjarri C, Chikri M, *et al.* Disease-specific health-related quality of life instruments among adults diabetic: a systematic review. *Diabetes Res Clin Pract* 2008;80:171–84.
49. Garratt AM, Schmidt L, Fitzpatrick R. Patient-assessed health outcome measures for diabetes: a structured review. *Diabet Med* 2002;19:1–11.
50. Gibbons E, Fitzpatrick R. *Patient Reported Outcome Measurement Group. A structured review of patient-reported outcome measures (PROMs) for diabetes.* University of Oxford, 2009.
51. Leksell J, Funnell M, Sandberg G, *et al.* Psychometric properties of the Swedish Diabetes Empowerment Scale. *Scand J Caring Sci* 2007;21:247–52.
52. Speight J, Reaney MD, Barnard KD. Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. *Diabet Med* 2009;26:315–27.
53. Wikblad K, Smide B, Leksell JK. Check your health validity and reliability of a measure of health and burden of diabetes. *Scand J Caring Sci* 2014;28:139–45.
54. Wikblad KF, Wibell LB, Montin KR. The patient's experience of diabetes and its treatment: construction of an attitude scale by a semantic differential technique. *J Adv Nurs* 1990;15:1083–91.
55. Wredling R, Stalhammar J, Adamson U, *et al.* Well-being and treatment satisfaction in adults with diabetes: a Swedish population-based study. *Qual Life Res* 1995;4:515–22.
56. Peyrot M, Burns KK, Davies M, *et al.* Diabetes Attitudes Wishes and Needs 2 (DAWN2): a multinational, multi-stakeholder study of psychosocial issues in diabetes and person-centred diabetes care. *Diabetes Res Clin Pract* 2013;99:174–84.
57. Borg S, Palaszewski B, Gerdtham UG, *et al.* Patient-reported outcome measures and risk factors in a quality registry: a basis for more patient-centered diabetes care in Sweden. *Int J Environ Res Public Health* 2014;11:12223–46.
58. Streiner DL, Norman GR. *Health measurement scales: a practical guide to their development and use.* Oxford: Oxford University Press, 2008.
59. Patrick DL, Burke LB, Gwaltney CJ, *et al.* Content validity—establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: part 1—eliciting concepts for a new PRO instrument. *Value Health* 2011;14:967–77.
60. Food and Drug Administration. *Guidance for industry patient reported outcome measures: use in medical product development to support labeling claims.* U.S. Department of Health and Human Services, 2009.
61. Nussbaum MC, Sen AK. *The quality of life.* Oxford: Clarendon Press, 1993.
62. Robeyns I. Sen's capability approach and gender inequality: selecting relevant capabilities. *Feminist Econ* 2003;9:61–92.
63. Alkire S. Why the capability approach? *J Hum Dev* 2005;6:115–33.
64. Robeyns I. Selecting capabilities for quality of life measurement. *Soc Indicators Res* 2005;74:191–215.
65. Sen A. Human rights and capabilities. *J Hum Dev* 2005;6:151–66.
66. Polit DF, Beck CT. *Nursing research: generating and assessing evidence for nursing practice.* Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2012.
67. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;24:105–12.
68. Campbell R, Pound P, Pope C, *et al.* Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Soc Sci Med* 2003;56:671–84.
69. Howell D, Molloy S, Wilkinson K, *et al.* Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. *Ann Oncol* 2015;26:1846–58.
70. Ekman I, Swedberg K, Taft C, *et al.* Person-centered care—ready for prime time. *Eur J Cardiovasc Nurs* 2011;10:248–51.
71. Ivers N, Jamtvedt G, Flottorp S, *et al.* Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012;6:CD000259.
72. Boyce MB, Browne JP. Does providing feedback on patient-reported outcomes to healthcare professionals result in better outcomes for patients? A systematic review. *Qual Life Res* 2013;22:2265–78.
73. Kotronoulas G, Kearney N, Maguire R, *et al.* What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. *J Clin Oncol* 2014;32:1480–501.
74. Mesbah M, Kreiner S, Christensen KB. *Rasch models in health.* London: Wiley, 2013.
75. Robeyns I. The Capability Approach in Practice*. *J Polit Philos* 2006;14:351–76.
76. Sveriges framtida befolkning 2015-2060 [Elektronisk resurs]: Statistiska centralbyrån, 2015.