Patient Perspectives brought to the Fore for Diabetes Care

Descriptions as well as Development and Testing of the Diabetes Questionnaire

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Adult with type 1 diabetes

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ABSTRACT

Aim: The overall aims were to describe perspectives of living with diabetes, to develop a patient-reported outcome and experience measure for the Swedish National Diabetes Register, and to initiate the evaluation of evidence of measurement quality for that measure. A further aim was to describe health-related quality of life and to assess its associations with glycaemic control.

Methods and results: In **study I**, aspects important to adults with diabetes embracing experiences of daily life and support from diabetes care were identified through 29 semi-structured qualitative interviews. In **study II,** those aspects were used to develop the Diabetes Questionnaire. Expert reviews, six cognitive interviews, and a regional survey of 1,599 adults with diabetes yielded supporting evidence for content and face validity, test-retest reliability, and answerability. For **studies III-IV**, the Diabetes Questionnaire and the SF-36v2 were presented to 4,976 adults with diabetes in a nationwide cross-sectional survey. In **study III**, adjusted regression analyses showed that adults with high-risk glycaemic control have lower health-related quality of life than those with well-controlled glycaemic control. In **study IV**, correlation, machine learning and adjusted regression analyses demonstrated support for construct validity. The Diabetes Questionnaire captures some SF-36v2 dimensions while adding information not targeted by clinical variables or the SF-36v2 and it is sensitive to differences between groups of glycaemic control.

Conclusion: The Diabetes Questionnaire has the potential to support clinical meetings and assessments and hence help to bring patients' perspectives to the fore for diabetes care.

Keywords: Diabetes Mellitus; Patient-Reported Outcome Measures; Qualitative Research; Surveys and Questionnaires; Cross-Sectional Studies

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SAMMANFATTNING PÅ SVENSKA

Bakgrund: Det Nationella Diabetesregistret (NDR) har traditionellt fokuserat på medicinska aspekter med betydelse för komplikationsrisken, som exempelvis långtidsblodsocker. NDR används vid patientbesök och för förbättringsarbete i diabetesvården genom utvärdering mot nationella riktlinjer och jämförelser mellan olika vårdenheter. Diabetes kräver ett stort ansvar av individen i vardagen. Hur vuxna med diabetes mår och har det med diabetes i vardagen och om de får det stöd som just de behöver från vården är därför viktigt att veta för att vården ska kunna erbjuda ett lämpligt stöd. Det har tidigare dock inte funnits något passande sätt att ta reda på det och föra in det i NDR. Därför behövdes *Diabetesenkäten*.

Syfte: Att beskriva hur det kan vara att leva med diabetes, att utveckla en enkät för patientrapporterat utfall och erfarenheter av vården samt att påbörja utvärdering av dess mätsäkerhet. Ett ytterligare syfte var att beskriva hälsorelaterad livskvalitet och studera dess samband med långtidsblodsocker.

Metod och resultat: I **delstudie I** identifierades betydelsefulla aspekter i vardagen med diabetes och diabetesvården via 29 intervjuer med vuxna som hade diabetes. I **delstudie II** utvecklades *Diabetesenkäten* utifrån dessa aspekter. Sammantaget visade expertkonsultationer, sex intervjuer och en regional enkätstudie till 1599 vuxna med diabetes stöd för att *Diabetesenkäten* har ett viktigt innehåll, ger stabila resultat när ingen förändring har skett samt att den är lätt att besvara. För **delstudie III-IV** genomfördes en nationell enkätstudie till 4976 vuxna med diabetes där deltagarna tillfrågades om att besvara både *Diabetesenkäten* och den icke sjukdomsspecifika enkäten SF-36 version 2 (SF-36v2). I **delstudie III** visade statistiska analyser att de vuxna som har ett långtidsblodsocker som innebär hög risk för komplikationer också har sämre hälsorelaterad livskvalitet jämfört med dem som har långtidsblodsocker inom de rekommenderade intervallen. I **delstudie IV** studerades via olika statistiska analyser hur utfall från *Diabetesenkäten* samvarierar med medicinska aspekter och utfall från SF-36v2. Dessa analyser visade stöd för att *Diabetesenkäten* till viss del mäter liknande aspekter som SF-36v2 samtidigt som *Diabetesenkäten* tillför ny information som varken traditionella medicinska riskfaktorer eller SF-36v2 mäter. Därtill är *Diabetesenkäten* känslig för skillnader mellan grupper med hög risk för komplikationer och de som har långtidsblodsocker inom de rekommenderade intervallen.

Slutsats: *Diabetesenkäten* har potential att i både patientbesök och utvärderingar av diabetesvården tillföra viktigt underlag och med det synliggöra patientperspektivet i diabetesvården.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Svedbo Engström, M, Leksell, J, Johansson, U-B, Gudbjörnsdottir, S. 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

II. Svedbo Engström, M, Leksell, J, Johansson, U-B, Eeg-Olofsson, K, Borg, S, Palaszewski, B, Gudbjörnsdottir, S. A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: Development and evaluation of content validity, face validity, and test-retest reliability. Patient Education and Counseling 2018;101(1):139-146. doi: 10.1016/j.pec.2017.07.016

III. Svedbo Engström, M, Leksell, J, Johansson, U-B, Borg, S, Palaszewski, B, Franzén, S, Gudbjörnsdottir, S, Eeg-Olofsson, K. Health-related quality of life and glycaemic control among adults with type 1 and type 2 Diabetes – a nationwide cross-sectional study. Health and Quality of Life Outcomes 2019;17(141):1-11. doi: 10.1186/s12955-019-1212-z

IV. Svedbo Engström, M, Leksell, J, Johansson, U-B, Borg, S, Palaszewski, B, Franzén, S, Gudbjörnsdottir, S, Eeg-Olofsson, K. New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables. *Manuscript*.

CONTENT

ABBREVIATIONS

AcDC	Access to Diabetes Care (a scale in the Diabetes Questionnaire)
BMI	Body mass index
BP	Bodily Pain (a domain in the SF-36v2)
CGM	A technical device for continuous glucose monitoring
CoDC	Continuity in Diabetes Care (a scale in the Diabetes Questionnaire)
DiEx	Diet and Exercise (a scale in the Diabetes Questionnaire)
FreW	Free of Worries about blood sugar (a scale in the Diabetes Questionnaire)
GenW	General Wellbeing (a scale in the Diabetes Questionnaire)
GH	General Health (a domain in the SF-36v2)
HbA_{1c}	Glycated haemoglobin, a central medical measurement of glycaemic control in diabetes care
IQR	Interquartile range
IRT	Item response theory
LDL cholesterol	Low-density lipoprotein cholesterol
ManD	Capabilities to Manage your Diabetes (a scale in the Diabetes Questionnaire)
MDMT	Medical Devices and Medical Treatment (a scale in the Diabetes Questionnaire)
MH	Mental Health (a domain in the SF-36v2)

MoE	Mood and Energy (a scale in the Diabetes Questionnaire)
NDR	The Swedish National Diabetes Register
NLBS	Not Limited by Blood Sugar (a scale in the Diabetes Questionnaire)
NLD	Not Limited by Diabetes (a scale in the Diabetes Questionnaire)
PF	Physical Functioning (a domain in the SF-36v2)
PREM	Patient-reported experience measure
PRO	Patient-reported outcome
PROM	Patient-reported outcome measure
RE	Role-Emotional (a domain in the SF-36v2)
RP	Role-Physical (a domain in the SF-36v2)
SBP	Systolic blood pressure
SD	Standard deviation
SF	Social Functioning (a domain in the SF-36v2)
SF-36	Short Form 36, a 36-item self-report questionnaire for generic health-related quality of life
SF-36v2	SF-36 version 2
SuDC	Support from Diabetes Care (a scale in the Diabetes Questionnaire)
SuO	Support from Others (a scale in the Diabetes Questionnaire)
VT	Vitality (a domain in the SF-36v2)

1 INTRODUCTION

To live with diabetes as an adult means that the individual has to think about diabetes, consider diabetes during everyday life, and be responsible for the daily management of diabetes. Every day. For the rest of the life. Life with diabetes can be manageable, but it can also be challenging, stressful, exhausting and, at times, overwhelming. The Swedish National Diabetes Register (NDR) has enabled a fruitful assessment of the medical aspects of Swedish diabetes care for over 20 years. However, there was a need to amend the lack of systematic evaluations of adults' perspectives of daily life with diabetes and whether they are offered adequate support from diabetes care. By integrating the Diabetes Questionnaire in the NDR, the ambition is to bring patient perspectives to the fore for diabetes care by supporting a systematic focus on these aspects in individual clinical meetings and by broadening the health care provider perspectives in assessment and quality improvement efforts.

This thesis is a description of how the development and initial testing of the Diabetes Questionnaire were brought about; the results achieved up until the publication of this thesis; and some directions on the need for continued work. The introduction will give a general description of how it can be to live with diabetes, diabetes care, and the growing emphasis to include the perspectives of individuals living with diabetes in the outcomes of clinical diabetes care and research. Additionally, the theoretical frame of reference of Sen's capability approach and those measures needed to be considered when taking on the task of developing a new questionnaire are introduced, as is the taxonomy chosen for measurement quality. The medical aspects of diabetes have been given less space. Not because the medical aspects are less important; they are vital and very well described by others. The ambition was not to overshadow but to broaden the perspective. Simply, to bring patient perspectives to the fore.

1.1 DIABETES AT A GLANCE

Diabetes is a life-long and serious condition that globally as in Sweden is associated with higher mortality than in the general population [1-11]. According to current classifications, type 1 diabetes and type 2 diabetes are the two main forms of diabetes, with type 2 diabetes being by far the most common [2, 4, 12]. In Sweden, about 5% of the adult population is estimated to be diagnosed with diabetes [2, 13], with about 90% having type 2 diabetes [14]. Because symptoms often are diffuse, there are likely many persons with type 2 diabetes not yet diagnosed [2]. Mirroring lifestyle issues and increasing

average age, the prevalence of type 2 diabetes is rapidly growing on a global scale, which, it is feared, will continue to do so in the future. Type 2 diabetes has also turned more common at younger ages. A corresponding development, however, has not been seen in Sweden [15].

The major characteristic of diabetes is high blood glucose levels [2, 6, 7]. For many years, the level of glycated haemoglobin (HbA_{1c}) has been one of the most central outcomes in diabetes care. HbA_{1c} reflects glycaemic control through the average blood glucose level over approximately 2 or 3 months [2, 16]. Following the rapid development of technical devices for continuous glucose monitoring (CGM) in later years, there is a growing development towards complementing the HbA_{1c} level with more detailed measures such as time in range (TIR). TIR is a measure of the extent of time spent within the recommended frames for glucose levels [17]. Glycaemic control is one important factor for the risk of developing long-term micro- and macro-vascular diseases and death [2, 6, 7, 18-22]. Daily, there are also risks for potentially serious short-term complications related to either too low or too high blood glucose levels. Too low blood glucose (hypoglycaemia) can be inconvenient, frightful and, if not treated, it can lead to loss of consciousness, seizure, coma, or death [16]. Too high blood glucose (hyperglycaemia) and insulin deficiency can cause ketoacidosis, which can lead to a life-threatening coma [23].

Diabetes puts high demands on individual responsibility regarding daily self-management in order to avoid short-term complications and to delay the onset and to slow the progression of long-term complications [2, 3, 6-8, 16]. There is no consensus or a uniform definition of self-management. However, common descriptors relating to diabetes can be, to guided by support from health care providers, having the abilities, skills, and strategies needed, to be able to independently handle the emotional and physical impact of diabetes on everyday life through informed decision making [24-26]. Self-management activities to keep the blood glucose within target includes, for example, diet, physical activity, the monitoring of glucose levels, and the adjustment of medical treatment. Lifestyle aspects (such as diet and physical activity) are central in the treatment for all diabetes types. For some, it can be the only glucose-lowering intervention needed. For others, the combination of lifestyle aspects and medical treatment is essential [2, 3, 6-8, 16, 18, 27, 28].

1.2 TO LIVE WITH DIABETES AS AN ADULT

To live with diabetes and to handle the related self-management of the condition can be a complex, demanding, and difficult challenge in everyday

life [3, 29-32]. For some, and at times, life with diabetes can be manageable. Diabetes can even introduce positive aspects to a person's life [30, 31, 33], be experienced as an incentive, and help to live a healthier life [30, 31]. For others, and at times, living with diabetes can be extremely difficult and overwhelming [29-32]. Central challenges described for type 1 and type 2 diabetes are to accept and take on the personal responsibility and retain the flexibility and control of self-management and to continuously balance between living as good a life as possible in the present and the future, avoiding being ruled by the condition and overwhelmed by the self-management demands [31-39]. Enhanced difficulties are often experienced when, for example, going to the university, starting a new job, or becoming a mother [40-46].

The emotional burdens of diabetes, including the related treatment, the self-management demands, and the worries about or existences of related complications, are described as diabetes distress [47]. Diabetes distress is reported to be common [3, 47, 48], especially among women [48, 49]. In addition, it has been reported that adults with diabetes have lower health-related quality of life [50] and more commonly suffer from depression [3, 51, 52] and sleep disturbance [53-55] than those without diabetes. Depression and impaired health-related quality of life seem to be more common among women than in men [50, 51] and among those who have diabetes complications than those who do not [56]. In addition, depression and impaired health-related quality of life have been reported to be associated with higher mortality in people with diabetes [57-61]. Problems with depression, diabetes distress, and impaired sleep are described as often being interrelated and in a bidirectional and complex interaction to be associated with impaired self-management and glycaemic control, as well as a higher risk for diabetes complications [3, 30, 47, 51, 52, 55, 56, 62-64].

High-quality support from partners, family, friends and colleagues have the potential to improve diabetes-specific and general quality of life as well as self-management [3, 31, 32]. However, social relationships can be both supportive and hampering [31, 32]. For some, it can be difficult to get support for management from the nearest family members, whereas for others, it can be difficult to handle the overprotection of significant others [31]. Diabetes can have a negative impact on family life, affect roles, and impose changes in an individual's social life [30-32]. For example, diet constraints can lead to losing opportunities for social interactions, which, in turn, can lead to experiences of being alienated and feelings of guilt and shame [31]. Another example is if the person with diabetes wants to be treated normally while others treat them differently, which can be a source of conflicts. Still, the reversed situation can be experienced as a lack of support [32]. It can be a challenge to balance

between prioritising the needs of the person with diabetes and activities necessary to manage diabetes about the needs and preferences of family and friends [31, 32]. It is often difficult to get others to understand how it is to live with diabetes and that it can take personal strength to share feelings related to diabetes and to discuss what it is like to have such a condition. Reasons for not disclosing the condition could be to escape the negative attitudes and opinions of others, as well as the risk for stigmatisation, guilt, and shame [31]. It is common to experience a lack of respect, support, and understanding from others with uninvited judgements and opinions on for example what to eat [31, 32]. Peer support from others also living with diabetes can be an important contribution, adding personal experience of adapting to diabetes and the challenges in everyday life [31-39].

The balance between the needs of others and the needs of the person with diabetes can be particularly challenging at work [31, 32]. Factors in the work environment (such as stress, fewer opportunities to prioritise self-management needs, and blame and judgement from workmates and superiors) can lead to the ignorance of the individual's needs and the intentional avoidance of hypoglycaemia to avoid negative effects on his or her ability to work [65]. Furthermore, diabetes can affect the present employment and the future work opportunities, especially for those with type 1 diabetes [32].

1.3 SUPPORT FROM DIABETES CARE

Diabetes care is responsible for offering the patients evidence-based care that include support for self-management by taking the individual patient's resources, prerequisites, and wishes into account [2, 3, 5-8, 16, 18, 27, 28]. In Sweden, diabetes care is based on the national guidelines for diabetes care and offers consultations at outpatient clinics to support self-management, monitor risk factors, and prescribe medical treatment and technical medical devices. Adults with type 1 diabetes are most often referred to hospital-based outpatient clinics specialised in diabetes, endocrinology, or internal medicine. Generally, they meet with a diabetes nurse a few times a year and a specialist physician once a year. Adults with type 2 diabetes most often are referred to outpatient clinics in primary care and meet with a diabetes nurse or a nurse specialised in primary care one to two times a year, and a general practitioner once a year [2].

The development of several technical devices available for insulin administration and monitoring of glucose levels has had a large impact on easing self-management and reducing the burden of living with diabetes [27]. Technical devices, such as insulin pumps and CGMs has been described to

offer positive experiences because of their ability to provide greater flexibility and freedom that enhances control and independence in self-management. However, these technical devices might also be experienced by some as a burden [66-68]. The balance between potential benefits and barriers needs to be recognised and can vary as life changes [67]. The need for, choice of, and how to use the technical devices should be related to individual needs and skills to handle the devices [2, 27, 68, 69]. It is a continuous challenge for diabetes care to keep up with the development of technical innovations [27, 70].

Many factors influence the medical outcomes of diabetes [3]. In addition to patient factors, several health care provider factors influence the self-management of diabetes [32]. As underscored in an international position statement [3], in case of non-optimal outcomes, there should be a communication addressing different potential reasons for this, including duration of diabetes, access to diabetes care, and adequate information and support, adequacy of medical management, and other contemporary health conditions and related treatments. Nevertheless, the potential in the collaboratively developed regimens for treatment and lifestyle through which the individual with diabetes has the potential to affect outcomes and wellbeing should also be emphasised. However, there need to be a non-judgmental approach recognising and normalising that, during certain times, it might be difficult to continue the struggle for self-management when living with a life-long condition [3]. To be able to support individuals with diabetes, diabetes care professionals need to understand the challenges individuals with diabetes can meet in everyday life in the social context with family and work [31]. Therefore, diabetes care needs to address in the clinical meetings how the individual feels and how he or she deals with daily life with diabetes [3].

1.4 TIME TO BRING PATIENT PERSPECTIVES TO THE FORE IN DIABETES CARE

The large impact on everyday life and how the person with diabetes feels have increasingly been acknowledged in international and Swedish guidelines for diabetes care [2, 3, 5, 8, 18]. Accordingly, there is a growing emphasis on the importance of the perspective of the individual living with diabetes being included in the outcomes of clinical diabetes care and research [3, 5, 8, 71-73]. As put by Glasgow *et al.*:

> "It is time to put our diabetes care measures where our values and evidence are" (p. 1049) [73]

Patient assessments of daily life and experiences of care are labelled as patient-reported outcomes (PROs). In the definition lies the fundamental condition that it is information reported directly by the patient and that it is not censored by anyone else [74, 75]. PROs can, for example, be about health, health-related quality of life, and symptoms but also experiences of care as access to adequate support and relevant information, or satisfaction with medical treatments. PROs are often collected through self-reporting questionnaires designated as patient-reported outcome measures (PROMs) [75, 76]. The questionnaires used for evaluations of patients' experiences of care have increasingly been described as patient-reported experience measures (PREMs) [76].

International guidelines for diabetes care recommend the use of validated self-reporting measurement tools that address, among other things, diabetes self-management and life circumstances and psychological aspects that might influence self-management. Routine monitoring and assessment of such aspects as diabetes distress, eating issues, health-related quality of life, sleep, depression, social and family support, and contextual barriers are recommended [3, 5, 8]. There is a need to repeatedly assess the individual needs of each patient so that these specific needs can be addressed and interventions tailored that match the current situation. The use of measurement tools is not meant to replace verbal communication between the professional and the patient, but rather to be a complement and an opportunity for longitudinal follow-up. Measurement tools are recommended to be used at the first visit and at regular intervals, or when any special change occurs. Special changes could be related to an altered life circumstance, a change in treatment, or a marked change in disease progress [3]. Within diabetes research, there are both generic and diabetes-specific self-reporting questionnaires [77-88].

1.4.1 GENERIC SELF-REPORTING QUESTIONNAIRES

Generic functional status, quality of life, health-related quality of life and wellbeing in diabetes have internationally often been addressed using the EQ-5D from the EuroQoL group and different short-form variants originating from the Medical Outcomes Study: the SF-8, SF-12 and SF-36 [83, 87-90]. The SF-36 is often recommended with reference to reports on supported validity and reliability in both overall populations and in people with diabetes [83, 87-89, 91, 92]. An alternative to the SF-36 is the freely available RAND-36. The RAND-36 is conceptually equivalent to the SF-36 but is scored differently on two of the eight domains [76, 93].

1.4.2 DIABETES-SPECIFIC SELF-REPORTING QUESTIONNAIRES

Diabetes-specific aspects addressed in internationally used questionnaires are typically diabetes-related problem areas, diabetes-specific empowerment, diabetes-specific quality of life, diabetes treatment satisfaction, psychosocial aspects of automated insulin delivery systems, fear of hypoglycaemia, and fear of late complications [77-88, 94]. Many questionnaires were developed in the 1980s and 1990s. Among others, there are the Audit of Diabetes Dependent Quality of Life (ADDQoL), the Diabetes Health Profile (DHP), the Diabetes Quality of Life (DQOL), and the Diabetes Treatment Satisfaction Questionnaire (DTSQ), all developed in the UK [83, 87, 88]. An example of a more recent contribution from the UK is the Health and Self-Management in Diabetes (HASMID) questionnaire, which seeks to determine the impact of self-management in adults with type 1 or type 2 diabetes [95]. The Diabetes Empowerment Scale (DES) [96], the Diabetes Symptom Checklist-revised (DSC-R) [97], the Hypoglycemia Fear Survey (HFS) [98], and the Problem Areas in Diabetes (PAID) were developed in the US [87, 88]. More recently developed questionnaires in the US include the INSPIRE measures, which address positive expectancies regarding automated insulin delivery systems in different versions for adults and partners as well as youth and parents [94].

Some of these instruments were translated and adapted to a Swedish context at the end of the 20th and the first decade of the 21st century. These include the Swedish Diabetes Empowerment Scale (Swe-DES) [82], the Swedish version of the Hypoglycaemia Fear Survey (Swe-HFS) [78], the Swedish version of the Problem Areas in Diabetes Scale (Swe-PAID-20) [77], and the Swedish version of the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [86]. There are also a few diabetes-specific questionnaires developed in a Swedish context. The Semantic Differential in Diabetes (SDD) is a measure with nine polar adjective pairs addressing attitudes to diabetes [85]. More recent contributions include the Check Your Health [84] and the Self-Management Assessment Scale (SMASc) [99]. The Check Your Health measures four health dimensions: physical and emotional health, social wellbeing and overall quality of life, as well as the burden of diabetes in these four dimensions. The burden of diabetes is defined as the difference between quality of life as rated in the present and an estimation of how quality of life would be without having diabetes [84]. The SMASc is a screening instrument developed for use in primary healthcare to indicate barriers for self-management in individuals with type 2 diabetes [99].

1.4.3 RECOMMENDATIONS ON WHICH QUESTIONNAIRE TO USE

Recommendations on which questionnaire to use often propose using both a generic and a disease-specific questionnaire [75, 76, 83, 87, 88, 100]. In a review from 2006 for identification of generic and disease-specific self-reporting questionnaires for group-level application for long-term conditions within the UK's National Health Service (NHS), the SF-36 was the recommended generic choice for diabetes [87]. In an update in 2009, the recommendation was changed to EQ-5D, in combination with a diabetes-specific questionnaire. The reason for changing the recommendation was that the EQ-5D was shorter and for the availability of UK-derived preference values. The SF-36, however, was still among the top choices [88]. In Sweden, after the initiation of this project, there were ongoing discussions on whether all national quality registers for long-term conditions should use the same generic questionnaire because that would enable comparisons between patient groups and inform resource allocation. In 2013, the Swedish National Board of Health and Welfare was assigned by the Government to suggest which generic questionnaire to use. The most central alternatives under discussion were the EQ-5D, SF-36, and RAND-36. However, it was concluded in a report that there was a lack of supporting evidence to suggest a single questionnaire for use within all registers and that it would be difficult to implement. It was proposed that the national quality registers be supported in their efforts to use PROMs to support clinical encounters, assessments, and quality improvement, and to learn from these initiatives. Furthermore, it was suggested to follow and learn from the NHS project in the UK [101]. According to the UK recommendations, the choice of the diabetes-specific questionnaire was not straightforward because no single questionnaire covered the full spectrum of experiences, i.e. many instruments address a narrow aspect (e.g. treatment satisfaction or symptoms). Another issue is that there remains insufficient supporting evidence of measurement quality [87, 88]. This general opinion also applied to the Swedish context.

1.5 THE SWEDISH NATIONAL DIABETES REGISTER

Diabetes care in Sweden has a long tradition concerning the evaluation of quality indicators related to medical risk factors through the NDR [2, 14, 102]. Since the start in 1996, the NDR has grown to be an essential part of Swedish diabetes care. As a healthcare quality register, the NDR acts as a tool in clinical meetings and enables longitudinal assessment of diabetes care at the

individual, local, regional, and national levels [13, 102-104]. The NDR is a central means for quality improvement as well [102-107]. Summarising 2018, the NDR reached a coverage rate about 96% including approximately 425,000 individuals with diabetes [13]. The NDR was developed by the profession as a response to the Saint Vincent Declaration [104]. The Saint Vincent Declaration was a result of a workshop held in 1989, where representatives from European countries met and agreed upon recommendations for enhanced diabetes care and actions to prevent diabetes complications to reduce human misery and to save resources [108].

The variables collected in the NDR are closely related to the Swedish national guidelines for diabetes care [2, 102-104]. Traditionally, the focus has been on outcomes and processes related to medical aspects such as glycaemic control and other risk factors for diabetes-related complications [102-104]. An important way forward for the NDR has been to broaden the perspective of the health-care provider by adding a systematic collection of the perspectives of adults living with diabetes. In addition to their experiences of daily life with diabetes, it is important to be able to evaluate the patients' experiences of whether they receive adequate support from diabetes care [102]. Moreover, according to the criteria for certification at the highest level, Swedish quality registers are obliged to integrate PROMs [76].

To what extent any of the questionnaires previously known from research have been used on a larger scale in international or Swedish routine diabetes care is unknown. None of the questionnaires was considered fully suitable and feasible to act as both a tool in the clinical meeting and as an integrated longitudinal measure applicable to the NDR. Therefore, a decision was made to generate a new diabetes-specific patient questionnaire. There were several reasons for this decision. One reason is that most previous questionnaires were developed to address a specific aspect most often within a research setting. Consequently, the application for routine clinical use rarely evaluated. Hence, the previous questionnaires were not developed with the articulated objective to describe experiences that are central to the target group from an overarching perspective but rather focused on specific aspects or on a generic evaluation of health or quality of life. In addition, no measure covered the experienced support from diabetes care relevant to the Swedish context. To cover a broader perspective, it would be necessary to combine several questionnaires and complement these with newly developed items. The combination of several questionnaires in combination with study-specific items not covered by the other questionnaires was tested within the multinational Diabetes, Attitudes, Wishes and Needs (DAWN) initiative. The total amount of items were not specified but was reasonably quite high [109-112]. The DAWN initiative was

an important and inspiring research project; however, the approach was not feasible for implementation in the NDR. As a first step, co-workers at the NDR developed a questionnaire based on pertinent literature, established questionnaires, and clinical experience. This first attempt showed that patient perspectives were an important complement to medical outcomes [113]. However, an important point of departure for collecting patient perspectives is for the questionnaire to reflect aspects important to the target group [75, 114, 115], i.e. adults who have diabetes. In addition, health care professionals need to consider the questionnaire relevant to its intended use [75, 114, 115]. Therefore, strengthened by the added-extra of including patient perspectives, it was decided to develop a completely new questionnaire.

1.6 THEORETICAL FRAME OF REFERENCE: SEN'S CAPABILITY APPROACH

The theoretical frame of reference used in this project is Sen's capability approach, in which the individual's opportunities, prerequisites, and possible barriers are central [116-118]. The central concept is 'capability', which Sen distinguished from functioning. Functionings are described as the 'beings' and 'doings' that can be considered important in life, such as being in good health, being able to read and write or participating in social life. Capabilities are referred to as the real freedoms and opportunities to realise those functionings that individuals upon reflection value as important in their life. Hence, the difference is between what is realised and what is possible [118-120]. According to Sen, evaluations of quality of life or wellbeing should, if possible, focus on capabilities in order to acknowledge the dignified freedom to choose which available capabilities to use and to what extent to use them. It might also be relevant to consider the personal and surrounding barriers and resources that affect the available capabilities, such as physical condition, access to care, and social support [118].

Which are then the relevant capabilities to evaluate? Sen has been critisised for giving vague or no assignments on how to select relevant capabilities. Providing a general normative framework of thought, Sen has been deliberately non-specific concerning which capabilities are relevant, arguing that the decisions on which aspects are relevant should not be the task of the individual theorist [116, 118, 120]. Sen urges that assessments of quality of life or wellbeing should be based on what is considered important in life to the target group, and what is relevant for the specific situation and use, and at that specific time [117, 119, 121, 122]. Sen proposes a democratic and open process in which the target group should be directly involved [116, 119, 120].

1.7 TO DEVELOP A QUESTIONNAIRE FOR PATIENT-REPORTED OUTCOMES

To develop and build evidence of the validity and reliability of a questionnaire to measure PROs is a complex, cumulative, and iterative effort over a long period that includes different methods and strategies [75, 114, 123, 124]. A central prerequisite for a credible questionnaire is to involve the target group during the development and evaluation phases, and that evidence for usefulness from their perspectives can be presented [114, 125]. Qualitative research is essential to ensure that a questionnaire has relevant content, captures aspects important to the target group, and is pertinent for its intended use [114, 115, 124, 126]. Important sources for revision during the development process are expert reviews of the content and to what extent the questionnaire has prerequisites to work as intended. The group of experts should include people knowledgeable of the target group's situation, the addressed construct, and the construction of items and scales [75, 125, 127]. Important foundations for a well-working questionnaire are that the items and the questionnaire as a whole work as intended and that the target group can relate to the verbal phrasing. For instance, the questionnaire should have relevant and understandable instructions, and the items and response alternatives need to be understood and responded to as intended. How the target group perceives the questionnaire and how instructions and items work in practice can be pre-tested through cognitive interviews [114, 115, 126, 128]. The questionnaire needs to be administered to members of the target group to collect data for further evaluations of measurement quality and enable the construction of scales [75, 115, 127]. During development, there is a range of aspects of measurement quality that needs to be considered and evaluated [75, 123, 127]. Over time and in different research traditions, aspects of measurement quality have been labelled, defined, and described in different ways. The same labels have also been used with different meanings, adding to misunderstandings and difficulty to navigating [123]. In this thesis, the COSMIN taxonomy of measurement properties [123, 125] was used.

1.7.1 MEASUREMENT QUALITY: THE COSMIN TAXONOMY

The COSMIN taxonomy of measurement properties for health-related PROs is based on an international consensus on taxonomy, terminology, and definitions. The consensus was based on a Delphi study with experts in epidemiology, statistics, psychology, and clinical medicine. According to the COSMIN taxonomy, a questionnaire's measurement quality has different layers. In the top layer, there are three main quality domains, namely validity,

reliability, and responsiveness. These quality domains have inner layers that include measurement properties, which, in turn, can have another inner layer of aspects of measurement properties. The COSMIN taxonomy also includes interpretability, as it is an important characteristic of a questionnaire; however, it is not considered a measurement property (Figure 1) [123].

VALIDITY

The overall definition of validity is the extent to which a questionnaire measures what it is intended to measure. According to the COSMIN taxonomy, the domain validity contains three measurement properties: content validity, construct validity, and criterion validity [123].

Content validity refers to the extent to which the items reflect the construct the questionnaire seeks to measure and comprehensively covers important aspects concerning the target group and intended use [75, 114, 123, 124, 127]. Content validity also includes the aspect of face validity. Face validity concerns whether the questionnaire looks as if it measures what it is intended to measure to those taking it [123]. Content validity should be evaluated for the relevance and comprehensiveness of the items. Experts in relation to the construct, the situation of the target group, and its intended use should judge the relevance. When judging relevance to the target group, representatives of the target group are central experts [125]. When the questionnaire is administered to the target group, the number of missing responses can be another indication of its perceived relevance. Comprehensiveness can be evaluated by experts being asked for missing items and to judge the range of response alternatives. Comprehensiveness can also be assessed by studying the distributions in response levels when administered to the target group [125].

Construct validity involves the aspects of structural validity, hypothesis testing, and cross-cultural validity [123, 125]:

- Structural validity alludes to the degree to which the questionnaire is an adequate reflection of the dimensions of the construct that are intended to be measured and should be assessed for the creation and evaluation of subscales in a multi-item questionnaire [123, 125].

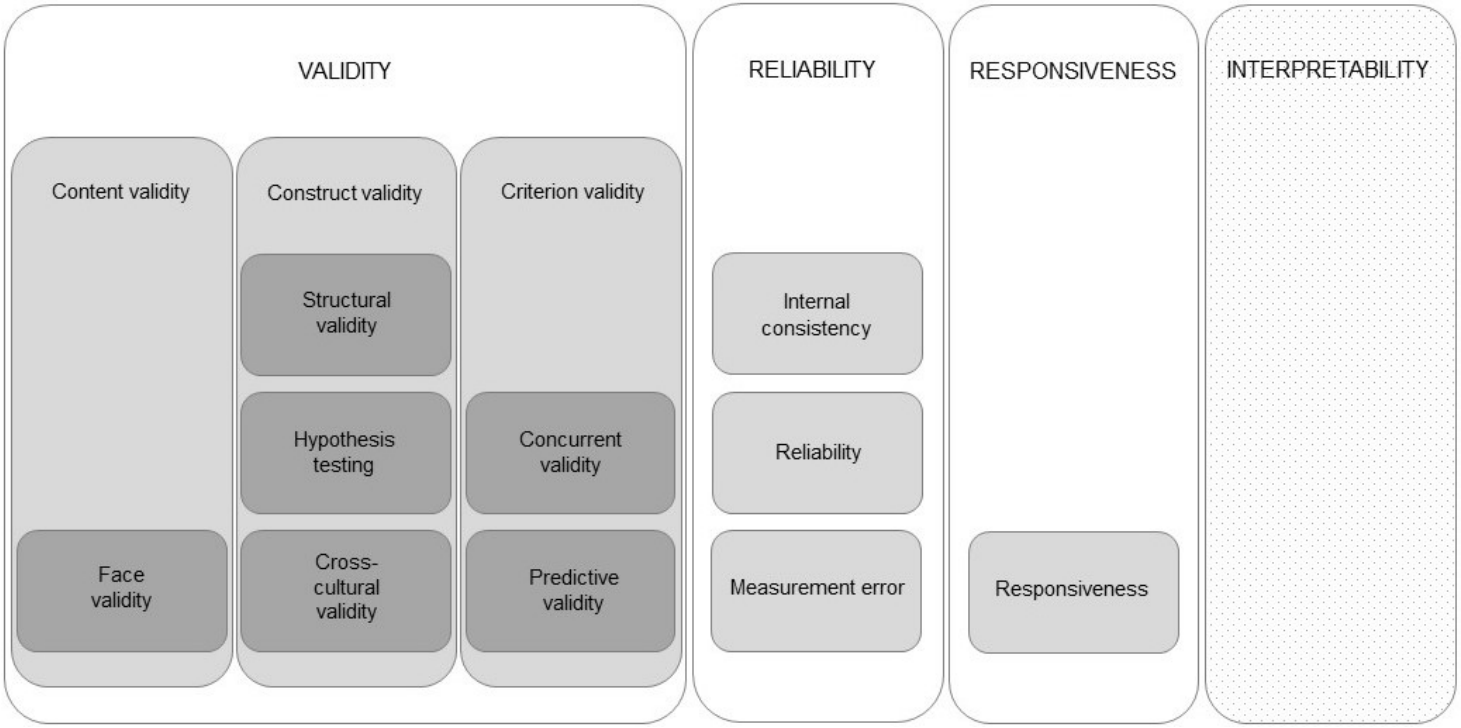

Figure 1. The COSMIN taxonomy of measurement properties for health-related patient-reported outcomes as described by Mokkink et al. [123]. White areas: quality domains. Light grey areas: measurement properties. Dark grey areas: aspects of measurement properties. Dotted light grey area: important characteristic.

- Hypothesis testing denotes the degree to which the scores of a questionnaire are consistent with pre-specified hypotheses concerning logical relationships to other measures, patient characteristics, or differences between relevant groups [114, 123, 125]. Other measures could be clinical variables, demographics, or scores on other questionnaires. Hypotheses about correlations should state if they are expected to be positive or negative and include assumptions on absolute or relative magnitude. Hypothesis testing is an iterative and ongoing process [125].
- Cross-cultural validity should be assessed when translating a questionnaire into other languages and signifies the degree to which different versions are adequate reflections of each other [123].

Criterion validity comprises the aspects of concurrent validity and predictive validity [75, 123, 125]:

- *Concurrent validity* refers to the relation to a golden standard measured at the same time or the "true" value. However, a golden standard or a true value is hardly found for PROs [75, 114, 123, 125]. If there already were a gold standard measure, the argument to develop a new one could be questioned [75]. Criterion validity is therefore only relevant for the evaluation of a shortened questionnaire in relation to an original longer version [75, 123, 125]. Another possible approach to evaluate concurrent validity would be by comparing the answers in a questionnaire to a detailed, in-depth interview with the same individual and to qualitatively assess the agreement between the two approaches [75].
- *Predictive validity* concerns the ability of a questionnaire to predict future changes and events [123].

RELIABILITY

The domain reliability indicates the extent to which the measurement is free from measurement error. The reliability domain can also be defined as the extent to which the scores of a questionnaire are stable in situations when no change has occurred. According to the COSMIN taxonomy, the reliability domain embraces the measurement properties internal consistency, reliability, and measurement error [123].

Internal consistency expresses the interrelatedness between items in the questionnaire and to what extent items in a subscale measure the same concept [123, 129].

Reliability as a measurement property concerns the proportion of the variance in measurements that can be attributed to "true" differences between the respondents. This can be tested in a test-retest on two occasions for the same respondents when no change has occurred [123].

Measurement error is about variations in the scores from respondents that are not the result of an actual change, but rather the result of a systematic or random error [123].

RESPONSIVENESS

According to the COSMIN taxonomy, responsiveness is regarded as both a measurement domain and a measurement property. Responsiveness pertains to the ability of a questionnaire to detect an actual and clinically important change over time in the construct in question [123, 129]. Responsiveness should be evaluated through hypothesis testing regarding the change in scores over time, similar to the evaluation of construct validity. There is no golden standard measure to which the change in scores should be compared. The exception is when comparing a shortened version with the original longer version [125].

INTERPRETABILITY

Interpretability connotes the degree to which the scores of the questionnaire can be easily understood and if qualitative meaning can be assigned to the scores or a change in scores [123, 129].

1.8 PROBLEM STATEMENT

Living with diabetes as an adult and to handling related high demands on individual responsibility for self-management can be a complex, demanding, and difficult challenge. Swedish diabetes care has a long tradition of fruitful evaluation of quality indicators related to medical risk factors through the NDR that acts both as a tool in the individual clinical meeting and a means for assessment and quality improvement. However, for diabetes care to be able to provide adequate support that takes the individual resources, prerequisites, and wishes into account, more information than medical data are needed. Therefore, there was a need to amend the lack of systematic evaluations of adults' self-reported perspectives of daily life with diabetes and whether they are offered adequate support from diabetes care. Despite a large number of

questionnaires used in research, none was found feasible as a clinical tool and longitudinal measure within the scope of the NDR. Strengthened by the first step to test the inclusion of patient perspectives as an add-on to the important medical perspective, a decision was made to develop and test a new diabetes-specific questionnaire.

To develop a questionnaire with satisfactory measurement quality is a cumulative effort over a long period that requires a combination of different methods and strategies. Consequently, this was too large an effort to be comprehensively covered in one thesis, but the intention is that this thesis will be a starting point. In line with Sen's capability approach and recommendations for the development of questionnaires targeting PROs, the first vital step was to identify which aspects are considered important to adults living with diabetes and to gather material for a questionnaire with verbal phrasing that the target group can easily relate to. During the development and initial evaluation, representatives of the target group, diabetes care professionals, and experts in questionnaire design, evaluation, and use needed to be consulted. In addition, it was important for the developmental versions to be tested before presenting large-scale surveys to the target group, which, in turn, were required to enable the initiation of statistical evaluations. In addition, studies about the relationships to other measures needed to be initiated. The NDR provides an important source of clinical variables relevant to diabetes care. However, to study the relationships to other self-reported aspects about how life with diabetes can be, other measures have to be added. We initially chose to initiate these evaluations by using the SF-36, an often recommended, well-tested, and frequently used generic measure of health-related quality of life. To be able to use the SF-36 as a comparator, there was a need to learn more about how this measure works in a large-scale diabetes setting in Sweden.

2 AIM

The overall aims of this thesis were to describe perspectives of living with diabetes, to develop a patient-reported outcome and experience measure for the Swedish NDR, and to initiate the evaluation of evidence of measurement quality for that measure. A further aim was to describe health-related quality of life and to assess its associations with glycaemic control.

The specific aims for each of the included studies in this thesis were:

Study I	To inform the development of the PROM, the specific aim of this study was to describe important aspects in life for adults with diabetes.
Study II	To describe the development and evaluation of content validity, face validity and test-retest reliability of a disease-specific questionnaire measuring patient-reported outcomes and experiences in conjunction with the NDR for adults who have type 1 or type 2 diabetes.
Study III	To describe the health-related quality of life and assess its association with glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.
Study IV	To study evidence for construct validity, the aim was to describe the outcome from the Diabetes Questionnaire, to assess the associations of that outcome with clinical variables and generic health-related quality of life, and to study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

3 PARTICIPANTS AND METHODS

3.1 SAMPLES AND DATA COLLECTION

A summary of the different designs, data collection, samples, and analysis used in **studies I-IV** is presented in Table 1.

Table 1. Description of designs, data collection, samples, and analysis

Study	**Design**	**Data collection**	**Sample**	**Analysis**
I	Qualitative	Individual semi-structured interviews	Adults with type 1 (n=15) and type 2 diabetes (n=14) Purposive sampling	Content analysis
II	Methodological study: Qualitative and quantitative approaches	Expert reviews	Adults with type 1 (n=1) and type 2 diabetes (n=2) Representatives from working teams at two patient organisations Diabetes nurses (n=2) Physicians (n=2) Researchers (n=4) Review panel, Statistics Sweden Purposive sampling	Qualitative analysis Content Validity Index
		Individual cognitive interviews	Adults with type 1 (n=3) and type 2 diabetes (n=3) Purposive sampling	Qualitative analysis
		Regional postal survey: Diabetes Questionnaire	Adults with type 1 (n=800) and type 2 diabetes (n=799) Selected at random Test-retest: Adults with type 1 (n=170) and type 2 diabetes (n=170) The first to respond	Cohen's Kappa statistics
III-IV	Cross-sectional study	Nationwide postal survey: Diabetes Questionnaire, SF-36v2	Adults with type 1 (n=2485) and type 2 diabetes (n=2491) Selected at random	Spearman's rank correlation Multiple regression analyses Machine learning (Study IV)

3.1.1 QUALITATIVE INTERVIEWS

The first step to enable a sound basis for the Diabetes Questionnaire was to conduct interviews with a heterogeneous group of adults with type 1 or type 2 diabetes with differing experiences (**study I**). The decision to carry out new interviews and not to rely on previous research was based on two central arguments. First, there was a need for a broad approach that described aspects considered important by the target group of today. Second, access was needed to the patients' own words for the formulation of items, i.e. we wanted to avoid the mistake of using academic or professional jargon.

In late 2012 to mid-2013, 29 individual qualitative interviews were conducted. Purposive sampling was adopted to obtain a heterogeneous group representing a mix of adult (≥18 years of age) men and women with type 1 or type 2 diabetes. They should vary in age, civil status, education, and occupation, and vary in diabetes duration, diabetes treatment, glycaemic control, risk factors, and presence of diabetes complications. As the interviews aimed to describe life with diabetes, the inclusion criteria for diabetes duration was set at a minimum of 5 years. The potential participants needed to be able to describe their situation in Swedish. The sample was monitored for heterogeneity in participant characteristics and the interview material for repetitive information indicating that further data were not likely to add substance to the analysis. The interview data were judged repetitive after 25 interviews. However, there was a lack of young adults among the participants. After another four interviews with younger individuals, the data were deemed sufficient. The recruitment was mainly assisted by 10 diabetes nurses employed at four hospital-based outpatient clinics and four primary healthcare clinics participating in the NDR in two regions of Sweden. Participants were also invited directly by members of the research group, two for pilot interviews and two to complement younger individuals.

The semi-structured face-to-face interviews lasted, on average, 90 minutes (range 30 to 120 minutes). Following an interview guide (Appendix 1), the participants were asked to tell about their experiences of living with diabetes, including aspects important for a good life with diabetes, and any barriers they experienced. They were also asked about their experiences and thoughts regarding diabetes care. Situation-bound probes were used (such as "Tell me more about…", "What do you mean by…", "Do I understand you correctly…") to confirm and deepen understanding. Our interview guide was based on the literature on diabetes and the capability approach, clinical and research experience in the research group, and discussions with experts in qualitative research. The interview guide was pre-tested in two pilot

interviews, resulting in minor revision of the order in which the questions were posed and the decision that the background data needed not to be audio-recorded but put in writing by the interviewer. Because no major revision of the interview guide was made, the interviews provided useful information, and the participants had given their informed consent, it was decided that the pilot interviews should be included in the analysis. The interviews were audio-recorded and held in a room, enabling privacy with no one but the interviewer and the participant present. Most interviews (n=26) were conducted at the outpatient clinics where the participants were listed. Following participant preference, two interviews were held in the participants' homes and one at a university.

3.1.2 EXPERT REVIEWS

During the development process of the Diabetes Questionnaire in **study II**, different experts were consulted. An overview of the process of development and testing, the expert consultations, and the different developmental versions of the Diabetes Questionnaire are depicted in Figure 2. Representatives from a working team at the Swedish Diabetes Association (the national patient organisation) and a review panel at the Department of Measurement Technique at Statistics Sweden reviewed the first developmental version. After revision, representatives from a working team at the Greater Stockholm Diabetes Association (a local patient organisation) and an external expert panel reviewed the second developmental version. The external expert panel was consulted in two rounds to assess content validity, with some revisions made between the two rounds. The external expert panel included the following participants:

- Adults with type 1 (n=1) and type 2 diabetes (n=2)
- Diabetes nurses (n=2) and physicians (n=2) with vast experience in diabetes care
- Researchers (n=4) knowledgeable in the development, design, and testing of items and scales, with two having experience in diabetes care and research
- Representatives from working teams at the two patient associations (only in the second round)

The first round reviewed the second developmental version of the Diabetes Questionnaire to assess its content validity and gave comments supporting revision. The second round reviewed the third developmental version of the Diabetes Questionnaire and aimed for a formal assessment of content validity and minor revision (Figure 2). Two of the researchers not experienced in

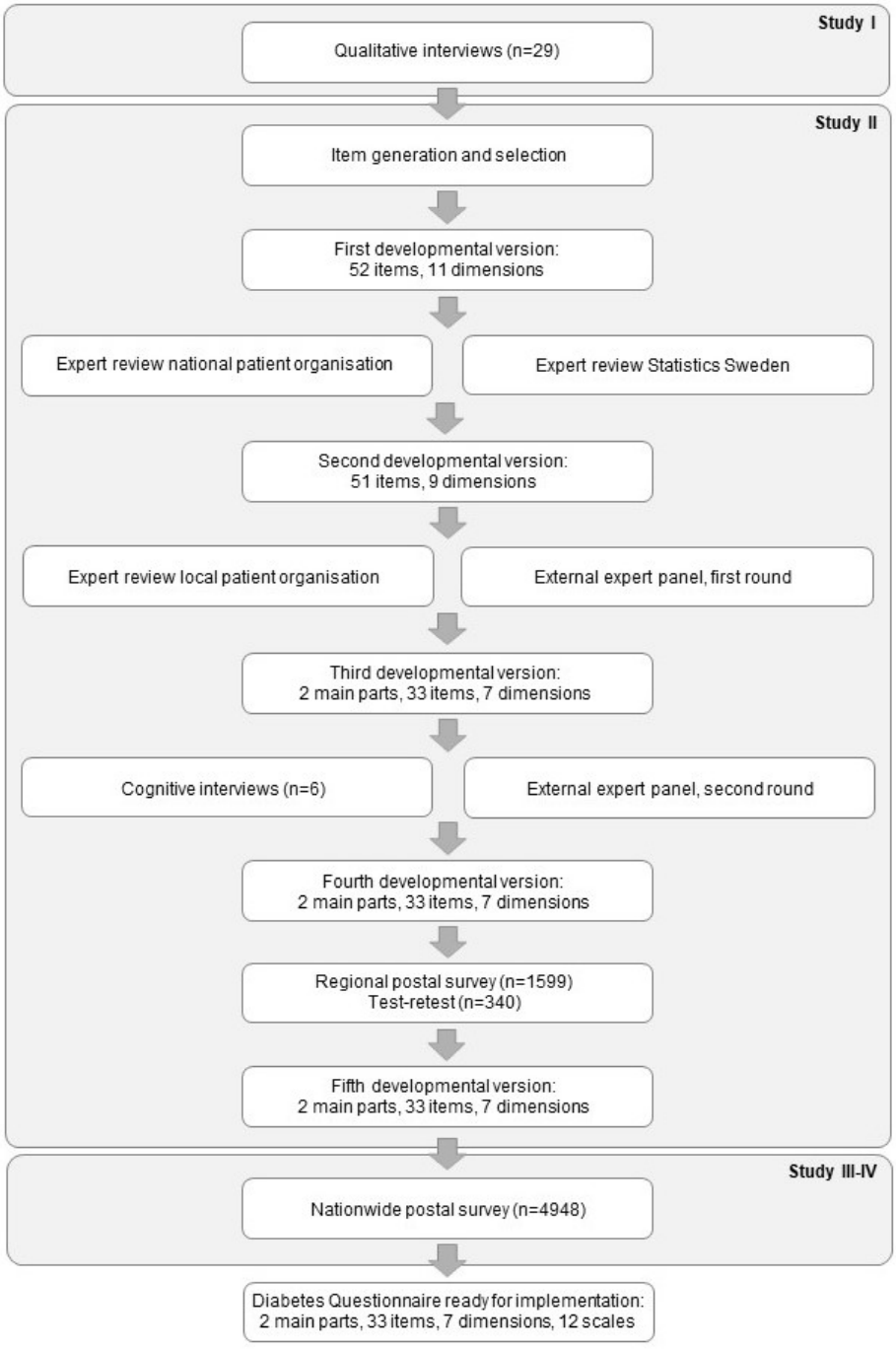

Figure 2. Overview of the different phases of development, testing, and corresponding developmental versions of the Diabetes Questionnaire.

diabetes focused on the design, structure, and measurement aspects. The other participants in the expert panel rated the content validity on a four-point ordinal scale ranging from "not at all relevant" to "highly relevant". All participants in the expert panels were invited to give comments and suggestions for revision on the overall relevance and usability, content, number of items, level of detail, wordings, and missing items. In the second round, one diabetes nurse and one researcher could not participate because of time constraints. Instead, representatives from the two patient organisations previously consulted were asked to assess content validity, one rating per organisation. In addition, an expert in lay communication (plain language) was consulted to take further measures for a questionnaire easy to understand and answer.

3.1.3 COGNITIVE INTERVIEWS

Using the third developmental version of the Diabetes Questionnaire, six individual cognitive interviews were conducted in **study II** during October and November 2014 (Figure 2). The participants were recruited from the sample in **study I**. Purposive sampling was applied to ensure heterogeneity with regard to diabetes type, diabetes treatment, sex, age, civil status, education, and occupation. Inclusion criteria were adults (≥18 years of age) who have had type 1 or type 2 diabetes since at least five years, who were living in Sweden, and who were able and willing to express their experiences and opinions in Swedish.

The face-to-face cognitive interviews lasted, on average, 54 minutes (range 38 to 65 minutes) and followed an interview guide (Appendix 2) inspired by Willis [128]. First, the interviewer informed the participants about the purpose of the interview and gave instructions on how to complete the Diabetes Questionnaire while thinking aloud. The thinking aloud process involved reading aloud from instructions, items, and response alternatives, as well as describing their interpretations and their choosing from response alternatives. Participants were encouraged to indicate whenever they found anything unclear or felt uncertain on how to answer the items. The participants were told that any problem or unclear points were related to shortcomings in the Diabetes Questionnaire, and therefore important to reveal as the basis for revisions. Participants were also told that the interviewer would take field notes and might encourage thinking aloud and ask questions. The interviewer listened actively, observed body language for hesitation or being in doubt, and probed for elicited understanding. The time needed for thinking aloud ranged from 9 to 47 minutes (mean 30 minutes). After completing the Diabetes Questionnaire, the participants were asked about their views on its overall relevance, possible benefit, and usability. They were also asked about their

views on the number of items and items possibly irrelevant, offending, or missing. In addition, they were asked about the wordings, recall periods, and the range, relevance, and ease of choosing among the response alternatives. Additional comments or spontaneous suggestions for revision were also welcomed. The interviews were audio-recorded and held in a room enabling privacy between the interviewer and the participant. Four of the interviews were held at the outpatient clinics where the participants were listed, either in a consulting room or in a small meeting room. Based on the preference of the participants, one interview was conducted in the privacy of the participant's home and one in a small meeting room at a university. After obtaining consent, the participants were contacted by phone and asked to comment on revisions made.

3.1.4 POSTAL SURVEYS

Two postal surveys were conducted (Figure 2). The first was a regional survey for **study II** to test response rate, test-retest reliability, and gather information about possible revisions needed before a larger survey. The second survey was launched nationwide and provided material for evaluations of evidence for construct validity in **study IV** and descriptions of generic health-related quality of life in **study III**. Both surveys together provided data for scale development and initial evaluations of their measurement properties using item response theory (IRT). This process has been described in a separate work by Borg *et al.* [130] and will also be further elaborated on in an upcoming thesis by Borg. A summary, however, is provided in the discussion section of this thesis. Owing to the lack of data on the variation in standard deviations (SDs) for the Diabetes Questionnaire scores before these surveys, formal sample size calculation was not possible. For both surveys, the sample size was estimated to allow subgroup analyses.

REGIONAL SURVEY

For the cross-sectional survey in **study II**, 800 adults with type 1 and 799 with type 2 diabetes were selected at random from the NDR in the region of Västra Götaland, Sweden. Eligible for inclusion were adults 18-80 years of age with at least one recorded HbA_{1c} test in the NDR during the past 12 months. The fourth developmental version of the Diabetes Questionnaire and a prepaid return envelope were sent by mail in January 2015. Non-responders received one reminder that included the same material 30 days after the date of receipt of the initial questionnaire. The Diabetes Questionnaire was returned by 477 (60%) adults with type 1 and 495 (62%) with type 2 diabetes. For test-retest reliability, the first 170 adults with type 1 and the first 170 with type 2 diabetes to respond were sent the same questionnaire a second time 14 days after their

first response. This time, 117 (69%) adults with type 1 and 126 (74%) with type 2 diabetes returned the Diabetes Questionnaire.

NATIONWIDE SURVEY

For the second cross-sectional survey for **studies III-IV**, 2,479 adults with type 1 and 2,469 with type 2 diabetes were selected at random from the NDR. Eligible for inclusion were adults who were alive, 18-80 years of age, and had at least one recorded HbA_{1c} test in the NDR during the past 12 months. In October 2015, the fifth developmental version of the Diabetes Questionnaire was sent by mail together with the SF-36 version 2 (SF-36v2) and a prepaid return envelope. The same material was sent a second time to the non-respondents 30 days after they had received the first questionnaire. In total, 1373 (55.4%) adults with type 1 and 1353 (54.8%) with type 2 diabetes answered both questionnaires.

Diabetes Questionnaire (fifth developmental version)

For **studies III-IV**, the fifth developmental version of the self-reporting Diabetes Questionnaire was used (Appendix 3). This version contained 33 items and 12 scales divided into 2 main parts, as described in the separate work by Borg *et al.* [130]. Part 1 consists of 22 items on eight scales and acts as a PROM. The scales in part 1 are General Wellbeing (GenW), Mood and Energy (MoE), Free of Worries about blood sugar (FreW), Capabilities to Manage your Diabetes (ManD), Diet and Exercise (DiEx), Not Limited by Diabetes (NLD), Not Limited by Blood Sugar (NLBS), and Support from Others (SuO). Part 2 comprises 11 items on four scales and acts as a PREM. The scales in part 2 are Support from Diabetes Care (SuDC), Access to Diabetes Care (AcDC), Continuity in Diabetes Care (CoDC), and Medical Devices and Medical Treatment (MDMT). The scales are scored from 0 to 100, with higher scores representing the more desirable outcome. The scales ManD, NLBS, and MDMT are specific to diabetes type [130].

SF-36v2

The SF-36v2 is a self-reporting questionnaire for generic health-related quality of life [89, 91]. For **studies III-IV**, the self-administered standard form in Swedish was used together with the licensed software from QualityMetric Inc. Thirty-five of the 36 items measure eight domains: Physical Functioning (PF); Role-Physical (RP), i.e. role limitations due to physical health problems; Bodily Pain (BP); General Health (GH); Vitality (VT); Social Functioning (SF); Role-Emotional (RE), i.e. role limitations due to mental health problems; and Mental Health (MH). The eight domains are aggregated into two summary measures, the Physical Component Summary (PCS) and the Mental Component Summary (MCS). Domains and summary measures are scored

from 0 to 100, with higher scores indicating better health-related quality of life. The summary measures are reported as norm-based *T*-scores. The *T*-scores are standardised to the 2009 US general population with a mean of 50 and a SD of 10. Mean *T*-scores between 47 and 53 are within the average range for groups [89, 91].

3.1.5 BACKGROUND DATA

Background clinical and demographic data for **studies I-IV** were collected from the NDR. Diabetes type was defined by clinician diagnosis as recorded in the NDR. For the interviews in **studies I-II**, complementing background data were collected at each session. As a consequence of a few missing data in the NDR, some details were collected from patient records by the diabetes nurse.

3.2 ANALYSIS

3.2.1 CONTENT ANALYSIS OF QUALITATIVE INTERVIEWS

The interviews conducted relative to **study I** were analysed using qualitative content analysis following a procedure described by Graneheim and Lundman [131]. Qualitative content analysis can be defined as a scientific technique and a tool for making conclusions from qualitative material that is valid and possible to replicate [132]. Content analysis allows descriptions close to the text with emphasis on variations and focuses on differences and similarities [133]. Content analysis was chosen regarding the overall goal that the interviews would act as a basis for the Diabetes Questionnaire. The ambition was to develop a questionnaire that included aspects voiced as important by the target group, with items phrased using their own words, and the combination of items and response alternatives that could mirror a variety of experiences. With this goal, the collected data needed to be organised in different areas of importance, preferably mutually exclusive, to act as the basis for different dimensions in the questionnaire. In addition, the language expression with the words and phrases used by adults living with diabetes needed to be kept and traceable for use in the creation of the items.

The analysis approach was close to the text to maintain the verbal phrasing, considering each interview as the unit of analysis. As an overarching frame of thought, Sen's capability approach was used to guide the analyses to identify aspects that were described as important to the realisation of what was considered as important in life by the participants, including both resources

and barriers. While using a theoretical frame of reference, on a continuum from inductive to deductive, the analysis approach was inductive, moving from the unique to the common and deriving the categories from the data [133, 134]. Mostly assisted by a professional secretary, the interviews were transcribed verbatim, corresponding to 1,275 pages or 355,996 words. In an iterative process, the analysis was conducted in four main steps using a word-processing program:

1. The transcripts were checked for accuracy against the audio recordings and read several times to enhance understanding. Relevant parts were marked and preliminarily coded with descriptive labels.
2. For each interview, parts of similar content were gathered as meaning units, condensed, and coded. Examples are found in **study I** (Appendix, printed version).
3. The condensed meaning units and their codes were assembled in a shared document and organised into sub-categories according to differences and similarities. A decoded ID label accompanied each condensed meaning unit and its code to enable the back-and-forth process.
4. The sub-categories were grouped into categories and main categories according to content, and an overarching theme was formulated.

Research triangulation [127, 131] was conducted by regular meetings in the research group. In these meetings, the following was discussed: sampling in relation to the aimed heterogeneity, raised aspects in the interviews, coding and categorising, and the generation of descriptive labels and text with representative quotations. In addition, the markings of relevant parts were for the first 10 interviews compared with the markings by another member of the research group. The markings were almost identical, and the few differences were easily resolved. The discussion guided further analysis.

3.2.2 ANALYSIS OF EXPERT REVIEWS

The material collected from the consulted experts in **study II** were qualitatively analysed, with a focus on what was suggested to be revised. From the external expert panels, content validity index (CVI) was calculated. After the first and second round of external expert panels, the CVI was calculated at the item level (I-CVI): the number of experts rating each item as highly relevant or quite relevant divided by the total number of experts. After the second round, the CVI was now also calculated on the scale-level (S-CVI) for

each dimension. The S-CVIs were calculated as the averages (S-CVI/Ave) across the I-CVIs. Recommendations suggest that values should be at least 0.78 for I-CVI and 0.90 for S-CVI/Ave to be judged as indications of excellent content validity [135]. I-CVIs below 0.78 should give rise to revision, or if very low, deletion [135]. Considering the CVIs, the decision for revision was discussed in the research group based on the comments from the experts, the interview material from **study I**, and the capability approach.

3.2.3 ANALYSIS OF COGNITIVE INTERVIEWS

The cognitive interviews in **study II** were qualitatively analysed with emphasis on problems according to a procedure described by Knafl *et al.* [136]. The unit of analysis was each item in the Diabetes Questionnaire and the questions at the end of the interviews (e.g. about the overall usability and the number of items). A professional secretary transcribed each interview verbatim, which corresponded to 151 pages or 40,969 words. The transcripts were checked for accuracy and read several times to enhance understanding. Relevant parts were marked and given descriptive labels as a way to focus on the problems. The markings from the transcripts and the field notes were summarised in a matrix, where the units of analysis were listed as rows, and the interviews as columns (Table 2). The analyses continued during data collection so revisions could be performed and to test these revisions in the remaining interviews.

3.2.4 JOINT ANALYSIS OF EXPERT REVIEWS AND COGNITIVE INTERVIEWS

The results from the second round of the external expert panel and the cognitive interviews were gathered in a joint analysis expanding the matrix used for the analysis of the cognitive interviews. The gathered information was discussed in the research group with regards to the interview material from **study I** and the capability approach and was used to guide the decisions to revise, retain, or delete (Table 2).

3.2.5 STATISTICAL ANALYSIS OF SURVEY DATA

The survey data from **studies II-IV** were analysed separately for participants with type 1 and type 2 diabetes. The descriptive statistics for each variable are based on non-missing observations. The categorical variables are presented as numbers and percentages and the continuous variables as means and SDs. In **studies III-IV**, the continuous variables with skewed distributions are presented as medians and interquartile ranges (IQRs).

Table 2. Examples from the matrix used for the analysis of the cognitive interviews and the joint analysis with the expert reviews

Item #	Interview #1	Interview #2	Summary of all interviews	Expert review summary	Decision: Revise, retain, or delete?
1	---	Relates only to diabetes, and not general wellbeing. Has been good regarding diabetes but has not been feeling well in general.	Some perceive the item to be about general wellbeing, and for others that it is diabetes-specific.	I-CVI 0.9 (considered relevant by most). One rater questions the general approach related to the objective of a diabetes-specific questionnaire.	The general approach has support in the qualitative interviews and the ambition of a holistic approach. Retain but elucidate the general component in the item wording.
16*	The item is difficult to understand. What do you mean by unusual situations? How unusual does it need to be?	What do you mean by unusual situations? Unclear question, difficult to answer. Has lived with diabetes for a long time and has difficulties thinking about what situations could be unusual. While thinking aloud, the reasoning is as intended. / Contact after rephrasing: now clear.	Difficult to understand before revision. After revision, there is no problem.	I-CVI 0.7 (considered relevant by many). However, it was also questioned, mainly regarding the phrasing "unusual situations", which is considered problematic.	Retain in revised form after the fourth interview. The phrase "unfamiliar situations" is replaced by "when your ordinary routines are difficult to follow".
21	---	The item is difficult to read and understand; has to read it several times. Says that it is an important item, but it has to be phrased differently. / Contact after rephrasing: now clear.	Item rephrased after interview #2. After that, there were no problems.	I-CVI 0.9 (considered relevant by most). Needed to elucidate that social media could be involved? Suggestions for minor rephrasing.	Retain in the revised form after the second interview. No need to add ways of social contact, but rather keep it open.

*Item number in the third developmental version of the Diabetes Questionnaire. Item 11 in the fifth developmental and final version of the Diabetes Questionnaire. I-CVI: Item level content validity index.

The test-retest conducted in **study II** was analysed in collaboration with a statistician for the level of agreement at the item level using Cohen's Kappa statistics and agreement plots [75, 127]. Cohen's Kappa values ≥0.70 are considered very good and 0.60 to be minimally acceptable [127]. Because Kappa values are sensitive to the distribution of response levels, the Kappa values in **study II** were used to signal possible disagreement (<0.60), and then the patterns in the plots were reviewed and the agreement judged. Results are reported as weighted Kappa values [75], which considers the distance between the test and the retest scores.

Spearman's rank correlation [75, 127] was used in **studies III-IV**. In **study III**, the correlations between the SF-36v2 domain scores and HbA_{1c} level were calculated. In **study IV**, the correlations were first studied between the Diabetes Questionnaire scale scores and the clinical variables age, diabetes duration, HbA_{1c} level, body mass index (BMI), low-density lipoprotein (LDL) cholesterol, and systolic blood pressure (SBP). Then, the correlations between the scores from the Diabetes Questionnaire scales and the SF-36v2 domains were calculated. Correlations ≥0.60 between the questionnaires were interpreted as very strong, 0.50 to <0.60 as strong, 0.40 to <0.50 as moderate, and <0.40 as weak. The correlation analyses in **study IV** were related to pre-specified hypotheses. For the correlations between the Diabetes Questionnaire scale scores and the clinical variables, the following hypotheses were proposed based on clinical experience:

- There would be a small number of negative and weak correlations
- Observed correlations would mostly be related to the HbA_{1c} level
- There would be no correlations with SBP and LDL cholesterol levels

For the correlations between the scores in the Diabetes Questionnaire scales and the SF-36v2 domains, the assumptions were based on examinations of the content in the two questionnaires. The hypotheses formulated were:

- The Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, and NLBS would have more and stronger correlations to the SF-36v2 domains as compared with the PROM scale SuO and the PREM scales (SuDC, AcDC, CoDC, and MDMT)
- The observed correlations would be positive
- The strongest correlations would be seen in the Diabetes Questionnaire PROM scales GenW and MoE

- In the scales, there would be no strong correlations except for GenW and MoE

Machine learning using random forests [137] was conducted in **study IV** to investigate non-linear associations between the Diabetes Questionnaire scale scores and the clinical variables and SF-36v2 domain scores together. Random forest is a general tree-based regression and classification method that uses bootstrapping to create a large number of regression of classification trees that are combined to produce a model prediction. The use of a large number of trees allows the model to depict non-linear associations without the need to pre-specify these in a model, while at the same time guarding against overfit [137]. The clinical variables studied were age, sex, diabetes duration, HbA_{1c} level, BMI, LDL cholesterol, and SBP. In the first step, all Diabetes Questionnaire scales were examined to determine the per cent variance explained by the SF-36v2 domains and the clinical variables together. Next, the two Diabetes Questionnaire PROM scales GenW and MoE were examined to study the variable importance of the SF-36v2 domains and the clinical variables together as predictors of the scale scores. In addition, the per cent variance in HbA_{1c} explained by another clinical variable, the Diabetes Questionnaire scales, and the SF-36v2 domains together was also examined. The results were presented as per cent of the total variance. Each model contained 1000 trees.

To study group-level associations between questionnaire scores and glycaemic control as measured by HbA_{1c}, unadjusted and adjusted multiple regression analyses [127] were conducted in **studies III-IV**. In **study III**, the SF-36v2 domain scores were related to glycaemic control and in **study IV**, the Diabetes Questionnaire scale scores were related to the glycaemic control. For these analyses, HbA_{1c} was divided into three clinically relevant groups and represented a categorical variable. The three groups were well-controlled (<52 mmol/mol), sub-optimal (52-69 mmol/mol), and high-risk (≥70 mmol/mol). The groups relate to different levels of glycaemic control and thus to different levels of the risk of diabetes complications. The least square mean estimates and 95% confidence intervals were calculated for the three HbA_{1c} groups and each SF-36v2 domain and summary measure for **study III**, and for each Diabetes Questionnaire scale for **study IV**. Using a linear model, the scale observations were modelled with fixed effects for the HbA_{1c} group (exposure), and adjusted for age, sex, diabetes duration, BMI, SBP, LDL cholesterol, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, previous coronary heart disease, previous stroke, and receipt of antihypertensive and lipid-lowering treatments. The analyses were first performed separately for each imputed data set and then the results were combined using Rubin's rules.

The extent of missing data in the data collection process for **studies III-IV** is visualised using heat maps [138, 139] in Figures 3-5. For type 1 and type 2 diabetes together, the extent of missing data was 0% for age and sex, and 7.2% for the other clinical variables (range 0 to 36.5%) (Figure 3). The corresponding extent of missing data was 1.7% for the SF-36v2 domains (range 0 to 3.3%) for the different dimensions (Figure 4). For the Diabetes Questionnaire scales, the extent of missing data was 4.8% (range 0.3 to 34.7%) for the different scales (Figure 5). The greater extent of missing data in some of the Diabetes Questionnaire scales is likely related to the response alternative "not applicable", which at this stage was treated as missing data. The extent of missing data ranged from 0.3 to 2.8% for scales lacking the response alternative "not applicable". Missing data were imputed 10 times, using multiple chained equations.

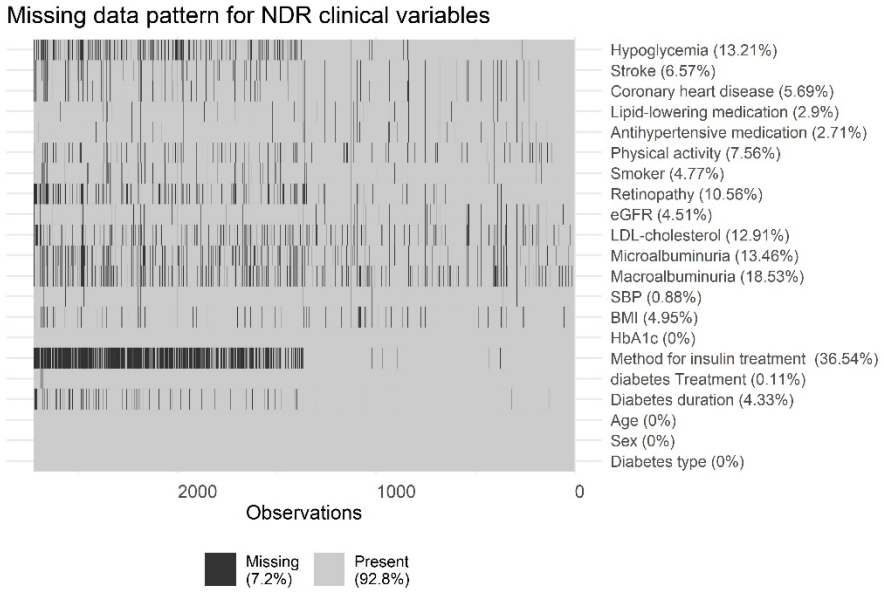

Figure 3. Pattern of missing data for the clinical variables collected from the NDR in studies III-IV.

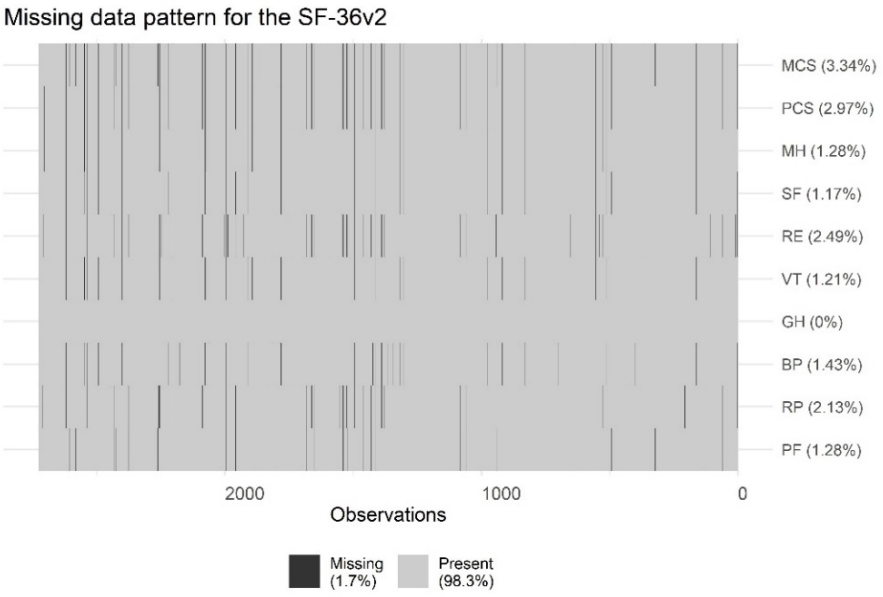

Figure 4. Pattern of missing data for the SF-36v2 domains in studies III-IV.

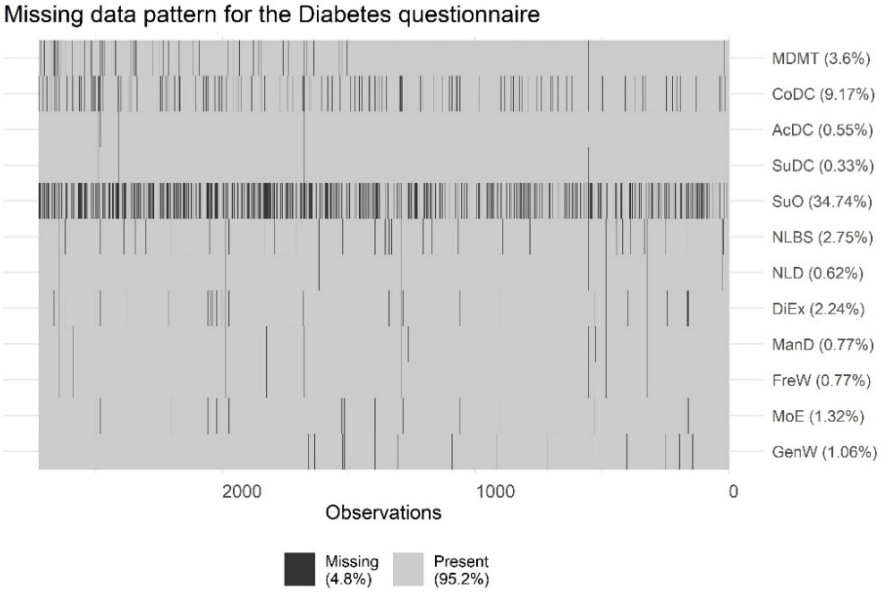

Figure 5. Pattern of missing data for the Diabetes Questionnaire scales in study IV.

For the Diabetes Questionnaire, the generation of questionnaire scores in **studies III-IV** has been described elsewhere [130]. The scores from the SF-36v2 domains were generated using the manual and licensed software from QualityMetric [91]. For the clinical and demographic data, the standardised mean difference was used to examine the data balance between the HbA_{1c} groups and deviation from the means. For all tests, a significance level of 5% was used without adjustment for multiple testing. Based on discussions within the research group, all analyses for **studies III-IV** were conducted by a statistician using SAS 9.4 and R 3.4.4.

3.3 ETHICAL CONSIDERATIONS

The studies conform to the Declaration of Helsinki and have been approved by the Regional Ethical Review Board in Gothenburg, Sweden. The registration number for **studies I-II** is 565-12 (amendment nos.: T912-12, T444-13, T729-13, T511-14, T696-14) and 029-15 (amendment no.: T600-15) for **studies III-IV**.

All participants gave their informed consent. The letter to potential participants disclosed information about the study's purpose and procedures, the voluntary nature of their participation, and their right to withdraw without specified reason or consequences. The letters also contained information about the NDR, those who were responsible for the study, and contact details. Information was also given about confidentiality measures, safekeeping of personal data, and the related legislation at the time (the Swedish Act for how to treat personal data, PUL). For the interviews in **studies I-II** and the expert panels in **study II**, the information was repeated orally and written informed consent confirmed. At the time of data collection, health care providers were, according to the Swedish Act for how to treat patient data (Swedish: Patientdatalagen), responsible for giving information about the registration in a healthcare quality register and the right to decline. However, written consent was not needed. A separate patient information leaflet about the NDR was attached to the postal surveys in **studies II-IV** to strengthen this information. Since the General Data Protection Regulation came into effect in 2018, health care providers are now responsible for collecting informed consent from their patients for participation in the NDR.

In reporting of the results, measures have been taken so that no individual is traceable. While the diabetes nurses, physicians, and researchers who took part in the external expert panels in **study II** consented to be mentioned by name as being part of the panel, the individual comments or ratings have not been revealed outside the expert panels or the research group. The participants

received information as to how they could access and read about the results after the completed study. In addition to scientific publications, the results have been presented at meetings for patients held by diabetes clinics, at meetings for diabetes care professionals, in annual reports from the NDR, and on the NDR website. The Diabetes Questionnaire has been sent on request to individuals participating in the developmental process.

Questions about daily life and the experiences and self-management related to diabetes might be experienced as an intrusion on the personal integrity of the participants and might evoke negative feelings. Consequently, all interviews in **study I** were closed by a dialogue on how the participants had experienced the interview. Should the interview arouse negative feelings, there were possibilities for dialogue and support. During the postal surveys in **studies II-IV**, the Diabetes Questionnaire and the SF-36v2 together collected information such as health-related quality of life, how the issues of everyday life with diabetes are going, and if adequate support is received from the diabetes care system. These aspects concern information important to respond to, especially if the ratings are low, indicating that a person for example is feeling down or not receiving the support needed. However, there was no possibility to act upon the individual responses as the questionnaires were administered by the NDR. All clinics connected to the NDR received an information letter about the study that invited them to make contact should they have questions or receive questions from invited participants. When implemented as a clinical tool, the Diabetes Questionnaire is administered by the clinic where the patient is listed and the diabetes nurse or physician is expected to pay attention to the responses, and if needed, act. Throughout the development of the Diabetes Questionnaire, the members of the research group have reflected on the risk of violating the personal integrity of the individual participant, as well as of any individual that the items in the Diabetes Questionnaire might relate to, such as family and friends, and diabetes nurses and physicians. This risk was especially addressed throughout **study II**. Items targeting certain factors (e.g. sexuality and personal details about others not consenting to participate in the NDR) were omitted. The expert reviews and interviews in **study II** revealed no indication that any part of the later versions of the Diabetes Questionnaire was experienced as violating the participant's integrity.

4 RESULTS

The results are summarised in Table 3. The main result of this thesis is the creation of a new diabetes-specific questionnaire, the Diabetes Questionnaire. The basis for the Diabetes Questionnaire was identified in **study I**, the development described in **study II**, and supporting evidence of measurement quality evaluated in **study II** and **IV**. These results are presented in section 4.1. While evaluating the Diabetes Questionnaire, data on self-reported generic health-related quality of life were also collected. Separate analyses from these data were conducted in **study III**, as presented in section 4.2. The characteristics of the participants are described in Table 4 while the characteristics of the non-respondents are given in **studies II-IV** (Appendix).

Table 3. Summary of results from studies I-IV

Study	Aim	Results
I	To inform the development of the PROM, the specific aim of this study was to describe important aspects in life for adults with diabetes.	Aspects important to adults with diabetes were identified to be used as the basis for the Diabetes Questionnaire. The overarching theme "To live a good life with diabetes" included experiences of everyday life and support from diabetes care.
II	To describe the development and evaluation of content validity, face validity and test-retest reliability of a disease-specific questionnaire measuring patient reported outcomes and experiences in conjunction with the NDR for adults who have type 1 or type 2 diabetes.	The process of initial development and testing of the disease-specific Diabetes Questionnaire was described. The study resulted in a 33-item self-reporting questionnaire with supporting evidence for content and face validity, answerability and satisfactory item level test-retest reliability, ready for scale development and further assessments.
III	To describe the health-related quality of life and assess its association with glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.	Adults with type 1 and type 2 diabetes who have high-risk HbA_{1c} levels have lower levels of generic health-related quality of life (as measured by the generic SF-36v2) compared with those who have well-controlled HbA_{1c} levels.
IV	To study evidence for construct validity, the aim was to describe outcome from the Diabetes Questionnaire, to assess the associations of that outcome with clinical variables and generic health-related quality of life, and to study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 diabetes and type 2 diabetes in a nationwide setting.	The Diabetes Questionnaire captures some of the generic health-related quality of life dimensions covered by the SF-36v2, while also adding diabetes-specific information not covered by the SF-36v2 or the clinical variables traditionally covered in the NDR.

Table 4. Clinical and demographic characteristics of the participating adults with diabetes in studies I-IV

	Study I		**Study II**				**Studies III-IV**	
Variable	Type 1 diabetes	Type 2 diabetes	Type 1 diabetes	Type 1 diabetes, test-retest	Type 2 diabetes	Type 2 diabetes, test-retest	Type 1 diabetes	Type 2 diabetes
Number	15	14	477	117	495	126	1373	1353
Men, n (%)	6	8	(50)	(46)	(62)	(52)	690 (50.3)	822 (60.8)
Age, years, mean (SD)	45.7 (16.4)	63.7 (10.4)	48 (16)	55 (15)	66 (9)	67 (9)	48.6 (16.4)	66.6 (9.1)
Diabetes duration, years, mean (SD)	22.7 (13.9)	13.4 (5.0)	25 (16)	29 (17)	9 (7)	9 (7)		
Diabetes duration, years, median (IQR)							22.0 (12.0-36.0)	8.0 (4.0-14.0)
HbA_{1c} mmol/mol, mean (SD)	62 (11)	59 (14)	60 (12)	58 (11)	51 (12)	50 (9)	62 (12.7)	53 (12.5)
BMI, kg/m^2, mean (SD)	26.6 (5.2)	29.4 (19.7)	26 (4)	26 (4)	30 (5)	30 (5)	26.0 (4.2)	29.9 (5.3)
Systolic blood pressure, mmHg, mean (SD)			127 (15)	129 (15)	134 (15)	132 (14)	127.0 (14.0)	134.3 (14.3)
Antihypertensive medication, n (%)			(40)	(55)	(66)	(75)	589 (44.7)	1070 (80.1)
LDL cholesterol, mmol/L, mean (SD)			2.5 (0.8)	2.5 (0.8)	2.5 (0.9)	2.6 (0.8)	2.4 (0.8)	2.5 (0.9)
Lipid-lowering medication, n (%)			(41)	(49)	(60)	(64)	642 (48.4)	900 (68.1)
Microalbuminuria, n (%)			(11)	(14)	(13)	(14)	132 (10.3)	194 (18.0)
Macro albuminuria, n (%)							31 (2.6)	52 (5.0)

	Study I		Study II				Studies III-IV	
Variable	Type 1 diabetes	Type 2 diabetes	Type 1 diabetes	Type 1 diabetes, test-retest	Type 2 diabetes	Type 2 diabetes, test-retest	Type 1 diabetes	Type 2 diabetes
eGFR, mL/min, mean (SD)							90.0 (23.5)	82.3 (23.5)
Retinopathy, n (%)			(61)	(72)	(16)	(14)	875 (65.9)	327 (29.4)
Coronary heart disease, n (%)							83 (6.3)	279 (22.4)
Stroke, n (%)							48 (3.6)	96 (7.8)
Smoker, n (%)			(7)	(8)	(15)	(11)	135 (10.1)	162 (12.9)
Physical activity, daily, n (%)			(25)	(33)	(24)	(26)	359 (27.6)	426 (34.9)
Diabetes treatment								
Diet alone, n (%)	0	1	0	0	(26)	(22)		195 (14.4)
Oral hypoglycaemic agent alone, n (%)	0	4	0	0	(49)	(54)		718 (53.1)
Insulin alone, n (%)	15	1					1335 (97.2)	130 (9.6)
Insulin alone or with oral agents, (%)			(100)	(100)	(23)	(23)		
Insulin and oral agent, n (%)	0	8					32 (2.3)	266 (19.7)
Insulin pump users among insulin users, n (%)	7	0	(24)	(18)	0	0	356 (26.2)	2 (0.5)

Table 4 continued. Participants in the cognitive interviews or expert panels in study II are not included because of low numbers.
eGFR: estimated glomerular filtration rate; IQR: interquartile range; SD: standard deviation.

4.1 THE DIABETES QUESTIONNAIRE AND EVIDENCE OF MEASUREMENT QUALITY

The Diabetes Questionnaire was developed based on the experiences of adults with diabetes and their everyday vocabulary that were identified in **study I**. The development and initial testing of the Diabetes Questionnaire were described in **study II** and further evaluation of evidence of measurement quality was delineated in **study IV**. The development and testing conducted up until the publication of this thesis have been related to the COSMIN taxonomy [123] as displayed in Figure 6. The development of scales with acceptable measurement properties and the additional evaluations of validity and reliability described in Borg *et al.* [130] are for reference also included in Figure 6.

4.1.1 THE BASIS FROM EXPERIENCES OF LIVING WITH DIABETES

The qualitative content analysis in **study I** revealed two main categories and five categories that acted as the underlying basis for the content and structure of the Diabetes Questionnaire. These main categories and categories are shown in Table 5 and summarised in the text below with exemplifying quotations.

Table 5. Theme, main categories, and categories that acted as the basis for the Diabetes Questionnaire

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

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

To feel good in the short and long term was the most central aspect identified, which was characterised as being strongly dependent on good diabetes management. However, diabetes management could be demanding, difficult, over-whelming, and diminish the ability to feel good in the present. If not

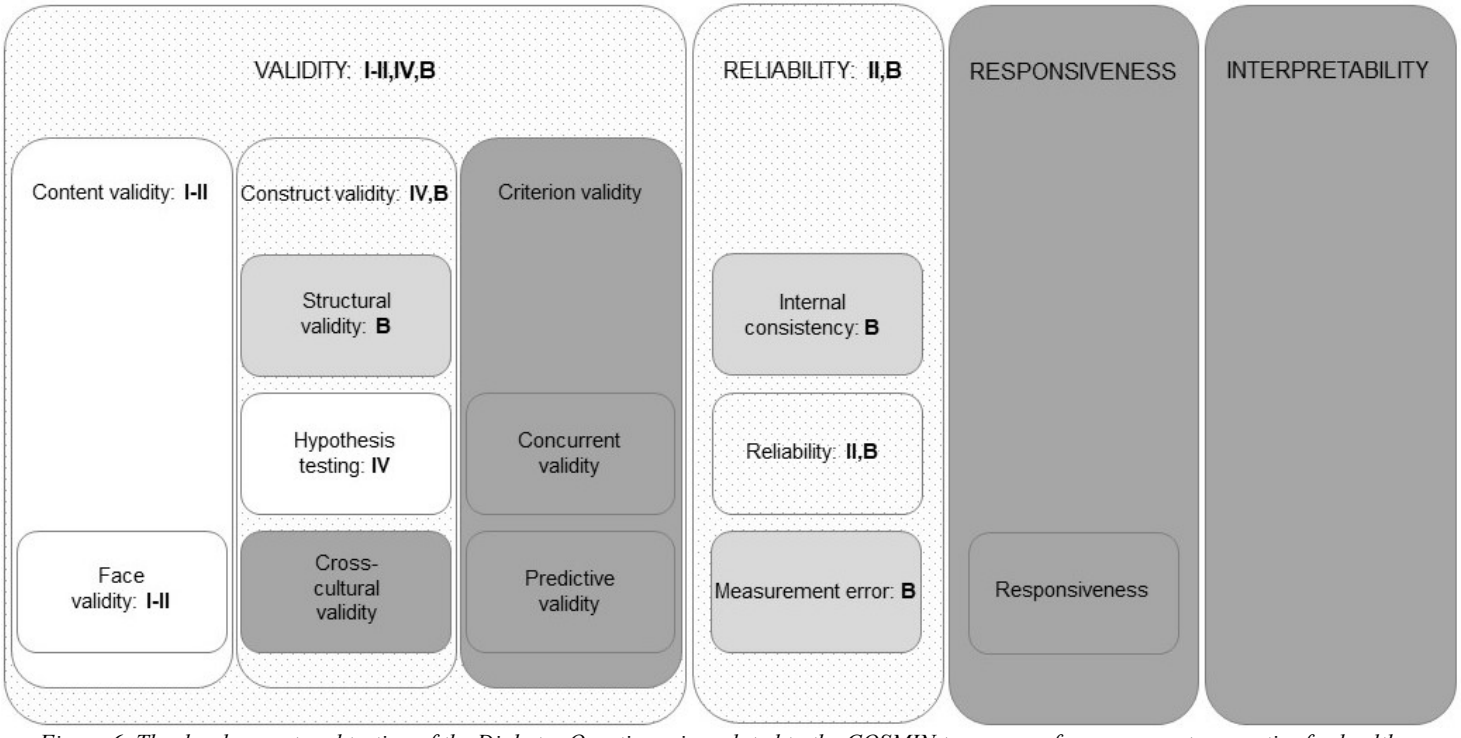

Figure 6. The development and testing of the Diabetes Questionnaire related to the COSMIN taxonomy of measurement properties for health-related patient-reported outcomes as reported by Mokkink et al. [123]. White areas: addressed aspects in studies in this thesis, referred to by their Roman numerals. Dotted light grey areas: partly addressed in this thesis and partly in work by Borg et al. [130], referred to in the figure as B. Light grey areas: addressed by Borg et al. [130]. Dark grey areas: future perspectives.

meeting the management demands, this could lead to negative feelings such as guilt, shame, and worry.

> "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." – Adult with type 1 diabetes

At the same time, the ability to manage diabetes was believed to be influenced by how the person currently felt, what was happening in life, and the social sphere. Diabetes management was easier to deal with in good times. When, for different reasons, certain life events led to more challenges, diabetes management was more difficult.

> "If you feel mentally good and feel that everything is going well, then you have more energy to care for your diabetes." – Adult with type 1 diabetes

Barriers related to diabetes

Another central aspect identified concerned barriers related to diabetes. Having diabetes could be experienced as a barrier to a good life, and different components related to diabetes could be barriers to a good life with diabetes. To which extent barriers were experienced varied between individuals, situations, and over time. For some, diabetes could be well integrated into life and diabetes management be dealt with without any special effort. Diabetes could also be experienced as always present and complex, highly affecting everyday life and social relationships. The self-management needs could be experienced as constraining and a barrier in social life, for acting spontaneously, and to trying new things.

> "The negative thing with diabetes is when people 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." – Adult with type 2 diabetes

The blood glucose levels – the highs, the lows, and the fluctuations in between the highs and lows – were central barriers for a good life with diabetes. The actual highs, lows, and fluctuations in between could be draining, frustrating, and a barrier to daily activities. In addition, the risk of these (high, lows, fluctuations), and the fears and worries they create could lead to abstaining from activities, being dependent on others, and difficulties being alone.

> "It's sad not daring to go on a trip. Since 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." – Adult with type 2 diabetes

Other potential barriers were linked to long-term complications such as anxiety, worries about the future, and real difficulties associated with losing eyesight or tactual sensation, and problems from the gastrointestinal tract.

However, the presence of long-term complications would not necessarily be a barrier in life, but something possible to live with.

> "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 to have a good quality of life." – Adult with type 1 diabetes

Support from others

The support needed and received from others (e.g. family, friends, colleagues, acquaintances, and others with diabetes) varied between individuals, situations, and over time. When the support from others was in harmony with individual needs and wishes, it could ease the burden of self-management and the experiences associated with barriers.

> "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 great support for me." – Adult with type 1 diabetes

When support was not tailored to individual needs and wishes, the diabetes burden could be elevated. The absence of support might lead to disappointment for the person with diabetes. On the other hand, too much attention or effort from others could be construed as excessive and overprotection or even as being placed on public view. Although the attention is well meant, it could be ill-advised and inconsiderate. The need for support from others could also be related to feelings of bad conscious and being a burden, even though others show a sincere interest to help.

> "Going away and doing something by myself is almost unthinkable. Sometimes you feel like a burden." – Adult with type 1 diabetes

SUPPORT FROM DIABETES CARE IN MANAGING DIABETES

Support from diabetes care tailored to individual needs

For the adult to be able to emotionally and practically deal with diabetes, support from diabetes care is a crucial resource. Support adjusted to individual needs nurtured the ability and knowledge to manage diabetes and thereby elevated mood and improved life in the face of diabetes. The individual needs were related to access, content, and timing of the contacts with diabetes care. Individual needs were also related to personal treatment, avoiding professional jargon, and taking the current situation and emotional aspects into account. There was a wish for diabetes care to relate to their situation and how they could handle diabetes in everyday situations and more specific and less frequently occurring situations. Everyday situations could entail varying levels of physical activity, wanting to sleep longer on the weekend, or work aspects on how to deal with diabetes in relation to demanding activities, working

different hours, or unsympathetic attitudes from colleagues or employers. The less frequent situations could be how to handle being sick, festivities, or travels. Flexible diabetes care that was adapted to individual needs was highly wished for and received by some. However not by everyone. They especially wanted to be listened to and that their experience, knowledge, and wish for shared decision making be acknowledged. Continuity in terms of meeting with the same professional over time was seen as a prerequisite for a good an open dialogue. Despite expressing the gratitude for, and understanding the importance of, medical examinations, diabetes care could be experienced as an examination for the sake of diabetes care, and not for the person with diabetes, and was compared to vehicle tests.

> "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."
> – Adult with type 2 diabetes

Their everyday self-management of diabetes, their situation, their need for repeated and updated information, and their emotional aspects of living with diabetes were experienced as being treated as less important than the medical examinations.

> "There's a lot of focus on numbers and values. They don't 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." – Adult with type 1 diabetes

Technical devices and medical treatment tailored to individual needs
Everyday life and well-balanced glucose levels were said to be facilitated by technical devices and medical treatment well matched to individual needs. Technical devices for insulin administration or monitoring of glucose levels could make life easier and give the individual with diabetes greater freedom. Despite the positive aspects, however, handling medical devices and acting on alarms from monitors could be difficult, demanding, and impair sleep. Furthermore, as medical devices were not subsidised for everyone, they could be either an economic burden or something the individual had to do without, creating unequal opportunities for management.

> "If I couldn't afford to pay for the CGM [Continuous Glucose Monitoring device], I wouldn't have such a good blood count" – Adult with type 1 diabetes

4.1.2 FROM THE BASIS TO THE DIABETES QUESTIONNAIRE

The relationships between the main categories and categories from **study I** and the parts and dimensions of the Diabetes Questionnaire as developed in

study II are presented in Figure 7. The two main categories correspond to the two main parts of the Diabetes Questionnaire while the categories correspond to the dimensions. The wordings and phrasings of the instructions, headings, items, and response alternatives of the Diabetes Questionnaire are based on the phrasing and wordings used by the adults with diabetes interviewed in **study I**. Figure 7 also shows the relationships to the final scales that were constructed in Borg *et al.* [130] and which were used in the analyses in **study IV**.

Study II generated five developmental versions of the Diabetes Questionnaire with revisions made between versions that were informed by the experts consulted and the cognitive interviews. The fifth developmental version emerged as the first final version ready for implementation. The different developmental versions and the revisions made between versions are summarised in Table 6. The final version of the Diabetes Questionnaire is attached in Swedish in Appendix 3. In Appendix 4, the dimensions and items are listed in English. This list is only given for publication reasons and it does not present a validated translation.

4.1.3 SUPPORTING EVIDENCE FOR CONTENT VALIDITY

While relying on the results from **study I**, the supporting evidence for content validity of the Diabetes Questionnaire was evaluated in **study II** for the second and third developmental versions. The second round of the external panel reviewed the third version of the Diabetes Questionnaire and resulted in 28 items with I-CVIs above the recommendation of 0.78 for excellent content validity and 5 items below (range from 0.6 to 1.0). The items with the lower ratings targeted sleep, eating, physical activity, and dealing with diabetes when the ordinary routines are difficult to follow. The S-CVI/Age ranged from 0.72 to 1.0 between dimensions. Three dimensions reached or were above the recommendation of 0.90 for excellent content validity, whereas four dimensions were below (Table 7). The overall S-CVI/Age that included all dimensions was 0.86, slightly below the recommended 0.90. The items and dimensions not reaching the recommendations for CVI were scrutinised. Revisions were made referring to the material collected in **study I** and the joint analyses that included the comments from the experts and the findings from the cognitive interviews in **study II**. The I-CVIs from the second round of the external panel presented an improvement from the first round. In the first round, when the second developmental version was reviewed, the I-CVIs ranged from 0.44 to 1.0 (18 items were below 0.78).

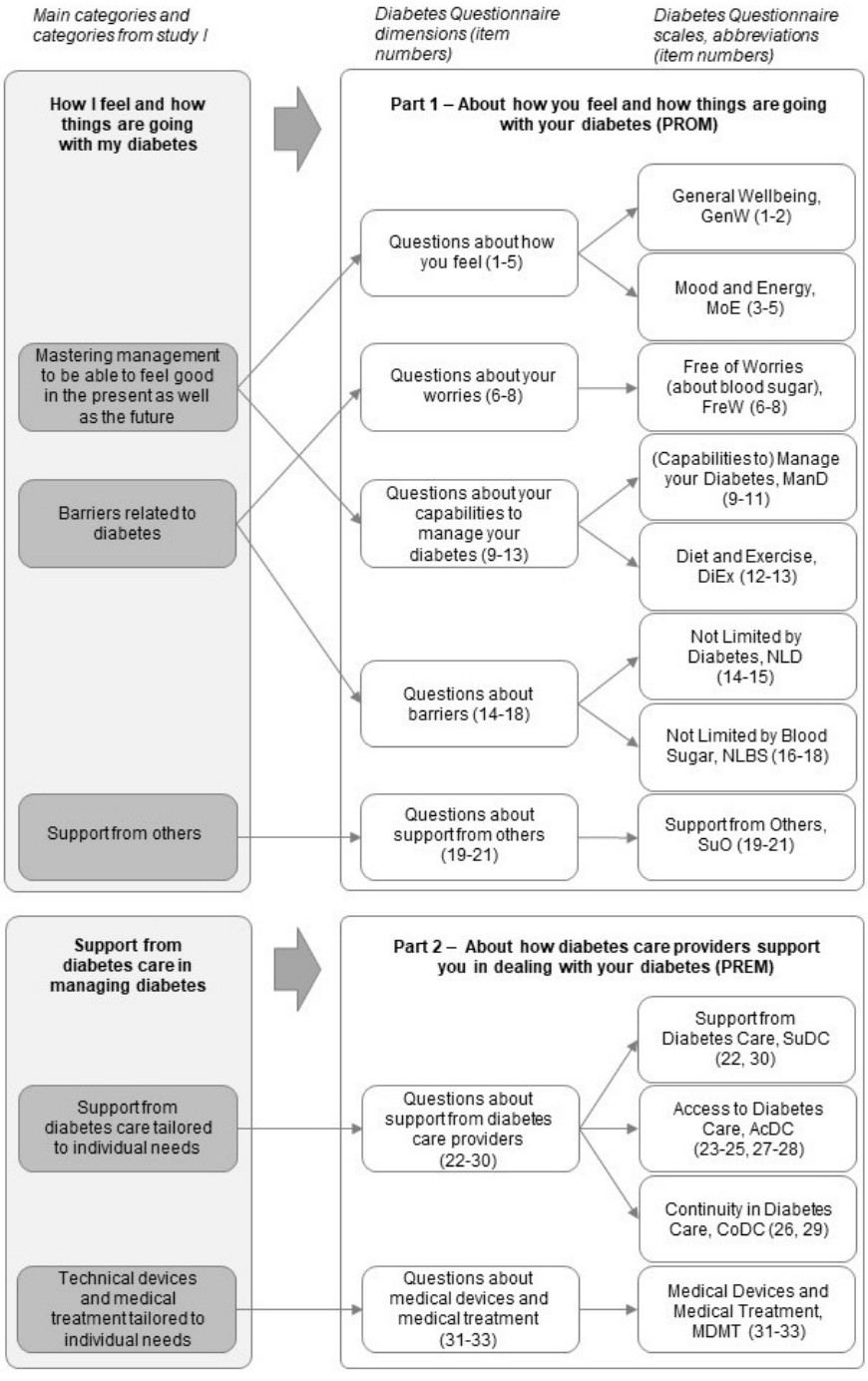

Figure 7. The relationships between the qualitative study I and the dimensions and scales of the fifth developmental (final) version of the Diabetes Questionnaire.

Table 6. The developmental versions of the Diabetes Questionnaire, the related activities for evaluations, and main revisions made between versions

Developmental version	**Activities for evaluation**	**Main revisions made for the next version**
First: 52 items, 11 dimensions	Expert review national patient organisation and Statistics Sweden	• A shortened recall period (from 3 months to 4 weeks). • Items deleted: for example, an item addressing hypoglycaemia that might result in a high number of missing data related to the risk of losing a driving license. • Items added: for example, related to acceptance, referral to a dietician or psychologist, information about patient organisations, or to enhance the level of detail in items considered too broad. • Items phrased as statements were rephrased into questions. • Changed order of items • Rewordings of items, response alternatives, instructions, and layout to enhance clarity.
Second: 51 items, 9 dimensions	Expert review by a local patient organisation and the first round of the external expert panel	• The number of items reduced. • Too detailed items were merged into more comprehensive items. • Items that targeted aspects already covered by other parts of the NDR were omitted. • Rewording of items to enhance clarity and minimise the risk for misinterpretation. • Changed order of a few items.
Third: 33 items, 7 dimensions divided into 2 main parts (PROM and PREM)	Cognitive interviews and second round of the external expert panel	• Rewording of headings, instructions, and a few items to enhance clarity. • Changed order of a few items. • Changed order for two of the dimensions.
Fourth: 33 items, 7 dimensions divided into 2 main parts (PROM and PREM)	Regional postal survey	Minor changes in design and layout: for example an updated NDR logo.
Fifth: 33 items, 7 dimensions divided into 2 main parts (PROM and PREM)	Nationwide postal survey	Need for revisions not yet identified.

Table 7. Content validity index at the item and scale level for the third developmental version of the Diabetes Questionnaire

	Dimension (number of items)	I-CVI	S-CVI/Ave
Part 1	Questions about how you feel (5)	0.9, 0.7, 0.9, 0.9, 0.9	0.86
	Questions about your worries (3)	1.0, 1.0, 1.0	1.00
	Questions about barriers (5)	1.0, 1.0, 0.8, 0.8, 0.8	0.88
	Questions about how you manage your diabetes (5)	0.9, 0.7, 0.7, 0.6, 0.7	0.72
	Questions about support from others (3)	0.9, 0.9, 0.9	0.90
Part 2	Questions about support from diabetes care providers (9)	0.9, 0.9, 0.9, 0.9, 0.8, 0.9, 0.8, 0.8, 0,8	0.85
	Questions about medical devices and medical treatment (3)	0.9, 0.9, 0.9	0.90

I-CVI: Item level content validity index; S-CVI/Ave: Scale level content validity index calculated as the averages across I-CVIs.

4.1.4 SUPPORTING EVIDENCE FOR FACE VALIDITY AND THAT THE DIABETES QUESTIONNAIRE WORKS AS INTENDED

The cognitive interviews in **study II** with representatives of the target group revealed that the third developmental version of the Diabetes Questionnaire was perceived to measure what it was intended to measure, the instructions guided the respondents, and the items were in general understood and answered as intended. The response alternatives seemed relevant and distinguishable. However, the interviews also indicated the need for some clarifications. For instance, there was a need to clarify that the first item about how the person has felt the past 4 weeks was intended to be holistic rather than diabetes-specific. When adding the phrase “in general”, the intent of the item was perceived to be clear. Another example is that the phrase “unusual situations” was problematic. When replaced by “when your ordinary routines are difficult to follow”, the item was no longer open to doubt. During the process of cognitive interviewing, there were some minor changes in the wording of some text and the order in which the items were presented. The changes were shown to be successful in the remaining interviews or approved by participants when contacted by phone and asked for their comments.

All items were considered answerable, relevant for the intended use, and there were no indications of items being offensive. However, it was noted that it might be difficult to answer the items about professional support from diabetes care providers during the clinical meeting. However, if it were possible to answer the questionnaire in private, it would be okay. No other concerns were raised about the items targeting support from diabetes care. To be able to give

the items careful thought, they would prefer to answer the questionnaire at home before the clinical meeting rather than in the waiting room.

4.1.5 SUPPORTING EVIDENCE FOR RELIABILITY

For the fourth developmental version of the Diabetes Questionnaire, the evaluation of test-retest reliability at the item level in **study II** showed acceptable agreement. The weighted Kappa values ranged from 0.31 to 0.78 for adults with type 1 diabetes and from 0.27 to 0.74 for adults with type 2 diabetes (Table 8). Examination of the patterns in the agreement plots for items with possible disagreement (<0.60) showed fair agreement between test and retest. The lower Kappa values were likely driven by skewed distributions in response levels in which a majority of the participants' scorings were found in either of the first two response alternatives.

Table 8. Weighted Kappa values from the test-retest of the fourth developmental version of the Diabetes Questionnaire

	Dimension (number of items)	Weighted Kappa type 1 diabetes, range 0.31-0.78	Weighted Kappa type 2 diabetes, range 0.27-0.74
Part 1	Questions about how you feel (5)	0.50-0.65	0.40-0.63
	Questions about your worries (3)	0.49-0.60	0.46-0.52
	Questions about your capabilities to manage your diabetes (5)	0.31-0.64	0.45-0.57
	Questions about barriers (5)	0.41-0.67	0.32-0.64
	Questions about support from others (3)	0.66-0.78	0.56-0.61
Part 2	Questions about support from diabetes care providers (9)	0.45-0.69	0.43-0.74
	Questions about medical devices and medical treatment (3)	0.46-0.58	0.27-0.52

4.1.6 SUPPORTING EVIDENCE FOR CONSTRUCT VALIDITY

Supporting evidence for construct validity was based on the work in **studies I-II**, and statistically assessed in **study IV** for the fifth, and final, developmental version of the Diabetes Questionnaire in relation to clinical variables and the generic SF-36v2. The results are summarised below while the figures and tables are provided in **study IV** (Appendix, printed version).

LINEAR CORRELATIONS WITH THE CLINICAL VARIABLES

In line with the pre-specified hypotheses (see pages 30-31), the analyses in **study IV** showed few statistically significant correlations with the clinical variables. Most observed correlations were negative, as expected (i.e. when the clinical variables were lower, the Diabetes Questionnaire scale outcome was

higher). As expected, the observed correlations with the clinical variables were all weak and most were found relative to the HbA_{1c} level. The strongest correlations were seen in the scales ManD and DiEx for participants with type 1 diabetes, and in the scales MoE, FreW, and ManD for those with type 2 diabetes. In addition, there was no correlation with LDL cholesterol, or SBP, except for a weak correlation between a lower SBP and higher scores in the MoE scale.

LINEAR CORRELATIONS WITH THE SF-36V2 DOMAINS

In line with the pre-specified assumptions, the linear correlations observed in **study IV** between the Diabetes Questionnaire scales and the SF-36v2 domains were positive, meaning that higher Diabetes Questionnaire scale scores were correlated with higher SF-36v2 domain scores. As anticipated, the strongest correlations were found between the Diabetes Questionnaire PROM scales GenW and MoE and the SF-36v2 domains GH, VT, and MH. Also as expected, either weak or no correlations were revealed between the PREM scales and the SF-36v2 domains.

NON-LINEAR ASSOCIATIONS TO CLINICAL VARIABLES AND SF-36V2 DOMAINS TOGETHER

The machine learning analyses in **study IV** showed similar results for both diabetes types. The SF-36v2 domains together with the clinical variables explained about 40-45% of the variance in the PROM scales GenW and MoE. The variance explained in the other scales was low, especially in the PROM scale SuO and the PREM scales. The GH, VT, and MH domains in the SF-36v2 were shown to be the variables with the highest importance as predictors of GenW and MoE; in contrast, LDL cholesterol and SBP had low variable importance.

SENSITIVITY OF THE DIABETES QUESTIONNAIRE SCALES TO CLINICALLY RELEVANT GROUPS OF GLYCAEMIC CONTROL

The regression analyses in **study IV** demonstrated that the Diabetes Questionnaire is sensitive to differences between clinically relevant groups of glycaemic control. Adjusted for demographics, other risk factors, and diabetes complications, the high-risk group (HbA_{1c} ≥70 mmol/mol) had statistically significantly lower scores than the well-controlled group (HbA_{1c} <52 mmol/mol) in most Diabetes Questionnaire scales among participants with type 1 diabetes, and in almost all scales among those with type 2 diabetes. Statistically significant differences between all three groups were seen in two scales among participants with type 1 diabetes, and in five scales for those with type 2 diabetes.

4.2 GENERIC HEALTH-RELATED QUALITY OF LIFE AND GLYCAEMIC CONTROL

From the separate analyses of the SF-36v2 data regarding glycaemic control in **study III**, correlation analyses showed statistically significant, although weak, correlations between having a lower HbA_{1c} level and higher SF-36v2 domain scores. This pattern was seen in five SF-36v2 domains (PF, RP, BP, GH, and VT) among participants with type 1 and in all but one domain (MH) among those with type 2 diabetes (Table 9).

Table 9. Spearman's rank correlations with p-values between SF-36v2 domain scores and HbA_{1c} levels in type 1 and type 2 diabetes

SF-36v2 domains	Type 1 diabetes	Type 2 diabetes
PF	-0.15 (<.0001)	-0.17 (<.0001)
RP	-0.12 (<.0001)	-0.18 (<.0001)
BP	-0.14 (<.0001)	-0.13 (<.0001)
GH	-0.19 (<.0001)	-0.14 (<.0001)
VT	-0.13 (<.0001)	-0.13 (<.0001)
SF	-0.08 (0.0025)	-0.12 (<.0001)
RE	-0.08 (0.0056)	-0.12 (<.0001)
MH	-0.06 (0.0319)	-0.08 (0.0059)

PF: Physical Functioning; RP: Role-Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role-Emotional; MH: Mental Health.

On the group level, the regression analyses adjusted for demographics, other risk factors, and diabetes complications showed that adults with high-risk HbA_{1c} levels (≥70 mmol/mol) had lower levels of health-related quality of life than the well-controlled group (<52 mmol/mol) in most domains of the SF-36v2. Among participants with type 1 diabetes, the high-risk group had statistically significantly lower mean scores than the well-controlled group in five domains (RP, BP, GH, VT, and RE) and the MCS (Figure 8). For the participants with type 2 diabetes, the high-risk group achieved the statistically significantly lowest means in both MCS and PCS, and in all domains except BP (Figure 9).

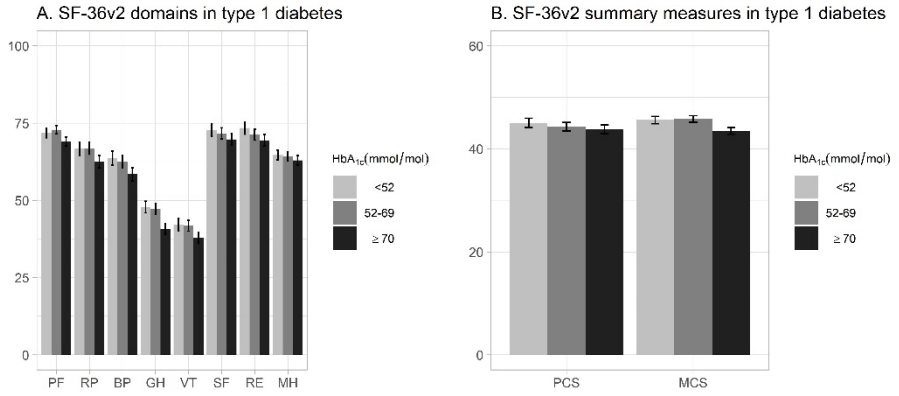

Figure 8. Adjusted regression analyses for HbA_{1c} level and SF-36v2 domains (A) and summary measures (B) in type 1 diabetes. Adjusted for age, sex, diabetes duration, body mass index, systolic blood pressure, LDL cholesterol level, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, receipt of antihypertensive and lipid-lowering treatments, previous coronary heart disease and previous stroke. PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health; PCS: physical component summary measure; MCS: mental component summary measure. Previously presented in Svedbo Engström et al. [140].

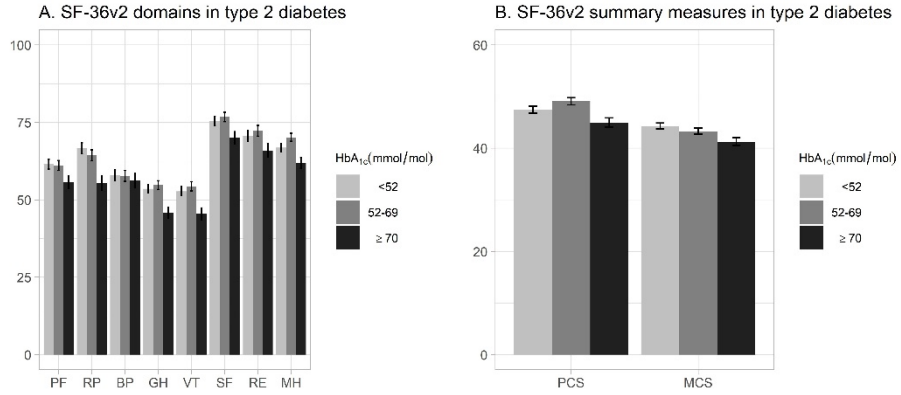

Figure 9. Adjusted regression analyses for HbA_{1c} level and SF-36v2 domains (A) and summary measures (B) in type 2 diabetes. Adjusted for age, sex, diabetes duration, body mass index, systolic blood pressure, LDL cholesterol level, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, receipt of antihypertensive and lipid-lowering treatments, previous coronary heart disease and previous stroke. PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health; PCS: physical component summary measure; MCS: mental component summary measure. Previously presented in Svedbo Engström et al. [140].

5 DISCUSSION

5.1 SUMMARY OF MAIN RESULTS

The main result of this thesis is the creation of the new diabetes-specific questionnaire, the Diabetes Questionnaire. The Diabetes Questionnaire was developed based on aspects identified as important to adults living with diabetes that embraces experiences of daily life with diabetes and support from diabetes care. The initial evaluations show supporting evidence for content and face validity, test-retest reliability, and that it is easy to understand and complete. In addition, the Diabetes Questionnaire was shown to capture some dimensions of generic health-related quality of life while also contributing diabetes-specific information that is not targeted by the traditional clinical variables covered in the NDR or the SF-36v2. Moreover, supporting evidence was found for the Diabetes Questionnaire to be sensitive to differences between clinically relevant groups of glycaemic control. It was also presented that adults with type 1 and type 2 diabetes who have a high-risk glycaemic control generally have lower self-reported generic health-related quality of life as measured by the SF-36v2, as compared with those with well-controlled glycaemic control.

5.2 ASPIRING TO ACHIEVE A SOUND BASIS IN PATIENTS' PERSPECTIVES AND WORDS

The ambition of the Diabetes Questionnaire has been to help bring the perspectives of adults living with diabetes (i.e. the patients) to the fore for diabetes care. The goal has been to create a tool that can support individual clinical meetings as well as the assessments and quality improvement efforts at different group levels. The most central prerequisite for the development of the questionnaire was to gain knowledge about what is important to those who live with diabetes [114, 115, 124, 126]. That it is important to base assessments on what the target group considers important in life is also a core characteristic of Sen's capability approach [117]. Sen provides a normative general frame of thought and not a ready-made recipe for application [116] and intentionally urges that the context and specific purpose need to be considered in the selection of what aspects to evaluate [119, 121, 122]. In line with recommendations for questionnaire development and Sen's capability approach, **study I** aimed to identify aspects important to adults living with type 1 or type 2 diabetes. The interviews gave unique descriptions of how life can be for these persons. Although their experiences varied considerably, these

unique descriptions also contributed to shared aspects that resulted in the derived main categories and categories. These main categories and categories subsequently served as the basis for the dimensions in the Diabetes Questionnaire in **study II**. The aspects identified in **study I** had similarities to the compiled body of research on the different features of living with diabetes and the support from diabetes care, which could be traced to reviews and position statements [3, 29-32]. A comprehensive review of the literature might have yielded comparable or related categories that could have acted as the base for the development of the questionnaire. However, a literature review would not have given the same sound base in regard to patient perspectives of today and would not have provided the words used by those who live with diabetes as the vital base for the wording of the Diabetes Questionnaire.

The importance of the words used in diabetes care has been emphasised in later years. The traditional use of language within the healthcare system often includes jargon that can be difficult to understand, can be disrespectful of the individual's autonomy, and be harmful (e.g. by inducing fear, guilt, or aggravate the power imbalance between diabetes care professionals and the person with diabetes). There needs to be more careful and reflective use of language that is easy to understand and that acknowledges the capacity of and efforts made by those who have diabetes. The words used (tacitly or implicitly) carry messages about attitudes and can have a strong impact on how individuals with diabetes view their diabetes and themselves. Moreover, it can influence their self-confidence and motivation in self-management, as well as in the prolongation of their health and wellbeing [141-145].

Questionnaires have traditionally been developed based on professional experience, preference, and research on which aspects are important or profitable to target, often using academic and professional jargon and vocabulary [146]. Assuredly, not by reason to make questionnaires irrelevant or difficult to understand, but rather because professional caregivers and researchers constitute a subculture with its interests and special vocabulary as other groups do in their area of specialised knowledge. However, that the target group can relate to the verbal phrasing of the questionnaire is, in addition to relevant content, an important foundation for a well-working questionnaire [114, 115, 126, 128]. Hence, the transcripts from the interviews in **study I** were as much needed to identify which aspects to target as to be the foundation for the phrasing. During the development, evaluation, and revision of the Diabetes Questionnaire in **study II**, special efforts were made to ensure that the wordings were easy to understand and relate to, and not to be disrespectful, offensive, or further augmenting the burden of diabetes.

5.3 SUPPORTING EVIDENCE OF MEASUREMENT QUALITY, SO FAR

The evaluation of evidence for validity and reliability is a complex and iterative process that takes place over a long time. The answer cannot be dichotomous (yes/no) as to whether a questionnaire is valid, but rather represents a continuous collection of supporting evidence using different methods and strategies on a wide range of aspects. Validity, in particular, cannot be proven and never questioned again [75, 123, 124, 127]. For the Diabetes Questionnaire, this thesis in conjunction with the work described by Borg *et al.* [130], merely serves as a starting point.

The content validity of the Diabetes Questionnaire relies on the interviews in **study I**. The evaluations in **study II** showed supporting evidence for content and face validity, and that the questionnaire is easy to understand, answer, and that it functions as intended. In addition, the response rates in the regional (~61%) and nationwide (~55%) surveys are quite high for surveys that are not part of a clinical trial, and therefore can be deemed a token of perceived relevance by the target group. The lower response rate in the nationwide survey might be related to a higher respondent burden given that two questionnaires were presented in the nationwide survey.

The choice of a joint questionnaire for type 1 and type 2 diabetes could be questioned, as there are many differences between the two conditions [2-4]. However, despite the differences, there are also shared challenges related to both types being life-long conditions with glucose regulation deficiencies that place demands on lifestyle and individual responsibility for daily self-management [2, 3, 6-8, 16, 30, 33]. There can also be noticeable differences within the same diabetes type. For example, there is a large variety in type 2 diabetes as to which medical treatments are needed and prescribed, and where different treatments can bring different challenges [3]. Another point to consider is that different diabetes types can be difficult to distinguish [4]. Type 1 and type 2 diabetes are both heterogeneous diagnoses, and the need and potential benefit for further detailed classifications are currently under discussion [147]. For the intended use as an integrated part of the NDR, the same questionnaire for both types had pragmatic benefits. The main aim has not been to enable comparisons between diabetes types; rather, the intention has been to enhance clinical usability and to be able to assess and describe both types in a similar manner. From the initiation of this project and further during the development and evaluation of the Diabetes Questionnaire, the question of whether the differences between diabetes types would be too large to overcome has been pondered by members of the research group and in the expert

consultations in **study II**. However, the interviews in **study I** and both the expert consultations and cognitive interviews in **study II** supported that the content items included in the questionnaire were relevant to both diabetes types. In addition, the evaluations performed in Borg *et al.* showed that most scales have equal performance for type 1 and type 2 diabetes and allow comparisons between diabetes types. However, it is important to note that for the ManD, NLBS, and MDMT scales, there were some differences in performance and therefore these cannot be used when comparing diabetes types [130].

The process of construction and evaluation of the scales in the Diabetes Questionnaire was conducted in Borg *et al.* [130] and will be presented in an upcoming thesis. To summarise, starting with the seven dimensions in the Diabetes Questionnaire, the scale construction and evaluation relied on the results from **study I** and **study II** but resulted in the need to split four dimensions into more than one scale, as previously shown in Figure 7. Unidimensionality, local dependency, and monotonicity were evaluated using non-parametric IRT. Factor analysis was conducted to determine whether there were more than one factor and to detect those items fitting to another factor. Parametric IRT was used to evaluate item fit and for fitting scale models to score the individuals' responses. Differential item fit (i.e. whether items have a different meaning for different groups of respondents) was evaluated for age above or below the median, sex, and diabetes type. The work by Borg *et al.* also included analyses of the distribution of response patterns and the standard error of the IRT scores, which together indicated that some scales (e.g. CoDC and NLBS) might have lower sensitivity to changes and produce uncertain predictions in the upper end of the scale [130]. This possibility is of course a limitation. However, from a clinical and quality improvement perspective, it is more important to be able to identify individuals and groups that have lower scores and to evaluate possible changes than to be able to differentiate between very good and excellent continuity.

Test-retest reliability (i.e. stability in scores when no change has occurred) is an important prerequisite for the ability of a questionnaire to be responsive to changes as they occur [123, 129]. The test-retest reliability of the Diabetes Questionnaire was preliminarily analysed on the item level in **study II** to determine the potential need for revisions before the nationwide survey to enable the scale construction and evaluation by Borg *et al*. [130]. The results from **study II** showed acceptable agreement and it was deemed that there was no need for further revision regarding this aspect before carrying out the larger survey. In Borg *et al.*, test-retest reliability was reanalysed on the scale level

using intra-class correlation. This analysis showed good or excellent agreement for most of the scales [130].

The evaluation of construct validity calls for a complex process that considers different aspects and for the questionnaire to be related to a variety of other measures [75, 114, 123, 125]. To initiate this process for the Diabetes Questionnaire, the questionnaire's scale scores in **study IV** were related to clinical variables relevant to diabetes care and generic health-related quality of life as measured by the SF-36v2. The findings of **study IV** provided supporting evidence for the questionnaire's construct validity. In addition to being sensitive to differences between clinically relevant groups of glycaemic control, it was clear that self-reports from the Diabetes Questionnaire adds information that is not covered by the clinical variables traditionally targeted by the NDR. The reverse was as clear; self-reports targeted by the Diabetes Questionnaire cannot be used as a proxy for the highly important medical risk factors. The findings support the need for a combination, which is concordant with international recommendations for diabetes care [3, 5, 8, 71-73].

Concerning the SF-36v2, it was concluded in **study IV** that the Diabetes Questionnaire captures some but not all covered dimensions of health-related quality of life. Moreover, and as expected, the Diabetes Questionnaire contributes diabetes-specific information that is not targeted by the SF-36v2 and thereby is more relevant for routine use in diabetes care. With that said, the results, however, do not preclude the potential benefit of using the SF-36v2 to some extent in diabetes care. Indeed, the results from **study III** indicate that the SF-36v2 adds information not covered by HbA_{1c} levels and to some degree can show differences between different groups of glycaemic control. Despite the criticism that the SF-36 is not specific enough for diabetes [61, 83, 87, 88, 148], it might be important to address the generic aspects of health-related quality of life at some intervals. After all, there might be aspects or consequences related to, or important for, diabetes and diabetes care that a disease-specific questionnaire does not fully target [75, 76, 83, 87, 88, 92]. In addition, when comparing with other groups that do not have diabetes or with people with diabetes in other countries, other measures are needed, given that the Diabetes Questionnaire is specific to diabetes and thus far only available in Swedish. However, the Diabetes Questionnaire is likely more useful for routine use in diabetes care and as a measure to be integrated into the NDR to enhance focus on daily life with diabetes and how diabetes care can support individuals with diabetes.

5.4 POTENTIAL CLINICAL IMPLICATIONS

Traditionally, the NDR has been a tool to assess important medical risk factors and processes of diabetes care. That the collected data also provide opportunities for research has been a bonus but never the driving motivation. Likewise, the Diabetes Questionnaire is primarily designed for clinical use and to evaluate diabetes care at the local, regional, and national levels. If used in the clinical meetings together with the clinical variables, the Diabetes Questionnaire has the potential to support the patient's voice, perspective, and expertise in the endeavour of creating a viable partnership between clinicians and those with diabetes. The patient story and partnership are emphasised characteristics in the ethics underpinning the growing movement towards person-centred care [149]. In addition, Swedish legislation calls for shared decision making and the individual patient's prerequisites and wishes to be considered [150]. At the same time, the unique responses to the Diabetes Questionnaire can contribute to the common picture when evaluating diabetes care at different group levels. From research on the organisation features of Swedish primary diabetes care, a need for novel strategies to support adults who do not reach the recommended treatment targets has been suggested [151-154]. The work presented, is a starting point for a broader evaluation of diabetes care in Sweden, an ambition that has been recognised in a recent review [155]. The Diabetes Questionnaire has been included in the national guidelines for diabetes care as the basis for developmental quality indicators [2]. Optimistically, the patient perspective will soon be upgraded to other established quality indicators in diabetes care. The Diabetes Questionnaire with its PROM and PREM components is not the only solution, but we believe it is an important contribution to learn more about how life with diabetes can be, can change for the better, and which strategies and support are needed.

For PROs to become part of the established outcomes of diabetes care and to be used in clinical practice can be motivated on ethical and philosophical grounds [3, 5, 8, 71-73]. The use of PROMs has been suggested to emphasise the patient's voice, needs, and resources [29, 155, 156], as well as to enhance communication, decision making [155-159], and patient-centred care [156, 159]. However, to what extent the use of PROMs can influence PROs has been questioned because of the often low quality of many studies [157, 160-162]. Consequently, more high-quality research is required. In addition, research must consider taking a broader range of potential effects into account [155, 157, 160-162]. Among other aspects, the effects of the use of PROs is suggested to depend not only on the quality and relevance of the PROMs but also on the organisational readiness, the willingness of professionals to use the PROMs, and on implementation strategies [155, 160, 161, 163]. Research that

can inform implementation strategies is therefore also warranted [155]. Since its inception, the NDR has been dependent on the willingness of individuals with diabetes to take part in the register and the commitment of local health care personnel in Swedish diabetes care. This dependence will also be true for the use of the Diabetes Questionnaire, which is currently digitally and freely available to all diabetes clinics connected to the NDR.

The Diabetes Questionnaire has the potential to enhance knowledge and understanding about life with diabetes, the interventions and support needed from diabetes care, and the relationships between patient perspectives and medical outcomes. The Diabetes Questionnaire might contribute to a broader perspective and a useful complement as national guidelines turn towards individualised goals and person-centred care. The previous focus on medical outcomes and care processes with fixed levels as indications of successful diabetes care might be somewhat misleading when used as the only measure. The reason for not fulfilling the target levels or the recommended choice of treatment might be the manifestation of individual goal-setting, patient autonomy, and other aspects of more person-centred care, which are other goals fulfilled that are difficult to consider in the traditional group-level assessments. Perhaps the Diabetes Questionnaire can be an asset in this regard.

Being an interdisciplinary or even post-disciplinary framework not tied to a special discipline or scientific tradition, Sen's capability approach is said to facilitate cooperation and to meet between traditions. In addition, the combination with other approaches, models, theories, or measures is encouraged [118, 120]. In a recent study, Borg *et al.* [164] make an interesting application when testing another potential asset of the Diabetes Questionnaire in group-level assessments. In that study, efficiency analysis was found to be a useful method in type 1 diabetes to combine PROM and PREM components from the Diabetes Questionnaire together with risk factors from the NDR as a way to evaluate diabetes care interventions from a health-economic perspective [164].

5.5 METHODOLOGICAL CONSIDERATIONS

5.5.1 STRENGTHS

One strength of this thesis is the collective efforts to achieve a sound base in patients' perspectives and to evaluate the measurement qualities of the Diabetes Questionnaire. A second strength is that several experts have been consulted along the way and that this effort has been made in conjunction with the NDR. A third strength is the large number of participating adults with either

type 1 or type 2 diabetes. In the surveys conducted in **studies II-IV**, these adults, selected at random, were representative of the NDR population. Two other strengths include access to clinical variables relevant to diabetes care from the NDR and the possibility to compare the respondents to non-respondents.

There have been several measures taken to strengthen different aspects of trustworthiness [127, 131, 165]. The present author was responsible for conducting the interviews in **studies I-II**, carrying out the expert consultations, and answered for the development of the Diabetes Questionnaire in **study II**. To strengthen the credibility by reducing the risk of too much influence from one individual, there were continuous discussions in the research group. In addition, several measures were taken to involve members of the target group, professionals from diabetes care, and other experts in the process. As a registered nurse with training in diabetes care but a lack of experience from living with diabetes and working with outpatient diabetes care or the NDR, there was a potential risk of missing certain aspects in the interviews in **study I**. However, the lack of those experiences was also an advantage that enabled a more neutral position characterised by curiosity and less preconceived ideas. Moreover, it allowed an environment with less state of dependence in which the participating individuals could speak freely to depict their situation and experiences of diabetes care without risking negative consequences. Time was spent on follow-up questions to be given concrete examples and to clarify and confirm understanding. The position turned less neutral in **study II** when the Diabetes Questionnaire was qualitatively evaluated. This circumstance was handled by encouraging all participants to speak freely, emphasising that all comments that would help in constructing a relevant and well-designed questionnaire were welcome. An indication that this succeeded is that the participants' comments were both negative and positive.

Credibility has also been strengthened by the sampling procedure in **studies I-IV** that sought heterogeneity, including perspectives from adults with diabetes and experts that, by their different characteristics, could add a variety of experiences and perceptions. In addition, to guide decisions on whether the qualitative data in **studies I-II** were sufficient, the data were monitored during the data collection process for breadth, depth, sample characteristics, and discussed at length in the research group. The credibility in the analysis process of **studies I-IV** was strengthened by research triangulation during analysis and dissemination of the text. Another measure that was considered to strengthen credibility in **studies I-IV** was that the responsibility taken by the doctoral student was guided by actions of the research group. By the time the qualitative parts were conducted, the nearest

group, which consisted of the doctoral student and the student's supervisors, included three registered nurses and one physician (the latter is also the director of the NDR). Later on, another physician reinforced the group of supervisors. Throughout the project, other colleagues were consulted and involved when needed, together representing a team with vast experience in diabetes care and research, the NDR, PROs, development and evaluations of questionnaires, design, data collection, and analyses in qualitative and quantitative research.

The confirmability of those aspects identified in **study I** as important to adults with diabetes was strengthened by the fact that the Diabetes Questionnaire in **study II** was perceived to have a comprehensive and relevant content. Measures that were taken in **study I** to strengthen confirmability were to illustrate that the results were based on the participants' narratives and vocabulary by describing the process from interview transcripts to the categorisation and by quoting the participants' words. Efforts to strengthen dependability were made by presenting transparent descriptions of the methods used in **studies I-IV**. In addition, in **studies I-II**, all interviews were conducted using interview guides to assure that all participants covered the same areas. However, because the insights and interview technique evolved, the richness in the participants' descriptions differed, and because the probing was situation-bound, there were differences between interviews.

The transferability from **study I** to the development of the Diabetes Questionnaire in **study II** relied on the sample heterogeneity, variety in participant experiences, and that a special effort was made to ensure that the content and verbal phrasing reflected the interview material in **study I**. The results from the surveys in **studies II-IV** could be deemed transferable to adults living with diabetes in Sweden because the respondents in terms of clinical and demographic data were representative of the NDR population and that the NDR had a coverage rate of about 90% at the data collection stages of the surveys. To facilitate for others to decide on potential transferability from **studies I-IV** to other groups or settings, efforts were made to give transparent descriptions of the methods and results.

5.5.2 LIMITATIONS

A limitation of **studies I-IV** is that the analyses were limited to those that chose to participate and who might represent individuals that, for different reasons, had greater motivation and the possibility to participate. Another limitation is that all studies were restricted to those speaking or reading Swedish. In **study I**, foreign-born persons were in the minority (3 out of 29 participants). For the surveys in **studies II-IV**, the proportion of foreign-born is unknown, and we

suspect that it might be higher among the non-responders. A further limitation of the surveys is that despite access to clinical variables relevant for diabetes care, there might be other variables not accounted for (e.g., comorbidities or socio-economic parameters) that might have influenced the results. The choice of using the SF-36v2 in **studies III-IV** present both strengths and limitations. While being a widely used and often recommended measure of health-related quality of life with supported measurement qualities, it has been questioned if it is specific enough with regard to diabetes. Furthermore, because a cross-sectional design was used, a causal relationship could not be determined.

6 CONCLUSION

In this thesis, the development and initial testing of the Diabetes Questionnaire are described. The Diabetes Questionnaire is based on aspects identified as important to adults living with diabetes and includes their experiences of daily life with diabetes and the support they receive from diabetes care. Supporting evidence is presented for content validity, face validity, test-retest reliability, and that it is easy to answer.

From the analyses on generic health-related quality of life using the SF-36v2, adults with high-risk glycaemic control have been shown to have lower health-related quality of life than those with well-controlled glycaemic control. Weak individual-level correlations argue for the need for diabetes care to also focus on self-reported aspects of life with diabetes.

When studying the relationships between the Diabetes Questionnaire, the clinical variables, and the SF-36v2, evidence in support of construct validity shows that the Diabetes Questionnaire captures some dimensions of generic health-related quality of life while also contributing diabetes-specific information not targeted by the clinical variables traditionally covered in the NDR or by the generic SF-36v2. In addition, supporting evidence is presented showing that the Diabetes Questionnaire is sensitive to differences between clinically relevant groups of glycaemic control.

The Diabetes Questionnaire is likely more useful than the SF-36v2 for routine use in diabetes care and as a measure to be integrated into the NDR to enhance focus on daily life with diabetes and how diabetes care can support individuals with diabetes. The Diabetes Questionnaire has the potential to be a tool in clinical meetings by highlighting what is important to the person with diabetes, as well as to be part of the established quality indicators for assessment and quality improvement, bringing patients' perspectives to the fore.

7 FUTURE PERSPECTIVES

This thesis and the work by Borg *et al.* [130] provide supporting evidence that the Diabetes Questionnaire works well and can contribute to a deeper and broader perspective of diabetes care. The implementation of the Diabetes Questionnaire has begun; however, to build evidence for a questionnaire is a complex and never-ending process. The measurement qualities addressed so far need to be reviewed regularly. For example, aspects important to adults with diabetes and the vocabulary used may change with the passage of time and new developments in diabetes care. In addition, the evaluation of construct validity has only just begun and there is more work needed that relates outcome from the Diabetes Questionnaire to different concepts and measures.

There are also measurement qualities not yet addressed [123]. A key aspect that should be evaluated is whether the Diabetes Questionnaire is responsive to changes in medical and nursing interventions as in quality improvement efforts. There is also a need to evaluate the feasibility to select individuals or groups based on their scores on the Diabetes Questionnaire, or their combination of questionnaire scores and clinical data, and to target and evaluate interventions. It is also important to evaluate to what extent adults with diabetes and professional caregivers can understand and relate to the scores and any future changes in scores. Ongoing work will render a description of the attitudes to and experiences of implementing and using the Diabetes Questionnaire from the perspective of adults with diabetes and professional care providers. For the scale scores, there is more work needed to study the possibility of comparing scales. In addition, the Diabetes Questionnaire needs to be made available to other languages spoken within Sweden. When translated, cross-cultural adaption need to be considered in order to achieve equivalence between the original and adapted versions.

To bring patients' perspectives to the fore have been the overall goal of this thesis. The implementation of the Diabetes Questionnaire enables us to learn more about life with diabetes, adequate support from diabetes care, and the questionnaire's relationship to other contemporary and future measures.

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APPENDIX

INTERVIEW GUIDE STUDY I (In Swedish)

Berätta lite om dig själv (familj, boende, jobb, intressen etc.)

Berätta om när du fick diabetes – hur länge sen? (tankar, känslor, reaktioner…)

Vilka personer i din omgivning känner till att du har diabetes? (familj, vänner, släkt, jobbet…) Hur ser dessa personer på att du har diabetes? (stöd/hjälp?)

Vilka reaktioner möts du av när du berättar att du har diabetes?

Berätta om en vanlig dag för dig (igår?) – från när du vaknar tills du går och lägger dig.

- Hur ofta tror du personer med diabetes i allmänhet tänker på diabetes? Hur ofta tänker du på diabetes?
- Vad du gör, hur du tänker och hur du hanterar din diabetes? Vanliga problem. Ge exempel.
- Vad är viktigt i vardagen för att du ska klara av din diabetes på ett bra sätt? Hur stödjer diabetesvården dig (i detta avseende)?
- Hur ligger ditt blodsocker vanligen under en dag? Vanligt med högt/lågt/svängande blodsocker? Hur känner du igen tecken?
- Blodsockerkontroller? Hur ofta och varför?
- Vad brukar påverka ditt blodsocker?
- Vad brukar du göra för att justera blodsockernivå?
- Vilka beslut som har att göra med din diabetes fattar du under en dag? På vilka grunder fattar du dessa beslut?
- Vad behöver du veta för att klara av din diabetes på ett bra sätt? Har du den kunskapen? Hur klarar du av att använda den kunskapen?
- Självständighet/hjälp från andra.
- Vad har du fått för stöd från diabetesvården för att kunna fatta beslut som har att göra med din diabetes? Skulle du behöva ytterligare stöd? I så fall vad?
- Om du behöver hjälp eller stöd – vad gör du då? (närstående, träffar andra med diabetes, via internet/sociala medier, verktyg?)

Berätta om dina besök till diabetesvården. (Diabetessjuksköterska, läkare etc., Vad fungerar bra? Vad fungerar inte bra? Vad får du för stöd? Berätta om vad du har för tankar när du går från besöken.) Om du fick bestämma, hur skulle du önska att diabetesvården fungerade?

Närstående – hur ser stödet ut till dem? Hur tänker du kring det?

Hur påverkas ditt liv och din vardag av att du har diabetes? (Dominerar diabetes? Hinder? Arbetssituation? Utbildning? Kan du göra det du vill/skulle vilja? Din ekonomi – Har din diabetes påverkat din ekonomi på något sätt? Påverkar din ekonomi din möjlighet att hantera din diabetes på något sätt?)

Var har du för tankar och funderingar kring din diabetes? (problem, oro, nedstämdhet, fri/bunden, framtid; tillförsikt/hopplöshet/ljus/mörk/livsglädje…)

Har du någon skada eller sjukdom som du fått till följd av att du har diabetes? Om ja, hur påverkar det ditt liv och din vardag? Om flera - vilken skada eller sjukdom inverkar mest på ditt liv och din vardag?

Berätta om vad som är viktigt för dig i livet, vad värderar du? Vad är livskvalitet för dig (”bra liv”)? (familj/arbete/fritid, vad tycker du om att göra?…)

Vad tycker du är viktigt för att du ska kunna leva ett så bra liv som möjligt med diabetes?

Vilka förutsättningar och möjligheter har du för att göra det du vill göra (som är viktigt för dig?)

Är det något mer som du skulle vilja berätta för mig, lägga till som du tycker är viktigt att jag känner till innan intervjun avslutas?

Får jag ta kontakt med dig igen om det skulle vara så att det dyker upp några frågor?

Skulle du vara intresserad av att ta del av och ge synpunkter på den patientenkät vi har som mål att utforma?

INTERVIEW GUIDE STUDY II (In Swedish)

Så här går det till

Du kommer att få besvara enkäten och jag kommer att be dig att tänka högt när du svarar på frågorna:

- Läs frågan högt
- Tänk högt och berätta för mig hur och vad du tänker på…
    - när du läser frågan – hur tänker du?
    - när du svarar på frågan – hur tänker du när du läser svarsalternativen? är det möjligt att välja ett passande svarsalternativ?

… tänk högt och berätta för mig oavsett om du tror att det är viktigt eller inte!

Berätta så snart du stöter på något problem!

Till exempel:

- om du tycker att det är svårt att förstå vad vi menar med frågan, är den otydlig eller förvirrande?
- om du tycker att svarsalternativen är otydliga, förvirrande eller om det inte finns något svarsalternativ som passar dig
- om frågan inte känns relevant att svara på/om frågan inte känns viktig att ha med i enkäten
- om det är någon fråga som det inte känns ok att svara på

Var inte rädd för att säga vad du tycker, det är mycket värdefullt för oss att få höra om alla dina åsikter och reaktioner!

Förutom att du får tänka högt och berätta om dina tankar så kommer jag också att ställa frågor till dig under tiden, till exempel:

- om hur du uppfattar vad frågan betyder
- hur du skulle upprepa frågan med egna ord
- om frågornas formulering är svåra eller lätta att läsa
- om du tycker att frågan är viktig att ha med i enkäten
- om det går att välja ett svarsalternativ som passar
- hur du tänkte när du valde svarsalternativ

Intervjun spelas in med ljud och jag kommer att föra anteckningar under tiden.

Vi håller på max en timme. Är vi klara innan dess så slutar vi när vi är klara.

Du behöver inte tänka på tiden och att vi ska hinna med så mycket som möjligt, det är mitt ansvar att styra. Vi hinner med så mycket vi hinner. Har vi inte hunnit med alla frågor när en timme har gått, så är det så.

Har du några frågor innan vi börjar?

Till mig själv

Starttid:

Sluttid:

Exempel probes att använda som stöd om ”tänka högt” inte fungerar bra eller inte ger en tillräcklig bild:

- Kan du upprepa frågan med dina egna ord?
- Vad tror du att vi menar med frågan?
- Hur kom du fram till det svaret?
- Hur säker är du på ditt svar?
- Hur relevant är frågan för dig?

Spontant och vid behov: om respondent hoppar över frågor, bläddrar fram och tillbaka, inte kan välja svarsalternativ, tvekar etc. ställs spontana och riktade frågor kring detta!

Specifika frågor kring frågor/formuleringar vi har särskilda funderingar kring, ex. kopplat till recall-period etc.

Fråga 1-5 handlar om hur du har haft det de senaste fyra veckorna – vad tycker du om den tidsperioden? Kommer du ihåg hur det har varit?

Avslutande frågor (efter att respondenten besvarat enkäten):

Vad skulle du tycka om att besvara dessa frågor inför ett besök hos läkare eller diabetessjuksköterska? Skulle det vara till någon nytta för dig?

Överlag, tycker du att enkäten är användbar för att få en beskrivning av hur du mår och får det att fungera med att ta hand om din diabetes samt det stöd du får av diabetesvården?

Om du tittar tillbaka på frågorna, tycker du att de är viktiga att ha med? Är det någon eller några frågor som du tycker är onödiga, som vi borde ta bort?

Är det någon/några frågor som var svåra att förstå eller konstigt formulerade?

Vad tyckte du om svarsalternativen? Fanns det alternativ som passade dig?

Är det någon/några speciella frågor som det inte känns ok att svara på?

Är det någon/några frågor som du tar illa upp av?

(Om det inte redan kommit upp: Vad skulle du tycka om att svara på de frågor som handlar om diabetesvården inför ditt besök och gå igenom svaren med din läkare eller diabetessjuksköterska?

Vad tycker du om antalet frågor? Är enkäten tillräckligt omfattande, eller är den för omfattande?

Är enkäten tillräckligt detaljerad, eller är den för detaljerad?

Vad skulle du ändra på om du ville förbättra instrumentet?

Hur tänker du kring att dina svar på en liknande enkät, tillsammans med svar från andra som också svarar på enkäten, samlas och används för att vara till hjälp för förbättringsarbete i diabetesvården och beskrivs i rapporter från Nationella Diabetesregistret, precis som det idag görs med dina blodsocker, blodtryck, behandling osv?

THE DIABETES QUESTIONNAIRE (In Swedish)

NDR NATIONELLA DIABETESREGISTRET

Enkät till dig som har diabetes

Den här enkäten har två delar. Den första delen handlar om hur du mår och hur du har det med din diabetes. Den andra delen handlar om hur diabetesvården stödjer dig i att ta hand om din diabetes.

Gör så här:

- *Kryssa i det svarsalternativ som stämmer bäst överens med din uppfattning.*
- *De första fem frågorna handlar om hur du har haft det de senaste fyra veckorna. Alla andra frågor gäller hur du har det just nu.*

DEL 1 - Om hur du mår och hur du har det med din diabetes

Frågor om hur du mår

1. **Hur har du mått rent allmänt de senaste fyra veckorna?**
   - □ Mycket bra
   - □ Ganska bra
   - □ Ganska dåligt
   - □ Mycket dåligt

2. **Hur har du sovit de senaste fyra veckorna?**
   - □ Mycket bra
   - □ Ganska bra
   - □ Ganska dåligt
   - □ Mycket dåligt

3. **Har du känt dig nedstämd de senaste fyra veckorna?**
   - □ Mycket sällan eller aldrig
   - □ Ganska sällan
   - □ Ganska ofta
   - □ Mycket ofta eller alltid

4. **Har det känts jobbigt att ha diabetes de senaste fyra veckorna?**
   - □ Mycket sällan eller aldrig
   - □ Ganska sällan
   - □ Ganska ofta
   - □ Mycket ofta eller alltid

5. **Hur har du orkat ta hand om din diabetes de senaste fyra veckorna?**
   - □ Mycket bra
   - □ Ganska bra
   - □ Ganska dåligt
   - □ Mycket dåligt

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Frågor om oro

6. Oroar du dig för att få för lågt blodsocker?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

7. Oroar du dig för att ditt blodsocker ligger för högt?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

8. Oroar du dig för att din diabetes kan orsaka andra sjukdomar eller skador på din kropp?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

Frågor om dina möjligheter att ta hand om din diabetes

9. Hur tycker du att dina kunskaper är för att ta hand om din diabetes?
- □ Mycket bra
- □ Ganska bra
- □ Ganska dåliga
- □ Mycket dåliga

10. Hur fungerar det för dig att ta hand om din diabetes i vardagen?
- □ Mycket bra
- □ Ganska bra
- □ Ganska dåligt
- □ Mycket dåligt

11. Hur fungerar det för dig att ta hand om din diabetes när dina vanliga rutiner är svåra att följa?
- □ Mycket bra
- □ Ganska bra
- □ Ganska dåligt
- □ Mycket dåligt

12. Hur får du det att fungera med att äta på ett sätt som du tror är bra för just dig?
- □ Mycket bra
- □ Ganska bra
- □ Ganska dåligt
- □ Mycket dåligt

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13. Hur får du det att fungera med att röra på dig så mycket som du tror är bra för just dig?
- □ Mycket bra
- □ Ganska bra
- □ Ganska dåligt
- □ Mycket dåligt

Frågor om hinder

14. Hindrar din diabetes dig från att göra det du vill?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

15. Är din diabetes ett hinder i umgänget med familj, vänner och andra?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

16. Hur ofta är du hindrad från att göra det du vill för att ditt blodsocker är för lågt?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

17. Hur ofta är du hindrad från att göra det du vill för att ditt blodsocker är för högt?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

18. Hur ofta är du hindrad från att göra det du vill för att ditt blodsocker svänger mellan att vara högt och lågt?
- □ Mycket sällan eller aldrig
- □ Ganska sällan
- □ Ganska ofta
- □ Mycket ofta eller alltid

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Frågor om stöd från andra

19. Hur bra stöd för att ta hand om din diabetes får du från familj, vänner och andra som står dig nära? *Om du inte vill ha eller inte behöver något stöd, kryssa "Inte aktuellt".*

□ Mycket bra
□ Ganska bra
□ Ganska dåligt
□ Mycket dåligt
□ Inte aktuellt

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20. Hur bra stöd för att ta hand om din diabetes får du från andra personer som du möter i din vardag? Vi syftar på bekanta, arbetskamrater och andra. *Om du inte vill ha eller inte behöver något stöd, kryssa "Inte aktuellt".*

□ Mycket bra
□ Ganska bra
□ Ganska dåligt
□ Mycket dåligt
□ Inte aktuellt

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21. Hur bra stöd för att ta hand om din diabetes får du från andra som också har diabetes? *Om du inte vill ha eller inte behöver något stöd, kryssa "Inte aktuellt".*

□ Mycket bra
□ Ganska bra
□ Ganska dåligt
□ Mycket dåligt
□ Inte aktuellt

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DEL 2 - Om hur diabetesvården stödjer dig i att ta hand om din diabetes

Frågor om stöd från diabetesvården

22. Får du det stöd du behöver från diabetesvården?
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig

23. Är det lätt att få kontakt med diabetesvården när du behöver hjälp med din diabetes?
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig

24. Får du komma till sjuksköterska för din diabetes så ofta som du tycker att du behöver? *Om du inte går hos sjuksköterska för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

25. Får du komma på en tid som passar dig när du ska till sjuksköterska för din diabetes? *Om du inte går hos sjuksköterska för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

26. Får du, om du vill, träffa samma sjuksköterska vid besöken för din diabetes? *Om du inte går hos sjuksköterska för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

27. Får du komma till läkare för din diabetes så ofta som du tycker att du behöver? *Om du inte går hos läkare för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

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28. Får du komma på en tid som passar dig när du ska till läkare för din diabetes? *Om du inte går hos läkare för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

29. Får du, om du vill, träffa samma läkare vid besöken för din diabetes? *Om du inte går hos läkare för din diabetes, kryssa "Inte aktuellt".*
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig
- □ Inte aktuellt

30. Får du prata om det som är viktigt för dig vid besöken för din diabetes?
- □ Ja, alltid
- □ Ja, oftast
- □ Nej, inte så ofta
- □ Nej, aldrig

Frågor om hjälpmedel och medicinsk behandling

31. Hur nöjd är du med de hjälpmedel du har för att mäta ditt sockervärde? *Om du inte har några hjälpmedel för att mäta sockervärde, kryssa "Inte aktuellt".*
- □ Mycket nöjd
- □ Ganska nöjd
- □ Inte så nöjd
- □ Inte alls nöjd
- □ Inte aktuellt

32. Hur nöjd är du med de hjälpmedel du har för att ta insulin (till exempel insulinpenna eller insulinpump)? *Om du inte tar insulin, kryssa "Inte aktuellt".*
- □ Mycket nöjd
- □ Ganska nöjd
- □ Inte så nöjd
- □ Inte alls nöjd
- □ Inte aktuellt

33. Hur nöjd är du med den läkemedelsbehandling du har? Frågan avser alla läkemedel du tar. *Om du inte tar några läkemedel, kryssa "Inte aktuellt".*
- □ Mycket nöjd
- □ Ganska nöjd
- □ Inte så nöjd
- □ Inte alls nöjd
- □ Inte aktuellt

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MAIN PARTS, DIMENSIONS, AND ITEMS OF THE DIABETES QUESTIONNAIRE (In English*)

**This translation is only given for publication reasons and it does not present a validated translation.*

Part 1 – About how you feel and how things are going with your diabetes

Questions about how you feel

1. How have you felt in general in the past four weeks?
2. How have you slept in the past four weeks?
3. Have you felt depressed in the past four weeks?
4. Has having diabetes been difficult in the past four weeks?
5. How have you been dealing with your diabetes in the past four weeks?

Questions about your worries

6. Do you worry about getting too low blood sugar?
7. Do you worry that your blood sugar is too high?
8. Do you worry that your diabetes can cause other diseases or injuries?

Questions about your capabilities to manage your diabetes

9. Do you think your knowledge is sufficient to care for your diabetes?
10. How do you deal with your diabetes on a day-to-day basis?
11. How do you deal with your diabetes when your ordinary routines are difficult to follow?
12. How do you manage to eat in a way that you believe is good for you?
13. How well are you able to stay as physically active as you believe is good for you?

Questions about barriers

14. Does your diabetes prevent you from doing what you want?
15. Does your diabetes pose as an obstacle to spending time with your family, friends and others?
16. How often does low blood sugar prevent you from doing what you want?
17. How often does high blood sugar prevent you from doing what you want?
18. How often are you prevented from doing what you want because your blood sugar fluctuates between high and low levels?

Questions about support from others

19. How helpful is the support for your diabetes care from family, friends and others close to you?

20. How well do other persons that you meet in your daily life support you in dealing with diabetes?
21. How well do other people who also have diabetes support you in dealing with your diabetes?

Part 2 - About how diabetes care providers support you in dealing with your diabetes

Questions about support from diabetes care providers

22. Do you get the support you need from your diabetes care provider?
23. Is it easy to contact your diabetes care provider when you need help with your diabetes?
24. Are you able to see a registered nurse as often as you feel is necessary for your diabetes?
25. Are you able to make visits with your registered nurse that fit your schedule?
26. If you prefer, are you able to see the same registered nurse for your diabetes at every visit?
27. Are you able to see a doctor as often as you feel is necessary for your diabetes?
28. Are you able to make visits with your doctor that fit your schedule?
29. If you prefer, are you able to see the same doctor for your diabetes at every visit?
30. Are you able to talk about matters that are important to you at the appointments about your diabetes?

Questions about medical devices and medical treatment

31. How satisfied are you with the medical devices available for you to monitor your blood sugar level?
32. How satisfied are you with the medical devices that you have available for you to take insulin (for example, an insulin pen or insulin pump)?
33. How satisfied are you with your medication treatment? The question concerns all the medications that you take.