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THE USE OF SYSTEMATIC APPROACHES TO PATIENT INVOLVEMENT IN THE DEVELOPMENT AND EVALUATION OF A PATIENT REPORTED OUTCOMES TOOL FOR USE IN ROUTINE DIABETES CARE

BY
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CV

Søren E. Skovlund is currently a senior research scientist at the Department of Endocrinology at Aalborg University Hospital (AAUH) and the Department of Clinical Medicine at Aalborg University (AAU) in Aalborg, Denmark.
He has conducted research in the fields of person-centered diabetes care, health psychology and patient reported outcomes (PRO) in diabetes for 2 decades.

Since 2017, he has been the PRO-lead of the Value-Based Health Care and PRO in Diabetes project (VBS-PRO-DIA) at Aalborg University Hospital and has managed scientific and participatory aspects of the development of the Danish PRO diabetes questionnaire and clinical digital dialogue tool, *DiaProfil* in collaboration with Region North Denmark, the Danish Health Data Authority, the national PRO diabetes working group and the Danish Diabetes Association.
Skovlund completed his Master of Science in psycho-neuro-immunology at the August Krogh Institute at the University of Copenhagen, Denmark in 1996 and a supplementary degree in psychology from the Institute of Psychology at University of Copenhagen, Denmark in 1999.
Skovlund has co-authored more than 50 papers within the field of person-centered care and psychosocial aspects of diabetes and chronic illness and has been part of the development of multiple PRO diabetes questionnaires which are used widely today.

Skovlund has been actively involved in supporting international research collaborations to advance the delivery of person-centered diabetes care the past two decades through the Psychosocial Aspects of Diabetes Study Group of the European Association of the Study Of Diabetes (EASD) and the Behavioral Research In Diabetes Group Exchange Group. He was a co-developer of the European Patient Academy for Therapeutic Innovation (EUPATI), the Global Quality Guidance Framework for Patient Involvement Patient Focused Medicines Development (PFMD), and the global standard outcome measurement set for diabetes published in 2020 by the International Consortium for Health Outcomes Measurement (ICHOM).

ENGLISH SUMMARY

This PhD thesis includes three studies and four papers which were done as part of the development and initial evaluation of the Danish diabetes Patient Reported Outcome (PRO) questionnaire and a digital PRO dialogue tool, *DiaProfil*, for routine diabetes care in Denmark. The thesis focuses on the systematic use of patient involvement.
The overall aim of the research was to develop a PRO diabetes tool, improve active participation of people with diabetes (PWD) regarding their care, improve the quality of the dialogue between PWD and health care professionals (HCP), and help individualize care based on what generates most value for the individual.

The first study (study I) used systematic patient involvement methods to define a core set of diabetes outcome constructs for use in Denmark for value-based diabetes care which explicitly reflects the priorities of PWD. The study found that according to PWD both clinician and patient reported outcomes are required to adequately evaluate outcomes of diabetes care in Denmark. Multi-stakeholder consensus was reached for a first Danish national set of patient-important diabetes outcomes which require the assessment of psychological well-being, diabetes related distress and quality of life, symptom distress, medicine experience, confidence in self-management and access to person-centered diabetes care and support[1] beyond existing clinical outcomes (primarily A1c, late stage complications and hospitalization).

The second study (study II) aimed to evaluate feasibility, acceptability, benefits and risks, and implementation barriers and facilitators of the PRO diabetes tool among PWD and HCP in routine outpatient diabetes care. The study was a clinical single-arm mixed-method pilot study designed as part of the iterative formative evaluation of the Danish PRO tool with PWD as partners to guide refinement and larger scale evaluation of the PRO diabetes tool. The study found that the PRO diabetes questionnaire and the digital dialogue tool were both feasible, acceptable and appropriate for use by PWD and HCP in routine visits. The study also provided initial confirmation that the PRO tool can improve the active participation of the PWD in own care and the quality of the dialogue by increasing focus during the visit on what matters most to the PWD[2].

The third study (study III) involved the design of a study protocol and Likert-scale evaluation questionnaires for assessment of psychometric and clinical validity, reach, perceived effectiveness, and barriers and facilitators to implementation in different

health care settings in Denmark. A single-arm mixed-method multi-center implementation study protocol (M-PRODIA) and psychometrically tested evaluation questionnaires were developed using the RE-AIM (Reach, Efficacy, Adoption, Implementation and Maintenance) framework and methods for patient involvement. The study protocol was implemented nationally in 2020 with collection of qualitative and quantitative PRO and PRO evaluation data from more than 550 PWD and 30 HCP in hospital, municipality and primary care settings over the course of one year[3].

In addition to the three main studies, this thesis includes a narrative review paper (the fourth paper), which synthesizes recent studies and methodological developments within the specific field of research pertaining to use of PRO in routine diabetes care. This paper presents recommendations, tools and best practice cases pertaining to the design of digital PRO tools for use in diabetes care with systematic involvement of PWD and HCP in the process[4].

This thesis led to identification of patient-important PRO constructs for use in value-based diabetes care in Denmark, confirmed that the Danish PRO diabetes tool is acceptable and feasible for use in routine visits according to both PWD and HCP and identified how the tool may benefit PWD and improve the quality of diabetes care.
The studies applied systematic approaches to involvement of PWD and demonstrated the importance of soliciting the experiences and views of PWD during the design and the evaluation of PRO tools intended for routine care.
The final Danish PRO diabetes questionnaire was approved and recommended for national use by the steering group for PRO under the Danish Ministry of Health and the Danish Health Data Authority in March 2021. Implementation of the tool is now underway in several health care settings.

It is my hope that the methods for involvement of PWD in the design of the Danish PRO diabetes tool presented in this thesis and the initial study results regarding hypothesized benefits of using the PRO diabetes tool in practice can inspire future research in patient involvement and effectiveness of PRO tools for use in clinical practice.

DANSK RESUME

Denne Phd afhandling indeholder 3 studier og 4 artikler, der er udført som del af den videnskabelige udvikling og initiale evaluering af det danske PRO diabetes spørgeskema og et digitalt PRO dialogværktøj, *DiaProfil* til brug i den rutinemæssige diabetesbehandling. Afhandlingen fokuserer på anvendelsen af systematiske tilgange til brugerinvolvering i udviklingen. Det overordnede formål med arbejdet var at udvikle et PRO diabetes værktøj, der kan styrke den aktive deltagelse af personer med diabetes i egen behandling, forbedre kvaliteten af dialogen mellem borger og behandler og målrette behandlingen ud fra hvad der skaber mest værdi for den enkelte.

Det første studie anvendte metoder til systematisk patientinvolvering til at definere det første danske sæt af effektmål til brug i værdibaseret diabetesbehandling som reflekterer personer med diabetes' perspektiv og prioriteter. Studiet viste, at ifølge personer med diabetes bør evaluering af diabetesbehandlingen indbefatte både kliniske og patient-rapporterede effektmål. Studiet første til national ekspert konsensus om et set patient-vigtige effektmål for diabetes som udover etablerede kliniske kvalitetsindikatorer såsom blodsukkerregulering, senfølger og hospitalisering indbefatter psykologisk velbefindende, diabetes relateret stress og effekt på livskvalitet, symptombelastning, medicin oplevelse, tiltro til egenomsorgsevne og tryghed ved adgang til personcentreret behandling og støtte.

Det andet studie evaluerede feasibility og acceptabilitet, gavn og risici samt hæmmere og fremmere for implementering af PRO diabetes værktøjet i den rutinemæssige diabetesbehandling. Studie var designet som et enkelt-arms mixed-method pilot studie i samarbejde med personer med diabetes og indgik i den iterative formative evaluering af PRO diabetes værktøjet med henblik på at underbygge designet af et større evalueringsstudie. Studiet viste, at PRO diabetes spørgeskemaet samt den digitale PRO løsning, *DiaProfil* var anvendelige og acceptable til brug i praksis for både personer med diabetes og sundhedsprofessionelle i rutinemæssige diabeteskonsultationer. Studiet underbyggede derudover hypoteserne, at PRO diabetesværkøjet kan føre til at personen med diabetes er mere aktivt deltagende i egen behandling og forbedre kvaliteten af dialogen mellem borger og behandler ved at fremme fokus på hvad der er vigtigst for den enkelte person.

Det tredje studie indbefattede designet af en studie protokol og Likert-skala spørgeskemaer til evaluering af udbredelse, oplevet effekt og gavn og fremmere og

hæmmere af implementering samt psykometrisk og klinisk validitet af PRO diabetes redskabet i flere sundhedssektorer i Danmark. En protokol for et enkelt-arms mixed-method implementerings studie (M-PRODIA) blev designet og psykometrisk afprøvede skemaer blev udviklet med udgangspunkt i RE-AIM (Reach, Efficacy, Adoption, Implementation and Maintenance) metoderammen og ved brug af systematisk patientinvolvering. Studieprotokollen blev implementeret nationalt i 2020 hvor kvalitative og kvantitative data PRO og PRO evalueringsdata blev indsamlet fra flere end 550 personer med diabetes og 30 sundhedsprofessionelle fra både hospital, kommune og almen praksis over en pilot periode på 1 år.

Udover de 3 studier, indbefatter afhandlingen en narrativ oversigtsartikel, der sammenfatter de nyeste studier og metodemæssige udviklinger indenfor det specifikke forskningsfelt for brug af PRO i den rutinemæssige diabetesbehandling. Artiklen indbefatter anbefalinger, værktøjer og illustrative best practice cases for udviklingen af PRO værktøjer til klinisk brug ved hjælp af systematisk involvering af personer med diabetes.

Studierne i afhandlingen har identificeret patient-vigtige effektmål til brug i værdibaseret diabetes behandling i Danmark, bekræftet at det danske PRO diabetes værktøj opleves som anvendeligt og acceptabelt i rutinemæssige diabetessamtaler og har potentialet til at gavne personen med diabetes og behandlingskvaliteten.
Studierne anvendte systematiske metoder til patient involvering og viser vigtigheden af at anvende erfaringer og perspektiver fra personer med diabetes i udviklingen af PRO redskaber til klinisk brug. Det danske PRO diabetes spørgeskema blev godkendt og anbefalet til nationalt brug af Sundhedsministeriets styregruppe for PRO samt af sundhedsdatastyrelsen i marts 2021 og implementering er allerede i gang flere steder.

Det er mit håb at de anvendte metoder til involvering af personer med diabetes i designet af PRO diabetes værktøjet samt de initiale resultater angående PRO-værktøjets forventede gavn i klinisk praksis kan inspirere fremtidig forskning i patient involvering og effektevaluering af PRO i praksis.

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PREFACE

My past experiences of working to understand and amplify the perspective of people with diabetes in diabetes research and health care in order to improve access to person-centered diabetes care and treatments has shaped my approach to the research studies in this thesis.

Through my work as co-principal investigator and study lead of the Diabetes Attitudes Wishes and Needs (DAWN) studies [5–7], I have gained substantial experience involving a wide range of diabetes stakeholders in society including People With Diabetes (PWD) in a participatory design of a global research protocol to advance person-centered diabetes research and care[8]. The study involved diabetes population surveys in 17 countries with PRO questionnaires, and the results were used to guide national strategies to increase delivery of person-centered and psychosocial diabetes care [5].

Through my work as co-developer of multiple diabetes-specific PRO questionnaires for research and care, I have obtained hands-on experience regarding the use of interviews, focus groups, literature analysis, and surveys as well as psychometric and statistical methods for psychometric development and validation of diabetes PROs. Working as a PRO researcher from within the clinical diabetes care team at the Department of Endocrinology at Aalborg University Hospital for the past 3.5 years has provided a unique environment for mutual learning and innovation in relation to finding ways to put the perspective of both PWD and clinicians center stage in the detailed process of development and evaluation of a digital PRO tool for clinical use. A foundation for my research continues to aim at involving PWD and other relevant stakeholders as equal partners in all research phases.

I started as the PRO lead in the clinical care team at Aalborg University Hospital (Aalborg, Denmark) in 2017 and had the responsibility for conceptualizing, planning, designing, and carrying out patient involvement research studies to support each phase of the conceptualization, development and evaluation of the Danish PRO diabetes questionnaire and a new digital PRO dialogue tool (*DiaProfil*). These tools were to be used on a large scale to advance value-based person-centered diabetes care in Denmark.

At the end of 2017, I undertook the first study involving PWD to identify the basis for using PRO and clinical indicators for evaluating outcomes for diabetes in Denmark.

In 2018, I developed the scientific methods and participatory strategies that supported the national iterative participatory development process for the Danish PRO diabetes questionnaire.

In 2019, I oversaw the scientific finalization of the new digital PRO diabetes tool, *DiaProfil* for use by health professionals and conducted the first clinical pilot study of the PRO diabetes questionnaire. I then conceptualized and designed study III — the multi-center pilot study protocol, M-PRODIA — using the implementation framework of RE-AIM as a guide as we developed a series of psychometric evaluation questionnaires for use by PWD, HCP, and diabetes centers.
In 2020, I oversaw the scientific collection of quantitative and qualitative data for the multi-center pilot study at 7 diabetes centers across 3 Danish regions.
In January 2021, I conducted preliminary scientific analyses using the study data for use in the national evaluation report of the Health Data Authority. The report concluded that the PRO diabetes tool was acceptable, feasible and perceived as value-adding for use in routine diabetes by the participating diabetes clinics and centers.

This thesis includes three selected studies and four papers which were conceived and done by the author of this thesis from June 2017- February 2021 at AAUH (Aalborg University Hospital, Denmark) and AAU (Aalborg University, Denmark) in continuous collaboration with the clinical diabetes care team at AAUH.

Most of the research undertaken for the development and evaluation of the PRO diabetes tool is still ongoing. This thesis therefore presents only a subset of the overall work and focuses specifically on the systematic approaches to patient involvement.

The main research questions that are addressed are:

- Which diabetes outcomes are important to measure in routine diabetes care from the perspectives of PWD and their family members and other stakeholders?
- Is the Danish PRO diabetes tool feasible and acceptable for use in routine diabetes care visits? Does the PRO diabetes tool improve active participation of PWD in their care and improve the quality of dialogue between PWD and HCP? What are the possible mechanisms of actions?
- How can experiences of PWD and HCP related to the validity, acceptability, efficacy and implementation of the PRO diabetes tool be assessed as part of real-world testing in routine diabetes care?

Study I presents the first nationally endorsed set of outcome constructs for use in diabetes care which reflects the priorities and perspectives of PWD in Denmark.
Study II presents the first initial evaluation of acceptability and hypothesized impacts of the use of PRO diabetes tool when used in standard outpatient diabetes care visits.
Study III describes a mixed-method study protocol including purpose-built

psychometric evaluation questionnaires and data collection tools guided by the RE-AIM framework to enable evaluation of implementation and public health impact potential of the PRO diabetes tool across multiple health care settings.
Paper IV presents a narrative review of the emerging new research field pertaining to the integrated use of digital PRO tools in coordinated diabetes care [4].

The funding for the work presented in this thesis was provided by Region North Denmark and the Danish Health Data Authority.

The thesis includes the following original papers:

1. Skovlund, S.E., Troelsen, L, Klim, L., Jakobsen, P.E., Ejskjaer, N.
   The development of a national core set of person-centered diabetes outcome constructs for use in routine diabetes care across healthcare sectors. *Submitted to* BMC Patient Research Involvement and Engagement Journal. February 25, 2021.

2. Skovlund, S.E., Troelsen, L, Noergaard, L.M., Pietraszek, A., Jakobsen, P.E., Ejskjaer, N.
   Feasibility and Acceptability of a Digital Patient Reported Outcomes (PRO) Tool in Routine Outpatient Diabetes Care: A Mixed-Method Formative Pilot Study. *Submitted to* JMIR Formative Research Journal, March 1, 2021.

3. Skovlund, S.E., Nicolucci, A., Balk-Møller, N.C., Berthelsen, D.B., Glümer, C, Perrild, H, Nørgaard, L.M., Troelsen, L., Kjær, P., Pietraszek, A., Hessler, D. Kaplan, S., Ejskjaer, N.
   Perceived Benefits, Barriers and Facilitators of a Digital Patient Reported Outcomes (PRO) Tool in Routine Diabetes Care: A National Multi-Center Mixed-Method Pilot Study (M-PRODIA). *Submitted* to JMIR Journal of Research Protocols, March 4, 2021.

4. Skovlund, S. E., Lichtenberg, TH., Hessler, D. Jakobsen, P.E., Ejskjaer, N.,
   Can the Routine Use of Patient-Reported Outcome Measures Improve the Delivery of Person-Centered Diabetes Care? A Review of Recent Developments and a Case Study. Published in Current Diabetes Reports. 19, 9, 18 s., 84. 2019.

READING GUIDE

This thesis consists of five main parts:

CHAPTER 1. INTRODUCTION AND BACKGROUND

In chapter 1 the unique challenges of both living with and managing diabetes as well as the need for multi-stakeholder collaboration in the design of a national PRO tool aimed at facilitating value-based, person-centered diabetes care are introduced. This chapter briefly highlights some of the key methodological frameworks which were important for the design of the research studies in the thesis.

CHAPTER 2: THE DEVELOPMENT OF THE PRO DIABETES TOOL

Chapter 2 provides the necessary context for understanding the role of the three studies in this thesis in the broader development of the Danish PRO diabetes questionnaire and the digital PRO tool, *DiaProfil*. The chapter summarizes the key steps of the national PRO diabetes development program from 2017-2021 with emphasis on the use of systematic methods for patient involvement in each phase by the author of this thesis.

CHAPTER 3: SUMMARY OF THE THREE ORIGINAL STUDIES

Chapter 3 introduces the three studies of the thesis and provides a commentary on their aims, methods and key findings.

CHAPTER 4 IMPLICATIONS

Chapter 4 summarizes the key contributions of the research in this thesis and the implications for future research and care improvement.

CHAPTER 5 CONCLUSIONS

Chapter 5 briefly summarizes the main conclusions of the thesis.

CHAPTER 1. INTRODUCTION AND BACKGROUND

1.1. THE CHALLENGE OF LIVING WITH AND MANAGING DIABETES

Diabetes is a lifelong, demanding, self-managed chronic illness which affects multiple aspects of life [9]. Many People With Diabetes (PWD) experience negative impacts on their quality of life and are at high risk of acquiring late-stage complications due to gaps in access to coordinated person-centered diabetes care and support and due to psychosocial barriers to effective self-management. Extensive research regarding the lived experience of PWD and Family Members (FM) demonstrates that living with diabetes is often associated with a broad impact on most aspects of life over the course of the illness and a need for more support than is provided from traditional health care [6–12]. Both PWD and FM report major impacts and challenges in daily life related to diabetes which vary over the life span [6,13–15].

Depending on the progression of the disease, treatment intensity and modalities [16,17], and presence of comorbidities [7], diabetes can impose highly burdensome self-management demands [18,19], disabling side-effects from treatment [20,21], and affect both psychosocial well-being and health related quality of life overall [7,22].

1.2. THE NEED FOR MULTI-DISCIPLINARY AND WHOLE-PERSON CENTERED DIABETES CARE

To improve outcomes for PWD, care services are required which provide individualized [23], collaborative, person-centered [5,24,25] and psychosocial [5,7,26–28] diabetes care as feasible with the available healthcare resources [29,30].

Many PWD do not receive the level of individualized care and self-management and psychosocial support they need to achieve optimal care outcomes [7,31]. While numerous strategies and theory-based interventions have been developed for empowerment, problem-solving, peer support, self-management, and psychosocial support [32–35], the integration of such strategies in standard care that ensures access to all PWD has proven extremely challenging [32,34,36–38].

New feasible tools and strategies are required which can increase active involvement of PWD in their own care [5], improve coordination of care from the multi-disciplinary team [39] around the full range of needs of the PWD and FM and integrate ongoing self-management and psychosocial support into the standard diabetes care process [27,40].

It is important for future care tools to facilitate inclusion of PWD as equal partners in the planning of their own care including the definition of personal care goals [5,41].

Models for diabetes self-management highlight the multi-faceted role of biological factors, health beliefs, self-efficacy, interpersonal care quality, and social environmental influences on health behaviors and diabetes outcomes [42].

Providing information and multi-level support for autonomy and disease mastery to PWD and FM so they can be as actively engaged in the management of diabetes as they wish should be a key aim of efforts to improve outcomes of diabetes [5,34,43–45]. A multi-sector, whole-of-society approach to care, health promotion and prevention for diabetes is required which reflect the complexity of the illness and the interplay of everyday life circumstances, psychosocial, community and societal factors involved with diabetes treatment and self-management [46–50].

The WHO framework for innovative chronic illness care highlights the need for a systemic multi-level integrated care approach for chronic illness based on a person-centered approach that optimizes outcomes for PWD over the life span [39,51].

There is no single agreed definition of person-centered care or theory for person-centered diabetes care. The terms are often used to refer to an approach or a paradigm of care which acknowledges the priorities, rights, values, and preferences of patients. In this thesis, the terms “person-centered care” and “person-centered diabetes care” are used this thesis to refer to “care that is organized around understanding and meeting the needs, values and preferences of the individual patient and family members involved” [52]. Person-centered care in this thesis refers to an approach to care which puts focus on respectful engagement of PWD and FM as partners using a whole-person approach. One of the more widely adopted and supported concrete definitions of person-centered care highlights six main dimensions (Institute of Medicine Report (IOM) [52]: “1.Respect for the patients’ values, preferences, and expressed needs; 2.Coordination and integration of care; 3. Information, communication, and education; 4. Physical comfort; 5. Emotional support — relieving fear and anxiety; and 6. Involvement of family and friends “ [52].

The concept of person-centered diabetes care used in this thesis is aligned with the values outlined by the IOM [52] and is supported by person-centered diabetes research undertaken over the past two decades which provide empirical and theoretical support for many of the proposed components [5,23]. As previously published by the author, person-centered diabetes care should, to be true to its foundation on interpersonal relations and collaboration, be seen as a dynamic process which involves a continual learning cycle fueled by the active involvement of stakeholders across the whole support network [5]. Key elements of person-centered diabetes care supported by research involving PWD and FM as partners include [5]:

1) *Person-centered diabetes communication* [53,54]. Active listening, empathy, respect, sharing and explanation of information, support for autonomy and collaborative care represent important components of person-centered diabetes care which are important to PWD. General best practice recommendations for person-centered communication were defined by King et al as follows: "(1) fostering the relationship, (2) gathering information, (3) providing information, (4) making decisions, (5) responding to emotions, and (6) enabling disease- and treatment-related behavior" [53].

Person-centered communication involves consideration of PWD's own resources, support systems and successes [55] in care and focus on the PWD's perspective and decisions [56].

2) *Care focused on the "whole person"*, entails consideration of the overall health and life situation of both PWD, their FM and caregivers. This focus takes into account all relevant physical, social, psychological and life circumstance factors [5].

3) *Autonomy support and empowerment* through both an individual [57,58] and systemic approach [5,45] that allows PWD and FM to be able to optimally take an active role in the PWD's own care and self-management in line with their capabilities and preferences.

4) *Individualization of health promotion, education, and care goals* based on personal priorities, values, resources, preferences and needs of PWD and acknowledgement of the need for ongoing psychosocial and self-management support as part of care [5].

Generic models for person-centered care in general practice emphasize the focus on "patient preferences, coordination of care, emotional support, access to care. continuity, transition, information, education, and family and friends of PWD" [59].

The DAWN2 (Diabetes Attitudes Wishes and needs) study program defined indicators of person-centered diabetes care through an extensive multi-national multi-stakeholder participatory process [8]. The program identified the need for a biopsychosocial, social-ecological person-centered model of diabetes care which recognizes the significance of social determinants of health for PWD. The stakeholder's concluded that to improve the lives of PWD, diabetes care and education must be optimized in context of societal and environmental influences including factors such as community and societal support and public awareness [5].

The DAWN2 studies generated multi-national empirical evidence which pinpointed gaps in access to empowering and psychosocial care at individual, HCP, community and societal levels [6–12]. Multi-level regression analyses were used to identify relationships between person-centered care indicators and outcomes [6,10,11] which highlighted the importance of delivery of care which treat the whole person rather than focuses only on pre-defined clinical and behavioral targets. It was identified that care tools and strategies for value based diabetes care should rely on a shared robust

understanding of the perspective of PWD [5] and evidence-based recommendations for optimal quality diabetes care [23] including strategies for patient engagement [60] and psychosocial [27,61] and self-management support [40]. New tools should draw on the empirical research accumulated across the fields of diabetes psychology, behavioral diabetes, clinical and nursing research and the wider PRO and patient engagement research fields [60]. These approaches and guiding principles to person-centered care were considered in the research design of this thesis.

1.3. USE OF DIGITAL PRO TOOLS TO FACILITATE PERSON-CENTERED DIABETES CARE

While attempts to use digital PRO solutions in diabetes care is not new [62,63], the maturation of digital capabilities of many health systems today provide new opportunities for seamless integration of PRO tools in routine care in order to support key components of person-centered diabetes care such as empowerment, collaborative care, psychosocial care, and self-management support [2,4].

The consistent evaluation of each PWD's needs, priorities and preferences from a "biopsychosocial" perspective, as recommended for person-centered diabetes care [23,24], is difficult to do within the constraints of regular practice. The availability of digital PRO tools may facilitate more consistent monitoring of subjective indicators [4].

Digital app and web patient platforms which combine multiple data sources may facilitate aspects of individualized behavior change and cognitive theory-based support through monitoring of individual goals, barriers, preferences, resources, and results [64–66]. PRO tools, such as the Danish PRO diabetes tool, may play an important role by incorporating interpersonal relations, access to care, community and social support sources, general life challenges affecting diabetes, and care navigation.

An important diabetes-specific, empirically based operationalization of a key component of person-centered diabetes care relevant to the theoretical basis for use of PRO in diabetes is referred to as diabetes empowerment.

The diabetes-specific empowerment model developed by M. Funnell and R. Anderson [57] describe empowerment as a process and outcome of diabetes care with focus on the individual PWD. This model highlights the importance of the PWD feeling ownership of the process of learning about how diabetes impacts life, defining personal priorities and preferences for his or her own role, and being able to manage diabetes [67].

The use of the model initially focused on how HCP can facilitate empowerment. Methods such as guided self-determination have been developed in order to try to provide tools for HCP and PWD to help overcome critical barriers to implementing

empowerment in routine diabetes care [58].

This thesis discusses that the use of a digital PRO diabetes tool may facilitate aspects of individual empowerment by increasing self-reflection, expression of the PWD's own preferences and needs, active collaborative care planning and patient-led experimentation to improve patient-important outcomes [68,69]. A broader approach to empowerment emphasizes the importance of support from HCP, social relations, community, and civil society in making the PWD capable of engaging as an empowered and health literate "patient" [5]. The term "health-related empowerment" has been proposed to cover a broad concept of empowerment related to health literacy, self-awareness and capacity for collaborative care, self-efficacy and self-management support, the environment and opportunities for action [45]. Other research supports the importance of considering resilience and healthcare, social relations, and society at large for helping people live well and healthfully with diabetes [5,70].

PRO tools should reflect that PWD and FM depend on support at multiple levels to manage the PWD's diabetes: individual management and coping, family and social relations, context of everyday life, and culture and society [71,72]. Digital PRO tools to enable person-centered diabetes care should reflect the importance of HCPs and different health sectors working together to empower PWD to improve patient-important outcomes over the lifespan. Social determinants of health have been categorized into the following categories: "1) individual lifestyle factors, 2) social and community networks, 3) Living and working conditions, 4) general socio-economic, cultural and environmental conditions and 5) virtual world, information and communication technologies" [73]. While these do not represent outcomes, they should be considered in PRO tool design to ensure any relevant factors are incorporated to ensure a broadly unifying outcome measure and equitable health impact.

A social-ecological model allows for the required analysis of interactions between individual, healthcare, community and environmental factors as they influence the use and impact of PRO tools in routine care to improve health-related empowerment and outcomes [5,46,71,74]. A "whole of society" approach to the organization of the design process for PRO tools is key to improve care in an equitable way [49] which ties empowerment, healthcare access, community support, and societal policy for better health together.

1.4. HEALTH OUTCOMES MEASUREMENT

The field of health outcomes measurement originates from the requirements of the public health and clinical research fields to develop reliable, valid methods for assessment of individual health status and related outcomes. Several outcomes

taxonomies exist and a generic taxonomy of health outcomes has been proposed based on systematic review of trial research and includes 6 main categories of outcomes [75]: "1) Mortality, 2) Physiological or clinical outcomes, 3) Life impact: Global quality of life, perceived health status, emotional functioning and wellbeing, physical, social, cognitive functioning, 4) Experience of care, including satisfaction, patient preference, acceptability, availability, self-management, withdrawal from treatment, appropriateness of treatment, process, implementation and service outcomes, and personal circumstances, 5) Resource use: Economic, hospitalization, caregiver burden, societal burden, and 6) Adverse events" [75].

This generic outcome taxonomy does not describe how to measure or weigh the individual outcomes or what outcome components are important for a particular disease from the perspective of people living with the condition or their caregivers. The term patient-important outcomes has been used to refer to outcomes with an assumed direct impact on the patient's quality of life [76,77]. This concept differs, however, from outcomes determined to be person-centered as a result of systematic involvement of patients in their selection and definition. The assessment of the subjective impact of diabetes on functioning and well-being has been found to be important for decades, but subjective outcome indicators have rarely been used systematically [78–80].

Disease-specific outcome models are developed from extensive qualitative and quantitative empirical data from the target population with the aim of providing an informative and comprehensive picture of the outcomes relevant for the given disease and target group in accordance with the intended use of the outcomes. The scope and extent of health outcomes models therefore vary considerably based on the purpose and origin of the model, its theoretical underpinning, and intended use.

The term HRQOL (HRQOL) refers to the patient's appraisal of their current level of functioning, well-being and satisfaction specifically related to their health condition or treatment [81,82]. The majority of PRO questionnaires referred to as disease-specific quality of life instruments assess outcome constructs related to life impact, and treatment experience which is reflected in the outcomes taxonomy [75,82].

Outcome of diabetes care has historically been assessed predominantly by using clinical and physiological outcome indicators with limited measurement of outcome domains pertaining to direct impact [76] and subjective life impact [80]. Prior to study I in this thesis, there was no national quality assessment program that aimed at evaluating subjectively assessed life impacts of diabetes which appropriately reflect patient-important outcome domains as well as the values of person-centered diabetes care.

Study I of this thesis aims at defining an outcomes model for diabetes which builds on 1) empirical data regarding the multi-faceted subjective impact of diabetes on

physical, psychological and social aspects functioning and well-being [7], 2) perspectives and preferences of PWD and FM for outcomes assessment, and 3) evidence of complementarity of PRO data to physiological and clinical data [83].

1.5. VALUE-BASED HEALTH CARE AND OUTCOMES EVALUATION

The value-based healthcare (VBHC) framework designed by Michael Porter proposes that implementation of systematic measurement of core patient-important outcomes across health sectors is a key first step for driving improvement in health value and outcomes over the lifespan [48,84]. The hierarchy of health outcomes as it was originally proposed for use for value based healthcare includes the following three key tiers:
Tier 1) Survival, health status and degree of health or recovery
Tier 2) Process of recovery and disutility of the care process
Tier 3) Factors for sustainability of health [85].
The hierarchy of health outcomes was used in study I to guide the definition of a core set of patient-important diabetes outcome constructs for use for diabetes care in Denmark [1]. The VBHC outcomes framework was also recently used in the development of the first global outcome measurement standards for diabetes of the International Consortium for Health Outcomes Measurement (ICHOM) [86].

1.6. METHODS FOR DEFINING CORE HEALTH OUTCOME SETS

Harmonization of outcomes and indicators used across health care settings and countries for a specific disease is desirable as it facilitates benchmarking, efficiency of research and knowledge sharing [87,88]. The pursuit of "Outcome Sets (COS) or agreed standardized set of outcomes" which are agreed upon to be measured and reported as a minimum in all outcome evaluations for a given disease can be important for comparative research and scientific exchange [89,90]. The use of standardized outcomes can have important benefits for population-based quality improvement[91] and for setting comparative standards for clinical trial data regarding new medicines and medical devices. Key steps for development of a COS used in study I include 1) scope specification (setting, population, intervention), 2) stakeholder involvement (patients, HCP and researchers), and 3) consensus process (balancing views of patients and HCP, pre-defined criteria and process for selection) [87]. Specific methods to develop core outcome sets include consensus meetings, the Delphi method, the nominal group technique, surveys, systematic literature reviews, semi-structured discussions, and multi-stakeholder working meetings [89,92–95].

1.7. DIABETES SPECIFIC CORE OUTCOME SETS

Study I in this thesis focuses on the definition of a core set of outcome constructs for specific use in routine diabetes care. This answers the question of "what" should be measured, i.e. "what constructs are important and value-adding to measure?" The subsequent question of "how" to measure the identified constructs reliably and validly in practice in order to allow for reliable monitoring and benchmarking is a separate process involving psychometric methods to establish reliability and validity.

At the time of study I, there was no international consensus regarding which PRO constructs should be measured as core outcomes in diabetes alongside clinical outcomes. There was also no agreement about which generic and diabetes-specific PRO questionnaires should be consistently used in either clinical trials or quality monitoring in diabetes in order to facilitate comparability and benchmarking [96].

A recent review of outcomes used in 132 clinical diabetes trials found there was a combined use of more than a 1000 different outcome indicators [88] which highlights the need to identify core sets of outcome indicators for people with type 1 [97] and type 2 [86] diabetes in order to enable consistent outcomes assessment across settings [84].

Given the complex interactions that exist between outcome indicators and other factors such as socioeconomic status and co-morbidities, a set of case-mix variables must be defined based on clinical and statistical evidence so they can be considered in outcome analyses intended for benchmarking to ensure correct interpretation [86].

1.8. PRO RESEARCH METHODOLOGY

Evidence-based standards for the development and psychometric evaluation of PRO questionnaires (PROM) to optimize acceptability, content validity, reliability, responsiveness and utility have been developed based on extensive empirical research and measurement science [93,98–100]. The increasing use of PRO in clinical trials for medicines and technologies has facilitated the emergence of detailed and stringent standards for development and documentation of PROMs for trial research [101,102]. Both traditional and modern psychometric methods are used for questionnaire design as well as adaptation and assessment of validity, reliability, scoring and interpretation [99,102,103].

1.8.1. TYPES OF PRO QUESTIONNAIRES

PRO questionnaires are designed to collect direct reports from the patient regarding the subjective experience of health, health related constructs, and treatment. These questionnaires are used to assess health outcome indicators which can only be

assessed through direct report of the patient and complement outcome indicators assessing clinical or electronic comprehensive health outcomes assessments.

Patient Reported Outcome Measures (PROM) can be categorized according to whether they measure health perceptions, functional status, well-being, symptoms, HRQOL, treatment experience and satisfaction, and other health related constructs[104]. Other health-related constructs might include measures of health behavior, self-efficacy, health beliefs, resilience, support systems, resources, and health-related environmental factors. There is limited consistency in how PRO questionnaires are classified in the literature today. Some questionnaires are referred to as self-reported health status or HRQOL depending on the research team. Some psychometric clinical questionnaires referred to as PROMs include content that can be categorized as "Patient Reported Inputs" (PRI) [4], which include topics such as motivational drivers [105], treatment beliefs and attitudes [106], care and education preferences, and personal goals [4].

Questionnaires may use Likert scaling, visual analogue scaling, pictorial charts, animation, and other methods and use global rating items or multi-item scales with each method having its unique benefits and disadvantages [107].

PRO questionnaires may be developed solely by professionals, or co-developed to varying degrees with patients[90]. They may measure patient-relevant or patient irrelevant outcome constructs [108]. Thus, PRO questionnaires — like clinical outcome methods — may or may not be suitable for patient-centered outcome assessment.

PRO questionnaires may be generic or disease-specific and designed for: evaluative use, clinical use (screening, dialogue, care planning, shared decision-making), epidemiologic research, quality of care monitoring, and research purposes [15].

1.8.2. DEVELOPMENT OF PRO QUESTIONNAIRES

Key overall steps for development of PROMs include 1) Literature review, qualitative research and establishment of core constructs, a conceptual model and a measurement model, 2) Design of the questionnaire with patients and HCP to achieve the desired psychometric properties (validity, reliability, responsiveness, interpretability), and 3) Psychometric assessment of measurement properties based on sufficiently large patient sample to verify, modify, and finalize the PROM with patients and HCP. [4,16,102,109]. The quantitative assessment of measurement validity after collaborative development and the adjustment of the questionnaire in accordance with the psychometric analyses represent an important yet often overlooked step due to time and resource demands. Development of a PROM requires that systematic review of the literature is undertaken in advance of questionnaire development with explicit

consideration of both qualitative [110] and quantitative [101] empirical data. Qualitative research utilizing interviews, focus groups, surveys and other data is required for developing the iterative psychometric design with the participation of both patients and HCP using patient-centered quality criteria for each phase of the questionnaire design and validation [4,90,99,102].

1.8.3. PSYCHOMETRIC QUALITIES OF PRO QUESTIONNAIRES

Four main categories of psychometric assessment are often used when developing and evaluating a PROM: validity, reliability, responsiveness and interpretability[101,111].
A systematic empirical and analytical process is required to establish content validity of a PRO questionnaire [98]. Content validity includes face, construct, known-groups, and criterion (concurrent and predictive) validity. It also often encompasses cross-cultural validity when questionnaires are adapted from other languages. Assessment of reliability involves assessment of internal consistency, inter-rater reliability, measurement error and test-retest reliability [112].
Responsiveness refers to the extent to which a PRO questionnaire can quantify differences in the latent construct being measured over time or in response to an intervention [99]. Interpretability is essential for the effective clinical use of PRO results. Distribution and anchor-based methods for assessing the minimal clinically important difference (MCID) [113] are both important to facilitate interpretability of PRO scores for clinical and evaluative use [113–116]. Detailed guidance for clinical interpretation of change scores require quantitative and qualitative analysis as multiple factors may be involved with complex interrelationships [116].
Since responsiveness and interpretability are critical to clinical utility and patient benefit, it is important to elicit patient preferences for interpretability early in the process. Patients may prefer simple and transparent scoring methods, as we found in the Danish PRO diabetes program or may accept complex item-response-theory (IRT) based scoring methods such as those used in the Swedish PRO diabetes program [117,118].
Patient's perceptions of relevance and clinical utility is important during design to optimize usability of the PRO tool in routine care. Patient's perspectives on relevance, acceptability, responsiveness, and interpretability of status and change scores is an important part of the iterative design of questionnaire content and format.

1.9. DIABETES-SPECIFIC PRO RESEARCH

The assessment of HRQOL, psychological well-being and treatment satisfaction has been acknowledged as clinically relevant in diabetes for decades based on the role

psychosocial factors and self-management play in diabetes care [28,78]. Some of the first large-scale clinical diabetes trials to use PRO were the landmark Diabetes Control and Complications Trial (DCCT) [119] and UK Prospective Diabetes Study (UKPDS) [120] studies. In these studies, PRO questionnaires were included for longitudinal evaluation of self-reported health and quality of life alongside clinical outcome indicators. In the DCCT, the Diabetes-specific Quality of Life Questionnaire (DQOL) [119] was used to measure three domains: diabetes impact, diabetes worry and diabetes satisfaction. Follow-up studies also used generic health utility questionnaires [120]. The study reported that diabetes complications were associated with impaired quality of life whereas there was no significant impact of intensive therapy vs. conventional therapy on quality of life [119,120]. The UKPDS used the generic EuroQol (EQ-5D) and reported no direct impact of intensive blood glucose-lowering therapy on PRO outcomes. Hypoglycemia was however associated with negative impacts on self-reported indicators of quality of life [121]. Since these studies were completed, more diabetes-specific PROMs have been developed with input from PWD and have been used to show that diabetes treatments impact diabetes-related quality of life [15,19,78,79,122,123] and related PRO constructs differently [124–126]. There are many factors influencing quality of life and perceived impact of diabetes apart from medical treatment [11] which makes standardization and interpretation of PRO diabetes data difficult. Empirical research supports the importance of complementing clinical outcomes with subjective assessments of perceived impact of diabetes on physical, psychological, social functioning and wellbeing [15,19,78,79]. Self-reported assessment of physical health and symptoms is for example an independent predictor of prognosis and hospitalization in diabetes [83].

Hundreds of generic and diabetes-specific PRO questionnaires have been used in academic diabetes research and to a lesser extent in care improvement programs during the past decades [4,79,123,127,128].

Generic self-reported health and HRQOL instruments are often used PRO to evaluate outcomes in diabetes [121,129,130], yet diabetes-specific questionnaires are often required to achieve sufficient specificity and sensitivity [15,123]. The majority of diabetes PROMs published today adopt a reflective measurement model and aim to measure unidimensional latent constructs [117,131].

Diabetes PRO questionnaires are developed for a wide variety of purposes and span clinical screening instruments, treatment monitoring, clinical evaluative instruments, quality of care assessment, health psychological research tools [7,12,19,80,122,127,132–137]. PRO instruments reflect different theoretical constructs including self-reported health and daily functioning, mental health constructs, well-being, quality of life, diabetes-related quality of life, barriers and resources for living well with and self-managing

diabetes, satisfaction with diabetes treatment, confidence in self-management, experience of support, and access to quality person-centered care[4,79,133]. Versions of diabetes PROMs have also been developed for completion by FM [4,12,135,138].

To explain the perspective of the author of this thesis for reflexivity purposes, the next section outlines PROMs for diabetes which were psychometrically developed or adapted by the author in previous research. The list reflects the author's foundation in empirical research related to the assessment of both traditional health and quality of life outcomes, measures of person-centered care experience, and health-related constructs such as self-management, empowerment, health, and treatment beliefs as well as broader supports and barriers to care. All these factors are relevant in the consideration of how to involve PWD and FM in the design of a PRO tool for clinical use. The author co-developed or adapted the following measures prior to the research in this thesis: 1) Perceived impact of diabetes on life (Impact of Diabetes Profile (DIDP [7,8,122]), 2) Diabetes related distress (PAID-5, PAID-1 [137]), 3) Impact of diabetes on quality of life in youth with diabetes (MY-Q [135]), 4) Diabetes Quality of Life in Youth Short Form Questionnaire (DQOLY-SF [139]), 5) Diabetes Medication Satisfaction Questionnaire (Diab-MedSat [19]), 6) Insulin Treatment Satisfaction Questionnaire (ITSQ [16]), 7) Global Satisfaction with Diabetes Treatment Questionnaire (GSDT [134]), 8) Short Form of the Summary of Diabetes Self-Care Activities Assessment (SDSCA-SF [7]), 9) DAWN Short Form of the Diabetes Empowerment Scale (DES-DSF [8]), 10) DAWN Family Support Scale (DFSS [8]), 11) Support For Diabetes Self-management Scale (DSDSP [8]), 12) Perceived Support For Diabetes Scale (PSS[114]), 13) DAWN Short-Form health-care climate questionnaire (HCC-DSF[8]), 14) Insulin Treatment Appraisal scale (ITAS [106,136,140]), 15) Short-form Patient Assessment of Person-centered Chronic Illness Care (PACIC-DSF[8]), 16) Barriers to Medicine Scale (BM [134]), 17) Diabetes Symptom Measure (DSM [19]), and 18) Impact of diabetes on productivity (Diabetes Productive Measure [19]). The author also developed psychometric questionnaires for completion by family members of PWD [12,138], HCP [138,141], and co-developed multi-dimensional PRO diabetes questionnaires for clinical use [135,142] to support delivery of person-centered diabetes care. The author applied PRO questionnaires in diabetes relating to generic health (EuroQoL [7], SF-12 [134]), generic quality of life (WHO-QOL-BREF [8], WHO-5 [28,62,142–144]), and diabetes-specific quality of assessment (DSQOLS [145]).

The author collected qualitative insights into the perspectives of PWD and FM through the use of qualitative research methods (i.e. focus groups, interviews) [16,19,146], scale reduction methods[137,139], psychometric evaluation methods[16,19], and participatory research methods [8,135] in the development of PROMs.

1.10. SPECIFIC METHODS FOR DESIGN OF PRO FOR CLINICAL USE

The development of a PRO questionnaire for use in routine care requires that both its psychometric qualities and its functionality is optimized for its clinical purpose [4,109,147]. Standardized steps for design of a PRO for clinical use can include [148] (1) identifying the goals for collecting PROs in clinical practice, (2) selecting the patient target group, setting, and timing of assessments, (3) determining which questionnaire(s) to use, (4) choosing a mode for administering and scoring the questionnaire, (5) designing processes for reporting results, (6) identifying aids to facilitate score interpretation, (7) developing strategies for responding to issues identified by the questionnaires, and (8) evaluating the impact of the PRO intervention on the practice.

A PRO tool may be based on one [143,149] or multiple theoretical models [4] and as is the case with the Danish PRO diabetes questionnaire which contains a combination of PRO constructs that originated from different empirical or theoretical foundations. Each subcomponent of the PRO diabetes questionnaire should be psychometrically assessed in accordance with the specific intended use of the specific item or multi-item scale score. For example, a multi-item scale to measure psychological well-being as an outcome must have adequate reliability, validity, and responsiveness to be able to reliably monitor well-being over time and with adequate responsiveness to intervention effects, whereas certain global items intended for screening and dialogue use may not need to be able to detect and quantify changes over time. Different design approaches are used for PRO tools depending on their scope and may include user-centered design [150,151], theoretical models for behavior change [152], and frameworks to optimize public health impact [153].

1.11. PATIENT INVOLVEMENT IN DESIGN OF CLINICAL PRO TOOLS

Systematic patient involvement and multi-stakeholder participation is required in each step of development of a PRO questionnaire for clinical use. This is important to ensure the questionnaire obtains adequate psychometric characteristics and other design features in accordance with the intended use of the PRO tool [4,90,108,148,154–157].

An iterative, participatory design process is required in the development of PRO questionnaires which ensures detailed patient perspectives are reliably obtained and considered in relation to face validity, relevance, acceptability, appropriateness, interpretability, responsiveness, reliability, validity, implementation and public health impact optimization.

The author of this thesis developed a stepwise approach to patient involvement in the development of the Danish PRO diabetes questionnaire which is outlined in table 2. The three studies in the thesis represent examples of specific elements of the larger research program for patient involvement in the Danish PRO diabetes program. Research using data generated from this thesis to evaluate the value of patient involvement strategies for the PRO diabetes tool at each stage in order to provide guidance for how to prioritize strategies in future PRO research programs is ongoing.

1.12. QUALITATIVE METHODS USED FOR PATIENT INVOLVEMENT IN PRO RESEARCH

Qualitative health research methods, referred to here as the "collection and systematic analysis of non-quantitative data about peoples' experiences related to their health" [158], can be used and adapted in pragmatic ways to facilitate representation, rigor, transferability, and credibility of the patient involvement process in PRO [159]. Qualitative research methods such as participant validation, thick description, representation analysis, saturation, comparative analysis, and reflexivity can be adapted to improve the patient involvement process and its impact [158]. Qualitative research is used to strengthen integration of the lived experience of the disease [110] in different phases of PRO instrument development, evaluation, and implementation [90,160]. Qualitative research is used in medical and psychological intervention research to ensure solutions and evaluations reflect and are enhanced by a deeply nuanced understanding of the perspective and values of both patients and family members. These purposes align with the core intentions of patient involvement in the development of the PRO diabetes solution [90]. As ambition levels for and requirements to patient involvement increase in diabetes research, the need for rigorous systematic methods to document and report the quality and effectiveness of the patient involvement process increases [161]. The ambition to include more patients in research as well as use digital tools to engage patients creates a need for systematic qualitative research methods for collection and analysis of large amounts of data.

It is important to distinguish traditional qualitative research (where the patients are research subjects) from involvement of patients as contributors, partners and co-designers of the research design. In this thesis, patient involvement in research refers to the involvement of patients as partners in the research design.

While the use of qualitative research is a necessary part of PRO questionnaire development [98,162] and can be integral to effective patient involvement, the majority of PROMs today were developed without documentation of how patients were involved as partners at each stage of development of the PRO [90,163].

In this thesis, qualitative analysis methods were used to augment the process of patient and stakeholder involvement in the PRO diabetes development process in order to:
(1) more accurately and reliably elicit, document and consider both patients' and caregivers perspectives and experiences at each phase of planning, undertaking and reporting of research studies;
(2) ensure that divergent patient perspectives and important contextual factors are sufficiently documented to provide transparency regarding diversity and representativeness of input and potential biases.
(3) allow for the ongoing quality assurance and evaluation of the process quality of involvement as well as examine indicators of effectiveness and impact of patient involvement on the research aims.

1.13. USE OF MIXED-METHODS IN CLINICAL PRO RESEARCH

Mixed methods research, which combines both a quantitative and a qualitative research component [164,165], is a relevant methodological approach when the combination of quantitative and qualitative methods are expected to result in a better research outcome than if the qualitative and quantitative studies are done separately [165]. Mixed methods are often applied in a pragmatic framework with a focus on flexible and appropriate use of multiple methods to achieve the best possible research outcome [166]. Mixed methods research has been highlighted as particularly valuable for use in clinical PRO research due to the complexity of the design, implementation, and evaluation of PRO in clinical practice [159].

1.14. MULTI-STAKEHOLDER PARTICIPATION IN PRO DESIGN

Design of PRO tools for clinical use require multi-stakeholder participation in all phases using strategies that ensure effective participation, co-learning and collaboration of all the main stakeholder groups [167–170]. Planned strategies are required to ensure all relevant stakeholders (i.e. primarily patient. professional users, payers, and direct beneficiaries) are actively involved in the preparatory, execution, and application phases of the research program [168,171]. For the purpose of this thesis, the term "participatory research" is used to denote that explicit actions are taken to ensure practice-based inclusion of the relevant stakeholders in all the phases of the project. Multi-stakeholder participation is required to achieve a sustainable clinical PRO solution with a high potential for adoption, implementation, and public health impact. Multi-stakeholder participation is addressed in this thesis because it is hypothesized that for patient involvement to be most effective, patients must be involved as an

integral part of a multi-stakeholder participatory process which allows for mutual learning and exchange among PWD and professionals. The participatory strategies applied in this thesis to improve the research and to support the effect of systematic patient involvement activities in the development of the PRO diabetes tool are shown in table 4. The strategies focus on the significance of creating a respectful, trusting research environment which is conducive to effective mutual learning. The aim is to achieve an inclusive form of inquiry with a focus on enabling active participation of all involved stakeholders in each phase of the research. The aim with the applied participatory approach in this thesis is for patients to be involved on equal terms with other stakeholders to identify and address individual, health care, community, contextual and policy factors, which can influence the achievement of the project's patient-centered outcome goals[172].

1.15. PATIENT INVOLVEMENT IN RESEARCH

Patient involvement in research in this thesis refers to the involvement of patients as collaborators, i.e. active agents, in the research process to help guide the research process itself and part-taking in shaping the definition of aims, design the protocols, build the intervention, plan the analysis and application and dissemination of results. Patient involvement is used to refer to health research which is carried out with or by members of the public or patients rather than to, about or for them. It occurs "when patients meaningfully and actively collaborate in the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge (i.e., the process referred to as 'knowledge translation')" [173]. Many alternative terms are used to reflect patient involvement including public-patient involvement (PPI), patent engagement, patient involvement, patient partnering, user involvement, service user involvement, patient-centered, and patient-orientated research. The involvement of patients, the explicit elicitation and use of experiences, perspectives, and preferences of patients and their families is an important part of health research whether it is focused on improvements in medical care, organization of care systems, or quality of care improvement [60], or broader research [174]. In this thesis, a theoretical approach to patient involvement is used which is based on the hypothesis that incorporation of the lived experience and perspectives of the end users in the research process can help improve research relevance, appropriateness, efficiency, and impact potential of research outputs [175,176]. Patient involvement is also included in research from a rights perspective, i.e. that patients and the public have the right to be involved in research which affects the civil society.

Involving patients and the public as partners in health research provides an important opportunity to leverage the knowledge, skills, and experience of both researchers and clinicians as well as of patients and families in collaborating more effectively towards making the research more relevant for all. This involvement drives meaningful change in how research can become more beneficial for patients and society [176,177]. It is hypothesized that patient involvement in health research will increase focus on the research questions which are of greatest value to the patients (priority setting) [176]. The nature of the research and purpose of involvement determines the significance of involvement of patients and or the public [178].

Health and PRO research studies adopt different models for patient participation ranging from tokenism, highly limited ad hoc, or retrospective consultation with individual patients to engagement of patients as partners or leaders of projects. A single health research study often utilizes several types of patient involvement depending on the research phase, participants, and purposes of participation [172]. The different ambition levels for patient involvement in health research studies research can be illustrated by 5 distinct approaches to involving the patient: 1) Inform, 2) Consult, 3) Involve, 4) Collaborate, and 5) Empower [172] (or user-driven).

In the systematic approach to patient involvement presented in this thesis patients were involved in multiple capacities depending on the specific objectives and research questions being addressed at each stage of the process. This was done taking into account time and resource constraints. Criteria for theoretical purposive recruitment for patient collaborators and partners as well as strategies for education, training and engagement of patients were tailored based on the intended type of involvement.

The term “patient involvement” is not used in this thesis to denote the ambition level of involvement but to denote the engagement, participation collaboration, or partnership with patients [176]. While the author of the thesis believes it is relevant and important to pursue patient leadership of projects in PRO research [179], research in this thesis uses a collaborative approach to patient involvement as this was what was feasible with the available project resources.

In this thesis, systematic approaches to patient involvement refers to the use of explicit advance planning of patient involvement with clarity about the patient’s roles at each research stage as well as the methods used to partner with patients to achieve each of the pre-specified objectives of patient involvement.

Systematic patient involvement as the term is used in this thesis refers to patient involvement being done in a structured, pre-planned prospective manner with specification of methods and objectives for each research phase in contrast to involvement being done ad hoc and retrospectively. The term “systematic approach to patient involvement” is not used here to imply an extensive resource-demanding

comprehensive set of activities as research resources are often limited. A core feature of systematic patient involvement as proposed in this thesis is that patient input is applied in all stages, including at the first stage where patient-centered goals for the PRO tool are co-designed with and endorsed by all involved stakeholders. The establishment of a clear patient-centered measurable objective [5] with use of the PRO tool represents an important aspect of a patient-oriented, systematic approach to patient involvement in PRO [180]. Key patient-centered outcome goals for clinical PRO tools can be improvements in care experience, community support, health, and quality of life outcomes [4,5].

1.15.1. FRAMEWORKS FOR PATIENT INVOLVEMENT IN RESEARCH

Several methodological frameworks exist for how to involve patients in research [171,172,175,181,182]. Hypothesized benefits include enhanced research quality and appropriateness including benefits to research prioritization, optimizing relevance and applicability of research, efficiency of the research process, and dissemination [183].
A core feature of systematic patient involvement is that patient involvement is initiated early and across all phases. These phases are 1) Identification and prioritization of topics and focus for research, 2) Design of the research approach, 3) Development of the study protocol and methods, 4) The undertaking/management of the research, 5) Analysis/interpretation, 6) Dissemination of results, 7) Implementation of results, and 8) Monitoring and evaluation of implementation [175].
While there are a growing number of patient involvement guidelines and templates [161,168,184,185], there is no single methodology for patient involvement which has been internationally adopted as a standard and the scientific evidence-base for what methods work best remains very limited [161,175]. Most frameworks rely on best practice mapping rather than empirical evidence and theory while some frameworks recommend the creation of purpose-built patient involvement strategies with participants due to the intricate and unique nature of each research program and the relationship with patients [181]. There are ample best practice frameworks to rely on to guide patient involvement process quality [181], execution [175] and reporting [161,181,186].
The author co-developed the global “Patient Engagement Quality Guidance” (PEQG) using 3 steps: 1) A collaborative multi-stakeholder process, 2) Review and synthesis of international methodological frameworks for patient involvement and 3) Mapping and analysis of international best practice cases for patient involvement to iteratively design operational quality criteria [181]. The resulting guidance is flexible and non-prescriptive and can be used as an aid to design the patient involvement protocols[175]. Operational descriptions, practical tools, templates, and a database of case studies

with best practices were developed for each of the seven quality criteria as part of the PEQG to inspire planning and evaluation of patient involvement in health research[175]. For this thesis, the author worked with PWD to apply the PEQG quality criteria (table 3) in the patient involvement protocols for the Danish PRO diabetes development program and undertook a study to evaluate their value.

1.16. PATIENT INVOLVEMENT IN DIABETES RESEARCH

Involvement of PWD in diabetes research, care and policy has been in focus for many years and experiences are beginning to emerge regarding the value it brings [176]. There is general consensus that involvement of PWD should be prioritized at all levels: individuals, families, health care, community and civil society, and policy [5]. The author of this thesis has previously designed patient involvement as part of participatory multi-stakeholder person-centered diabetes research [5,29,30,135,187]. Despite a trend towards more focus on patient involvement in diabetes research and care, methodological approaches and reporting are not standardized in the literature and further methodological and theoretical research is warranted [176].

1.17. A PUBLIC HEALTH IMPACT MODEL FOR CLINICAL USE OF PRO

The RE-AIM (Reach, efficacy, adoption, implementation and maintenance) model was developed to provide an operational framework to optimize and evaluate the public health impact of health interventions, such as an office-based digital PRO intervention [63]. RE-AIM has been used to design or evaluate diabetes interventions [63,188–191] and diabetes PRO tools [153,192]. The RE-AIM model was used to guide research in this thesis and specifically the evaluation design in study III [3].

CHAPTER 2. DESIGN OF THE DANISH PRO DIABETES TOOL FROM 2017-2021

The three studies in this thesis (appendices I-III) are components of a broader set of research activities for development of the national PRO diabetes questionnaire and the digital dialogue tool, *DiaProfil*, which was overseen by the author. The aim of this section is to provide the reader with the overall context and to clarify how each of the three studies fit into the overall PRO tool development. The section provides a chronological overview of the development of the PRO diabetes questionnaire and digital tool from 2017-2021 and illustrates the use of systematic patient involvement at each stage.

Figure 1 provides an overview of the development of the PRO diabetes tool from 2017-2021. The first phase was an analysis and scoping phase in 2017 which also included definition of patient-important outcomes (study III). The second phase was the participatory creation of the PRO diabetes questionnaire through a series of multi-stakeholder and patient workshops in 2018. The third phase was finalization of the clinical digital tool, *DiaProfil*. The formative evaluation of *DiaProfil* occurred in 2019 (study II), and the fourth phase was design of the national pilot study in 2020 (study III). Table 1 shows the studies and articles undertaken or planned by the author of this thesis to clarify the context of the four papers that are included in this thesis.

2.1. CHRONOLOGICAL OVERVIEW OF THE RESEARCH

In the fall of 2017, initial literature review, scoping analysis and study I was undertaken. We engaged a broad group of PWD and FM from the diabetes community in Aalborg, Denmark to discuss the scope and aims of the national project for value-based diabetes care and identify patient-important diabetes outcomes. In November 2017 consensus was established to incorporate PRO constructs in the core outcomes set for use for value-based diabetes care in Denmark.

During 2018, the Danish PRO diabetes questionnaire was developed through a national collaborative multi-stakeholder process with systematic involvement of PWD in all steps. A series of carefully planned patient and multi-stakeholder workshops (figure 1) were undertaken to ensure detailed inputs and co-learning for each step of the PRO development process.

During 2018 and early 2019, the author oversaw the development of the new digital PRO diabetes tool, *DiaProfil*, which used a user-centered design approach involving a user panel of PWD, a multi-disciplinary clinical diabetes care team and an IT partner.
In spring 2019, the first pilot evaluation of the feasibility and acceptability of the first viable digital PRO tool was done in routine outpatient diabetes visits (study II).

In the fall of 2019, a longitudinal clinical study of the use of the PRO diabetes tool in a hospital setting was initiated (papers X-XII), and study III (a multi-center pilot study (M-PRODIA)) was designed to evaluate use of the PRO diabetes tool in different health sectors and regions in Denmark. A secondary aim of the study was to collect PRO data to characterize construct validity and other psychometric characteristics of the PRO diabetes questionnaire and it's scoring algorithms.

From December 2019- December 2020, data collection for the M-PRODIA study was completed as part of the national pilot testing of the PRO diabetes tool under the auspices of the Danish Health Data Authority. Covid-19 caused delays in recruitment and data collection. More than 550 people with diabetes and 30 health professionals completed the M-PRODIA study protocol and data collection was closed in April 2021.

In January 2021, the Danish Health Data Authority finalized a national pilot evaluation report about the PRO diabetes tool, building on 55 interviews with PWD, evaluation workshops with multi-disciplinary diabetes health professionals and preliminary M-PRODIA data by the author. The report concluded that the PRO diabetes tool was found to be feasible, acceptable, and helpful to improve the quality of dialogue and care visits [193]. All seven diabetes sites involved in evaluating the PRO diabetes tool concluded that the PRO diabetes tool was value-adding. Several diabetes centers opted to continue use immediately after the pilot study was completed.

On March 2 2021, the steering group under the Danish Ministry of Health approved the broad use of the PRO diabetes tool in routine diabetes care in Denmark.

Led by the author of this thesis, a scientific study (study XIII) is ongoing to evaluate the impact and value of patient involvement in the Danish PRO diabetes tool program from 2017-2021. The field work concluded with two final patient evaluation workshops in April 2021. Participating PWD provided very positive evaluations of the process of involvement and the resulting intervention. The complete results are

being prepared for analysis using the Nvivo database that was established at the beginning of the development program.

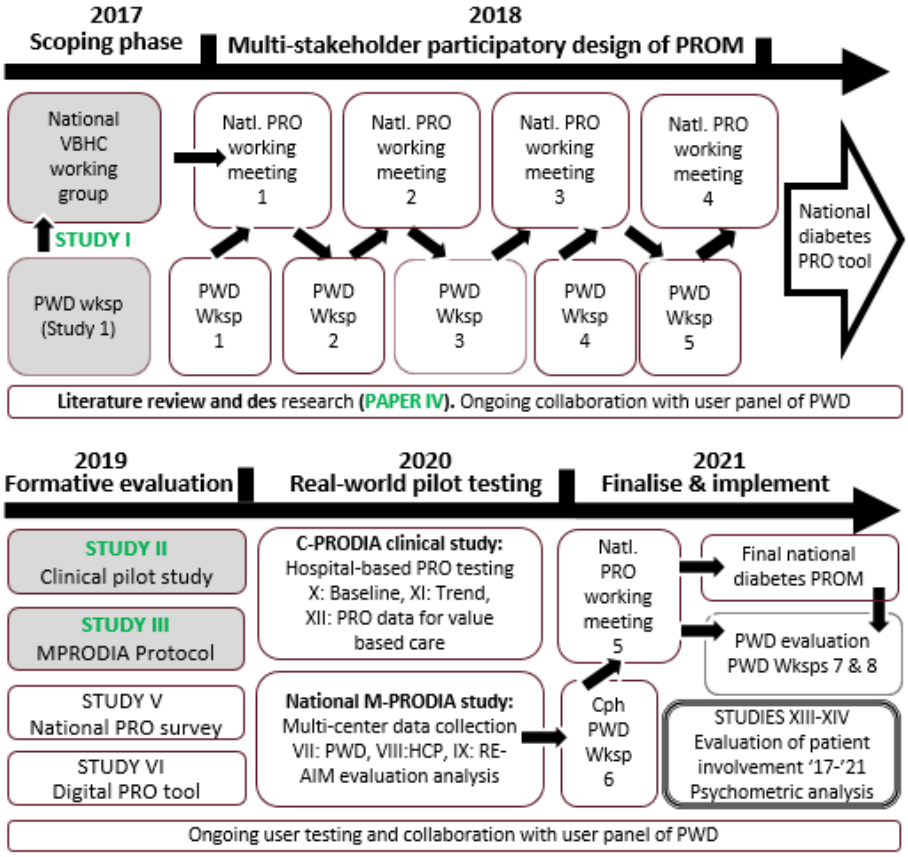

Figure 1. Illustration of phases and patient and multi-stakeholder involvement activities for the Danish PRO diabetes tool development program. Wksp: Workshop.

Papers 1-IV (part of thesis)	I: Core set of patient-important diabetes outcome constructs. II: Pilot study to evaluate clinical feasibility and acceptability. III: Design of the multi-center study M-PRODIA. IV: Narrative review about use of digital PRO in routine diabetes care.
Paper V	Results of a national Danish survey of 8,938 PWD: Psychometric validity of PRO diabetes items and clinical utility [194]. Factor structure, internal consistency, discriminatory, construct validity, predictive validity.
Paper VI	Design and clinical user testing of the digital PRO diabetes tool. A clinical multi-disciplinary, multi-stakeholder development process to define functionality, design, and content of a digital PRO diabetes tool.
Paper VI-IX	Results papers for the national multi-center study (M-PRODIA): VI: Primary outcomes for PWD. (n > 550 PWD using PRO, 7 sites). VII: Primary outcomes for HCP. (n >480 PRO visits, 31 HCPs) VIII: Public health impact potential for PRO diabetes (RE-AIM).
Paper X-XII	Results of the hospital based clinical trend study (C-PRODIA): X: Baseline clinical, PRO and health care utilization baseline data. XI: Follow-up analysis of clinical and PRO tend data over 1-2 years. XII: Use of PRO diabetes data for value-based healthcare.
Paper XIII	Methodological description and evaluation of impact of systematic patient involvement and multi-stakeholder participation at each step of the development of the PRO diabetes tool.
Paper XIV	Psychometric analysis of PRO data from national pilot study: Psychometric characteristics, norms, scale structure, and scoring [195].

Table 1. Overall publication plan and context for the 4 papers of this thesis.
Papers V-XIV are in development.

2.2. 2017: INITIATION OF THE VALUE-BASED DIABETES CARE PROJECT AND SCOPING PHASE

In fall 2017, the VBHC-PRO-DIA project was initiated by Region Northern Denmark under the auspices of the national value-based care program of the Danish Regions. The ambition of the project was to explore scalable models for implementation of principles of value-based health care [48] in Denmark. The aim was to create value for PWD in the healthcare system by aligning efforts across the care system towards measuring and improving a shared set of outcomes which matter to PWD [30].

While several aspects of the value-based care framework was found to not be easily applicable to either diabetes or the Danish health system, the value-based ambition to "Improve outcomes by focusing care on what creates the most value for each person with diabetes" which was established in the early phase of the project was found to be an appealing and unifying goal for both PWD and other diabetes stakeholders in Denmark.

The pre-defined goal of the first phase of the project was to establish consensus among a national multi-stakeholder working group on how to measure outcome ("value") of diabetes care in a way that reflects the priorities of PWD. Multi-disciplinary representatives agreed that no core set of outcomes existed at the time. The rationale was that having a clear and shared picture of what success looks like across stakeholders could facilitate improved collaboration for better care and potentially help to break silos across health sectors and professions as it facilitated consideration of long-term opportunities for shared population health accountability [84,196].

Study I describes how PWD were involved to strengthen the consideration of the perspective of PWD in the consensus process of the national working group for value-based diabetes care appointed by the Danish Regions [1].

As described in detail in study I, it was concluded that supplementing clinical outcome indicators with measurement of multiple PRO constructs [197] which reflect the priorities of PWD was a shared priority (Appendix I).

2.3. 2018: DESIGN OF THE NATIONAL PRO DIABETES QUESTIONNAIRE

In January 2018, the national PRO diabetes program was initiated under the auspices of the PRO Secretariat of the Danish Health Data Authority in collaboration with

VBHC-PRO-DIA with the goal to develop a national PRO diabetes questionnaire for use in the national PRO IT infrastructure [198,199].

The key objective was to develop a digital PRO diabetes tool (comprised of a questionnaire, scoring algorithms, and instructions) for use in routine care to increase the influence of PWD on their own care, the quality of the PWD-HCP dialogue, and the quality, coordination, and efficiency of care provided.

The program was initiated in close collaboration with the VBHC-PRO-DIA project in order to combine scientific and organizational resources and achieve one unified national PRO solution rather than having potentially overlapping solutions for use in different health care settings.

Figure 1 shows 5 workshops with PWD and 5 meetings of the national working group for PRO diabetes (KKG) which consisted of approximately 40 multi-disciplinary experts, diabetes advocates, and stakeholders representing all 5 regions in Denmark.

Multi-stakeholder participation was facilitated within the general framework and governance model of the Danish Health Data Authority for participatory design of PRO tools as starting point [167,198].

A stepwise approach to development of the PRO diabetes tool was used to structure planning of patient involvement activities for each stage (table 2). PWD and multi-stakeholder perspectives were solicited for each step of the process through a combination of workshops, meetings, and surveys (figure 1). Patient workshops covered all stages, including aims, program theory, PRO constructs, questionnaire content, clinical and practice use, iterative testing, pilot testing and implementation.

	Key steps for the development of the PRO diabetes tool	**Focus areas for patient involvement (examples)**
1	Aims, purpose, model. Program theory.	Co-design of aims, measurable patient-centered outcome goals and model for use of PRO across the care system for PWD.
2	Prioritization of PRO topics and constructs. Conceptual PRO model.	Required PRO constructs and topics. Definitions, rationale and prioritization of each topic.
3	Psychometric construction of questionnaire (items, scales, format, scoring, composition).	Requirements and quality criteria for content and format of PRO. Iterative co-design of PRO content.

4	Design of decision-making support algorithms, model for clinical use.	Acceptability, relevance and details of methods for use of PRO in visits
5	Formative evaluation of feasibility, acceptability, utility, and efficacy	Iterative testing, adjustment, and co-design of complete digital PRO tool
6	Pilot testing of feasibility, acceptability, value and public health potential.	Systematic large-scale evaluation of PWD experience of use and benefits
7	Adjustments, preparation and implementation planning.	Final adjustments required based on systematic evaluation and validation
8	Integration and quality assurance in standard care, ongoing improvement.	Strategies for effective dissemination, implementation and ongoing quality assurance

Table 2. Key steps for design of PROs for use in clinical practice with requirement for systematic involvement of patients.

The design of activities for patient involvement was developed by the author with PWD and the Danish Diabetes Association using seven quality criteria for patient involvement [160,181] and relevant best practices for patient involvement as guidance [4,200]. The seven quality criteria are listed in table 3 with a brief explanation of how they were operationalized in the research plan for design of the PRO diabetes tool.

	Quality criteria	**Application of criteria for PRO diabetes**
1	Aims and purpose	Co-design and co-ownership of scope, priority and goalsetting for PRO tool.
2	Respect and accessibility	Discuss needs and actions required to ensure respect for patient's roles and diversity of perspectives with participants early on.
3	Representativeness of stakeholders	Define how to ensure all the relevant perspectives of PWD are represented.

4	Roles and responsibilities	Ensure roles, responsibilities, and tasks of PWD and other stakeholders are clear to all.
5	Capacity and capability for engagement	Ensure all patients are supported as needed to have capacity and capability to fully fulfill the intended role as partner in each activity.
6	Transparency in communication	Communicate process and results of patient involvement transparently and facilitate broader, public information and discourse.
7	Continuity and sustainability	Plan how patient involvement activities can be used to set stage for sustainable involvement.

Table 3. The seven quality criteria used to facilitate patient involvement in the Danish PRO diabetes program. The seven criteria are adapted from Deane et al [181].

The quality criteria were used to define tangible strategies for patient involvement and allow for structured evaluation. Examples of tangible uses of criteria 1, 3, and 5 are provided below. An example of use of criteria 1 (aims and purpose) was: PWD were involved in open dialogue about the aims and scope of the PRO diabetes program already in the scoping phase. This provided the PWD with concrete opportunities to influence the foundation of the program and facilitated a sense of shared ownership. Patient input specifically facilitated the national decision to pursue one unifying national PRO diabetes questionnaire rather than pursue multiple questionnaires for different purposes. Patient input also led to specification of additional potential benefits of PRO diabetes which were of interest to PWD and had not been previously identified. For example, PWD noted that it would be helpful if the PRO diabetes tool could help PWD navigate in the diabetes care system and better understand their options for acting to improve their health. Example of use of criteria 3 (representativeness) included that input from PWD was used to guide the theoretical purposive sampling strategies for patient activities and studies II and III. This included defining the importance of representation of PWD with different types of complications, treatment regimens and care situations. Example of use of criteria 5 (capacity and capability) included specification of what was needed for PWD to be able to fully participate in each patient involvement activity. The requirements were defined based on the research goals of the activity and were used to identify which support strategies were suitable to ensure each PWD had the capacity and capability

to be fully involved. These strategies included the use of telephone conversations with patients prior to meetings to assess individual needs, provision of pre-reading materials in lay language, use of reflective questions prior to meetings to prepare patients, and instrumental support for making presentations at meetings (e.g. pictorial representation of patient insights on posters or presentation design).

Each of the patient workshops shown in figure 1 was planned around detailed patient involvement aims specific to each PRO development stage and key decision points of the next multi-stakeholder working meeting.

Registration and coding of data in NVivo was done to enable systematic use of patient insights on an ongoing basis to strengthen patient insights management, improve the formative evaluation process, and enable subsequent evaluation of the effectiveness of patient involvement [201]. Initial results of impact of patient involvement in first phases were presented by the author in 2019 [160].

Patient involvement in the *planning* of patient involvement in the scoping process led to important actions to ensure effective use of patient perspectives by the multi-stakeholder working group in accordance with the seven quality criteria; A stand-alone patient workshop was conducted prior to each national multi-stakeholder working meeting which generated robust patient insights relevant to the specific research and design questions that focused on the particular national working meeting. The patient workshops ensured that the relevant topics had been comprehensively discussed in a representative patient group in advance of each multi-stakeholder meeting. To ensure effective co-learning and consideration of the patient insights by the HCP stakeholders, the agenda of each multi-stakeholder working meeting started with a presentation by PWD of results of the outcomes of the preceding PWD workshop. Collaboration meetings were held with individual patient collaborators and the research team in advance of each multi-stakeholder meeting to ensure capacity and capability of the PWD for conveying the messages.

The central placement of robust presentations by PWD on the multi-stakeholder workshop agendas facilitated understanding, awareness, co-learning and respect regarding the relevance of patient perspectives among all stakeholders at each stage.

Patient involvement activities were developed for each of the eight steps of the PRO design tool in table 2 taking into account the general quality criteria listed in table 3.

For each development stage, project responsiveness to patient insights was registered by assessing concrete impacts of patient inputs on the program's design decisions.

As example, at step 2 (table 2) of prioritizing topics for inclusion in the PRO tool, a combination of home reflection assignments, group discussions, and voting led to saturation for the patient insight that a wide range of diabetes topics were relevant and value-adding to measure by use of PRO also beyond mental health, diabetes distress

and individual self-care goals. The verification of PWD's preference for evaluating a broad range of PRO constructs to evaluate outcomes (study I) was important because the prevailing recommendations for clinical practice focused on the use of PRO to mainly monitor mental health problems [27,86]. Without the systematic planning of patient workshops to examine this specific aspect early in the process, the PRO diabetes project could likely have ended up focusing only on psychological issues.

2.3.1. MULTI-STAKEHOLDER PARTICIPATION TO AUGMENT PATIENT INVOLVEMENT

Effective systematic patient involvement depends on effective integration of patient stakeholder involvement in the multi-stakeholder decision-making process [167,170,171] and multi-stakeholder co-ownership of patient-centered health objectives. A patient-orientated multi-stakeholder participation process [5,202] was therefore designed in the PRO diabetes program to ensure a research development environment which facilitated 1) iterative, contextual, mutual learning[182], 2) a collaborative environment with balanced decision power across stakeholders[176], and 3) a project governance that allowed for responsiveness of the overall project to insights resulting from involvement. Table 4 lists key strategies for multi-stakeholder participation used in the Danish PRO diabetes development program which synergizes with and serves to augment patient involvement activities [168,171].

1. Shared clear picture of national scope and mandate for all stakeholders
2. A clear patient-centered and measurable objective (e.g. improved the experienced quality of the PWD-HCP dialogue and diabetes care visit).
3. Clear, well-defined governance model from the outset.
4. A commitment to and plan for democratic involvement of all parties to achieve shared ownership: tailored approaches to equal involvement of each stakeholder group based on individual stakeholder needs and opportunities.
5. Planning of special activities and approaches to facilitate the understanding among all stakeholders of the perspective of PWD and FM using a humanistic and holistic approach to insights generation, management and dissemination.
6. Definition and articulation of purpose, objectives, and evaluation goals from the outset.
7. Definition of terminology and relevant concepts or conceptual framework.

8. Transparent communication and clarity regarding roles of all stakeholders.
9. Early, ongoing focus on identifying requirements for sustainable implementation including barriers, facilitators and critical organizational, political and resource issues.
10. Willingness to respond to and consider ongoing and iterative input and feedback to ensure an optimal end-result.
11. Open, respectful communication and collaboration across disciplines and sectors.
12. Project responsiveness and flexibility to react to empirical findings indicating requirements for adjustment of assumptions or pre-planned methods underway.
13. Systematic approach to evaluation, rooted in originally agreed goals and objectives, involves all parties, and with goals aimed also at long-term impact.
14. Intention and plans to secure continuity of established relations and collaborative capacity and support of ongoing quality and development over time.

Table 4. Strategies for multi-stakeholder participation used to augment patient involvement in the Danish PRO diabetes program. Adapted from Skovlund et al[199].

2.3.2. PROGRAM THEORY FOR THE PRO DIABETES TOOL

In step 1 of the process listed in table 2 in 2018 overall aims, methods and desired outcomes for use of PRO in diabetes were clarified using patient involvement and multi-stakeholder working meetings. Key elements of the program theory, defining 1) how the intervention is intended to work and for whom and 2) what the intended outcomes were and possible mechanisms of actions [203] are summarized in table 5. The hypothesized mechanisms of action of the PRO diabetes tool were refined by stakeholders during the design process and provide initial guidance for hypothesis testing in line with relevant clinical, behavioral, and psychological diabetes theoretical and methodological frameworks [4,152,204,205].

A. Target group	All adults (over 18 years) diagnosed with either type 1 or 2 diabetes. PRO tool to be used across the adult life span.
B. Setting	Secondary Care: Annual nurse visits, initial medical examination. Municipality: Initial, ongoing and evaluating diabetes visits. Primary Care: Extended primary care diabetes visits.

C. HCP use	Secondary care: Diabetes nurses, physicians and dietitians. Primary care: Physicians, nurses and relevant other staff. Municipality: Nurses, physiotherapists, dietitians, social workers.
D. PRO model	PWD completes PRO questionnaire 1-10 days prior to visit. HCP and PWD use PRO data as dialogue tool to plan care together.
E. Key aims and mechanisms of action:	
Aim: Improve diabetes care by increasing active patient participation and improving quality of patient-HCP dialogue. Specific aims: -Increase active participation of and influence of PWD on their care. -Improve quality of the PWD-HCP dialogue and the care visits. -Increase comprehensive review and attention to biopsychosocial needs -Improve priority setting in care based on what matters most to each PWD. -Improve quality of care and coordination Secondary uses and intended benefits of the PRO diabetes tool include: Visitation support: Tailor care plans according to individual needs to ensure more effective use of care resources and minimize waste. Decision support: Use individual PRO scores to support decisions about treatment. Analytical use of PRO-data: Use PRO data to improve quality of care and services locally and nationally, for value-based diabetes care and person-centered research.	

Table 5. Program theory for the Danish PRO diabetes tool. This program theory was synthesized by the author based on multiple data sources [3].

While it is not in scope of this thesis to present the detailed patient involvement methods and techniques applied in each of the steps of development, this section exemplifies process elements pertaining to systematic patient involvement in step 2 (prioritization of PRO topics) and 3 (questionnaire construction).

2.3.3. PATIENT INVOLVEMENT IN SELECTION OF PRO CONSTRUCTS

The constructs to be included and the hypothesized rationale for the use of each specific construct in routine care were co-designed through an iterative process involving patient workshops and focus groups which mapped topics of relevance across the patient journey in the healthcare system. The process included divergent and convergent phases. PWD and HCPs completed individual surveys prior to

meetings, the national working group achieved consensus on a final list through workshops and a plenary consensus process. Systematic literature reviews and relevant methodological frameworks guided and qualified the process.
Patient involvement activities focused on 1) Defining each construct and the rationale for its inclusion from the patient's perspective 2) Identifying where to use the outcome in the patient care journey and potential limitations to use, 3) Describing the latent construct in the language of PWD. 4) The author examined relevant theoretical and empirical research pertaining to potential known patient benefit, clinical utility, psychometric measurability and theoretical foundation. The topics and constructs agreed for inclusion in the Danish PRO diabetes questionnaire by the multi-stakeholder group are shown in table 6. Examples of research supporting the clinical relevance and measurability of each construct are cited.

1. General health [206,207] 2. Psychological well-being [7,143,149,208] 3. Depression [209] 4. Social Support [210,211] 5. Life issues affecting diabetes [42,59,135,142,212–215]
6. Diabetes in daily life [57,141,216] 7. Diabetes-related distress [18,19,137,217–222] 8. Limitations due to diabetes [19,223], 9. Diabetes Social Support [7,11,28,134,141,223–226],
10) Confidence in diabetes self-management related to global confidence, eating healthily, physical activity, weight, blood glucose monitoring, reacting to high and low blood sugars, insulin injection and dosing, diabetes knowledge, use of diabetes technology [67,69,227–236].
12) Symptom distress screening [237,238]; 13) Monitoring somatic symptom distress related to: Neuropathic pain [239–241], 14) Gastrointestinal [19,242–246], 15) Cardiovascular [238], 16) Sexual dysfunction [19,247–250], 17) Sleep [130,251–256], 18) Cognition, fatigue, tiredness [238,257–259] (excluded after pilot test) 19) Foot ulcer [260–262].
20) Annual checkup: Eyes and feet [7] 21) Confidence in access to HCP [263],
22) Medicine experience, challenges and satisfaction [16,19,134,243,264–272] 23) Blood sugar regulation and hypoglycemia [6,7,12,18–21,212,237,243,273–279]

24) Hypoglycemia unawareness [278,280–283] 25) Hypoglycemic event requiring assistance [21,284–286]
Wishes for Support [57] (excluded after pilot test) Desired topic to discuss at next visit [142].

Table 6. Overview of main constructs and topic categories for the PRO diabetes questionnaire.

Topics or constructs not qualifying as traditional "health outcomes [84] were included as "other health constructs" [5,50,104,133,287] or Patient Reported Input (PRI) [4] if considered essential for the PRO tool to serve its purpose by PWD and HCP. Relevant theoretical foundations and empirical evidence were considered as guidance for each topic from diabetes psychology [27,288], social cognition theory [289,290], health and illness beliefs model [291,292], self-determination theory [293,294], empowerment [45,68,69], behavior change theories [152], diabetes self-management education [35,290,295]. The process prioritized PWD's and HCP's experience-based perspectives but ensured consideration of psychometric evidence whenever relevant. As an example of the balanced approach, diabetes self-management had been identified as a priority topic to include, and stakeholders initially had different perspectives on what this construct entailed. Some HCP found it important to measure self-reported alcohol intake, smoking, unhealthy diet and sedentary lifestyle as it reflected on their care responsibility. PWD found the experience of confidence in managing diabetes more helpful (study I) and preferred questions about confidence compared to existing standard questions about alcohol consumption, smoking and unhealthy eating. PWD expressed that all questions in the PRO questionnaire should project trust and respect and should avoid a paternalistic approach. It was noted that even if it was just a few items that were perceived as insensitive or irrelevant by the PWD it could be counterproductive and demotivate the PWD. Assessment of confidence in diabetes management has been shown to function well as an intermediate outcome goal for diabetes self-management education [204,216,289,296,297]. While some self-assessment scales for health behavior and medicine taking correlate with objective indicators [298,299] it is difficult to obtain reliable measures of health behavior using short self-assessments as would be required for the PRO diabetes tool. The multi-stakeholder group agreed to include questions about confidence with self-management. Care centers requiring the use of detailed health behavior questions would then administer potential behavioral self-assessment items separate to the PRO diabetes tool.

Linked to self-management, PWD and HCP agreed to incorporate a broad global question about barriers to diabetes management covering general life issues, including

comorbidity, work, financial situation and other to complement the confidence assessment. Including such a construct is supported by clinical models for integration of social determinants of health [300], behavior change theory [152], and self-efficacy theory in diabetes care [42] which recognize the importance of psychosocial resources, beliefs, attitudes, and external barriers for diabetes management. Similar approaches were taken for all other constructs with use of empirical evidence to substantiate the decisions made by HCP and PWD and build on the patient-important outcomes identified in study I.

2.3.4. PATIENT INVOLVEMENT IN BUILDING THE QUESTIONNAIRE

Based on a literature review and desk research involving all the stakeholders in the development process, it was concluded early on that no previously psychometrically validated diabetes PROMs existed which covered all of the PRO topics selected for inclusion in the Danish PRO tool and fulfilled the additional requirements for clinical utility and person-centered language.

A protocolized stepwise procedure for patient involvement in selecting PRO items and scales for the development of a questionnaire battery was therefore undertaken as part of step 3 (table 2). For each construct [128,195], insights from PWD were combined with HCP practice experience, and psychometric methodology and literature review.

Requirements for items were defined based on workshops and meetings with PWD, the program theory, and literature review of patient-orientated PRO research [154,301]. The specific PWD preferences for items are listed in table 7. These criteria were applied as a supplemental to the requirement of psychometric validity and reliability of items in accordance with the intended use of each item or scale [4].

Items for use in the PRO diabetes questionnaire should
1) Be simple, easy and unambiguous to understand for all PWD in the target group.
2) Be unbiased, non-judgmental, non-paternalistic. Adoption of principles for person-centered non-stigmatizing diabetes language[5,54,302].
3) Balance positive and negative wordings and avoid one-sided problem focus.
4) Be evidently relevant for the PWD in the context it is used.
5) Yield easy-to-interpret outputs which PWD and HCP can understand and act upon.

5) Support active participation of PWD in own diabetes care.
6) Have the potential to lead to improvement in patient-important outcomes.

Table 7. Patient-based criteria for selection and development of items for use in the PRO diabetes questionnaire. Adapted from Skovlund et al [4]

Patient preferences regarding the questionnaire as a whole included not being too large, clear brief instructions, consistency in the way questions are asked, logical, intuitive order of topics and items, and the possibility to complete it on mobile, tablet or PC. The item criteria in table 7 defined by PWD had implications for the final design of the Danish PRO diabetes questionnaire. The multi-stakeholder working group placed greater weight on factors related to person-centered diabetes language than on including pre-existing scales with proven validity in line with growing recognition that non-person-centered diabetes language may contribute to diabetes related distress [5,54,302]. During the detailed review of candidate scales and items by PWD and the working group, internationally validated scales such as SF-12 [303], PHQ-9 [304], PROMIS-10 [130], EQ-5D [305], Diabetes Distress (DDS) [306,307], Problem Areas in Diabetes (PAID) [224], and Summary of Diabetes Self-Care Activities Assessment (SDSCA) [236] were not included based on one or more of the patient-based requirements.

Using the agreed patient-centered criteria, the following key steps were undertaken to select or design items for all of the constructs identified to be included:

1) Identifying and evaluating existing previously psychometrically validated PRO items or tools based on literature analysis and desk research [92]. Using existing items if they fit the construct and meeting agreed pre-defined criteria relating to acceptability, relevance, validity, and utility.

2) If no existing items/tools were available, evaluating basis for adaptation of parts of pre-existing tools or modification as feasible utilizing own and literature-based qualitative research as guidance.

3) If no existing items/tools were available or suitable for use or adaptation, co-developing new items based on the perspective of PWD as ascertained from working meetings, workshops, interviews and literature reviews through a collaborative process involving PWD and HCP. Verbatim notetaking was used in workshops with PWD to facilitate use of language reflective of the everyday lived experience.

To meet the preferences of PWD and achieve the required multi-dimensional topic coverage while maximizing brevity, techniques of branching logic, global rating items, and brief multi-item scales were used. As the primary purpose of this PRO tool was dialogue support and there was an interest from the project to potentially use

shorter versions in primary care or with vulnerable patients, global rating scales drawing on the method of "global essence domain items" [218] were used to co-design global items for select constructs. The method differs from scale reduction by selecting the item explaining the greatest amount of the variance [137,139] as this method may result in too narrow of a construct.

When new items were required, PWD were involved in early generation of global items to incorporate lay wording and capture the essence of the latent constructs. Response options were iteratively adjusted in order to cover a wide range matching the estimated variance in the population. The aim was to include a hypothesized hierarchical structure which would require psychometric validation pending quantitative data collection. All adapted or newly designed items were always evaluated by the entire national multi-disciplinary working group to optimize their face validity, clinical utility, and appropriateness from the perspective of all the stakeholder and care setting perspectives. Adjustments were proposed in a co-design process and consensus on a final version was established which also took into account relevant psychometric format and design considerations [92,102,104,128]. The latter involved soliciting qualitative insights and input important for face validity, acceptability, appropriateness, comprehension, comprehensiveness, content validity, perceived relevance, reliability, responsiveness, interpretability and utility, both from the perspective of PWD and HCP and related to the theoretical or empirical basis for the specific measurement impacting care quality and patient outcomes.

5-point Likert scales with verbal anchors and use of simple transparent scoring were generally preferred by PWD which was in line with psychometric evidence supporting acceptability, low cognitive burden, and user-friendly interpretability.

The final PRO diabetes questionnaire was reviewed and optimized in its entirety in patient involvement research workshops with PWD who were recruited using purposive sampling in fall 2018. The psychometric literature review and design process for the PRO diabetes questionnaire is not the focus of this thesis but examples of the use of related patient-centered psychometric to qualify the co-design process are provided in the following section. The main previously psychometrically evaluated questionnaires incorporated into the PRO diabetes questionnaire were the global health item from SF-1/PROMIS [130,206,207,308], the WHO-5 Well-Being Index [143], the MDI-2, a short form of MDI-2 [209], a 2-item loneliness scale from the national Danish Health Profile [211], the Diabetes Symptom Check List (DSC-R) [238,309], the PROMIS sleep quality item [254], Karolinska Sleep Scale Short Form [255,256], and the Hilleroed Screening Item for Hypoglycemia Unawareness [280,310]. The review and co-design process for PWD and HCP was guided by ongoing user testing, qualitative research and consideration of related psychometric research already done for the

identified constructs. Confidence in diabetes self-management was measured using a Danish adaptation of the Confidence in Diabetes Management Questionnaire [311] which uses simple questions asking about confidence in ability to manage different aspects of diabetes. User testing and workshops resulted in iterative re-wording of items to achieve the desired person-centered language. The measurement construct was supported by previous research related to the Perceived Competency For Diabetes Scale (PCD)[205] (Diabetes Self-efficacy Scale (DES)[216] Diabetes Self-Management Questionnaire (DSMQ)[235], the Perceived Diabetes Self-management Scale (PDSMS)[297]. Diabetes stress was for example assessed with consideration of research pertaining to PAID-1 [137], PAID and DDS [22,306], limitations due to diabetes was assessed with consideration of empirical diabetes research related to QDIS [217–219] and SF-12 [303], gastrointestinal symptom distress was assessed using the generic questionnaire format of the DSC-R [309] and with consideration of previous empirical psychometric research [19,246,312]. Similarly distress related to sexual dysfunction was assessed with iterative item adaptation to accommodate PWD's preferences and consideration of related psychometric research [19,247]. Satisfaction with medical therapy was assessed taking into account the broader patient-centered psychometric research field of treatment satisfaction and experience, focusing on the core components of perceived efficacy, side effects, convenience and ability to take the medicine as prescribed or desired [19,133,270,313]. Specific research questionnaires considered included ITSQ [16], GDTS [134], DiabMedsat [19,243], Treatment Satisfaction Questionnaire for Medication (TSQM) [270]. A multi-faceted model for understanding barriers to "treatment adherence" was considered in the co-design of a global item regarding medication taking [266,314]. The co-design of items to measure perceptions of blood sugar regulation and burden of hypoglycemia was guided by extensive empirical psychometric research related to perceptions of hypoglycemia, blood sugar fluctuations and perceptions of blood sugar regulation in general. Treatment-Related Impact Measure for Hypoglycemia (TRIM-HYPO)[277], DiabMedSat [19,243], Diabetes Care Profile (DCP) [286], DAWN2 [12], and the Fear of Hypoglycemia Survey (FHS) [315].

The content of the Danish PRO diabetes questionnaire which was tested in this thesis is presented in table A13 of appendix III. A final version of the Danish PRO diabetes questionnaire was approved by the Danish Health Data Authority in March 2021. A complete copy of the entire final PRO diabetes questionnaire is available to the reviewers of this thesis from the Department of Clinical Medicine, Aalborg University upon request. Information to PWD and a video about how the PRO diabetes questionnaire is used in practice is available at http:\www.diaprofil.dk.

2.4. 2019: ITERATIVE TESTING AND FORMATIVE EVALUATION OF THE DIGITAL PRO TOOL

In 2019, iterative user testing of the nationally agreed diabetes questionnaire was undertaken and PWD were interviewed using cognitive debriefing methods [316] to examine comprehension and the potential for measurement error.

A subset of items were included in a national diabetes survey study with the Diabetes Association using population survey research methods [8,317] to examine the psychometric performance of newly designed items in a population health setting [318]. Factor and correlational analyses showed that 3 items co-developed by PWD, as hypothesized, measured perceived negative impact of diabetes. The multi-item scale score had satisfactory internal consistency reliability (Cronbach α=0.78). Hypothesized, perceived negative impact of diabetes was associated with use of intensive insulin therapy, greater burden of late stage complications and a greater expressed interest in obtaining a referral to a psychologist ($p<0.05$, One-way Anova) [318]. A psychometric analysis of the entire questionnaire will be undertaken in April-July 2021 and published as paper XIV.

In 2019, the digital PRO dialogue support tool, *DiaProfil*, was finalized for clinical testing. The goal was to establish a digital health tool that would allow for a user-friendly completion of the PRO diabetes questionnaire by PWD at home via phone, tablet, or the internet and be suitable for seamless active use by HCPs during visits with PWD.

The functionality was co-designed with PWD and a multi-disciplinary clinical diabetes care team drawing on empirical insights from the author's previous digital PRO projects with teenagers [135,319] and adults [62,142] with diabetes using user-centered methods [150,151]. Previous research indicated that PRO tools may not necessarily change HCP care practices beyond dialogue quality [155,156]. As changes in care practice was considered essential for optimizing potential impacts of the PRO diabetes tool on health outcomes, and it had been agreed with PWD that questions should only be included in the PRO tool if HCP were able to act on the results, the digital PRO tool was designed with a new functionality, *action support*, to make it easier for HCPs to follow-up on every potential PRO output.

This involved that the author and the clinical diabetes care team at Aalborg University Hospital mapped dialogue tools, self-help resources, treatment and referral options, and community-based support resources for every PRO construct and individual PRO output through systematic outreach to the extended cross-sector network of diabetes care, education and support services inside and outside of the hospital. This data was built into the digital PRO dashboard for the HCP to access with one click for each

PRO output during the visit. A flexible database structure was created to allow each diabetes center and clinic to establish their own locally tailored action support database for use in care visits.

Team meetings provided a trusting, safe forum to facilitate formal and informal solicitation of views and perspectives as well as mutual learning by all members of the multi-disciplinary development during the digital tool design.

The *action support* feature was favorably rated by users and hypothesized to potentially help increase concrete HCP follow-up action on each flagged PRO topic in accordance with evidence-based integrated chronic illness care [320]. Specifically, it was intended to facilitate improved use of self-help resources, treatments and technology as well as both internal and external education and support resources.

The action support function was also inspired from patient workshops regarding aims of PRO where PWD noted they hoped the PRO tool could help PWD understand and navigate their options for acting to improve their health. Another key feature created in response to user input was the establishment of a "single-screen overview dashboard" which gives an at-a-glance overview of the PRO results of PWD. This was based on HCP input that to facilitate high adoption, as defined in the RE-AIM model for optimization of public health impact of the intervention, it was important the PRO tool was easy and quick to use in between visits in daily practice. An at-a-glance overview screen was achieved by clustering PRO results into 9 main themes which corresponded to key outcome constructs identified in study I. A third new feature, a screen suitable for shared equal use by PWD and HCP, was developed based on wishes of both PWD and HCP to be able to discuss results in a reciprocal way using person-centered communication [7,321,322]. This deviated from the existing HCP-orientated standards for PRO dashboards which showed PRO data inside clinical HCP interfaces. A traffic-light coloring scheme determined by a scoring algorithm for all PRO responses co-designed by the multi-stakeholder working group with PWD input was used to present the PRO results on the screen. Green indicated no problems, yellow indicated potential issues to discuss, and red indicated potential issues which should be addressed. The design of the colors was iteratively adjusted based on input from PWD to ensure optimal acceptability. For example, initial tones and sizes of red and yellow colors to make the screen appealing and minimize inadvertent signaling of danger or concern. The resulting dashboard was appealing to both HCP and PWD. PWD found it intuitive to read and confirmed it provided a good representation of their current diabetes situation. A screen shot of the PRO dashboard is depicted in study II and III (appendix). Study II evaluated the experience of use of *DiaProfil* in routine visits and collected data to guide the design of the longitudinal clinical study at Aalborg University Hospital (C-PRODIA) and the multi-center study, M-PRODIA.

Study III describes the M-PRODIA study protocol which involved two hospitals, four municipality diabetes centers and one primary care practice (study III).

2.5. 2020: NATIONAL MULTI-CENTER PILOT STUDY

During 2020, the national PRO diabetes questionnaire tool was pilot tested under the auspices of the National Health Data Authority in collaboration with VBHC-PRO-DIA. As part of this project, data was collected from more than 550 PWD and 30 HCP for mixed method evaluation of questionnaire reliability, validity, acceptability, and examination of perceived benefits as well as implementation barriers and facilitators (appendix III). Half-way into the study in mid-2020, statistical and psychometric analyses were done on preliminary data from the M-PRODIA study to examine distributions, scaling and response option issues, scoring algorithms, cut-of scores and potential interpretability issues together with the clinical teams. In some cases, scoring algorithms for color coding of questionnaire responses were adjusted due to ceiling and floor effects and to fit clinical experience. Initial psychometric testing, including factor analyses, correlation analyses and known-group validity testing was done to confirm the quality of the data.

2.6. 2021: NATIONAL EVALUATION AND APPROVAL OF THE DANISH PRO DIABETES TOOL

In December and January 2021, preliminary data from quantitative PRO data and PRO evaluation questionnaire data and interview data from the M-PRODIA study were consolidated by the author in order to support the final evaluation of the PRO diabetes tool pilot by the Danish Health Data Authority.

On January 19, 2021, the national clinical coordination group for PRO diabetes convened again for their fifth national meeting to review the completed national evaluation report, review the results of the pilot test at each of the participating sites, decide on final adjustments to the PRO tool based on the pilot data, and make final recommendations regarding implementation.

Each of the participating sites reported that they found the PRO diabetes tool fit for purpose and considered it acceptable, usable and value-adding as a dialogue support tool to augment their care for PWD. The tool was found useful both for people with type 1 and type 2 diabetes and in both hospitals and municipalities. Benefits that were reported were closely aligned with the pre-defined program theory.

The national working group agreed on minor adjustments to the questionnaire and scoring algorithms based on quantitative data analysis and qualitative analysis of evaluation inputs from PWD and HCPs during the pilot test. The final PRO diabetes

questionnaire was recommended for expanded use in outpatient diabetes clinics and municipality rehabilitation services for PWD. Due to the practical challenges and implications related to Covid-19, insufficient experience had been accumulated to make generalizable conclusions regarding utility of the PRO diabetes tool in primary practice so testing is anticipated to continue in primary practice in 2021.

Psychometric and qualitative analyses are now ongoing by the author drawing on systematically collected research data from PWD involved in the program from 2017-2021 in line with the publication plan shown in table 1.

CHAPTER 3. REVIEW OF STUDIES

3.1 RATIONALE AND AIMS

3.1.1. STUDY I:

The aim of this study was to facilitate agreement on a national core set of diabetes outcome constructs for use to evaluate outcomes of diabetes care that appropriately reflects what matters to both PWD and HCP [1]. Establishing consensus on how to measure value was defined as a critical starting point for the development of a possible future framework for use of value based diabetes care in Denmark [48].
By identifying these outcome constructs, it would subsequently be possible to develop the operational methods to measure these on an ongoing basis as part of clinical care. When this study started, no existing consensus set had been developed that allowed for the evaluation of outcomes of care as well as quality improvement and value-based care in a way that aligns with the perspectives of both PWD and of HCP.
While ample research has been undertaken regarding the general aspects of the lived experience with diabetes [29,110,146], this study aimed to systematically involve PWD and FM in Denmark as collaborators in exploring not only what issues affected them, but also what relevant outcome constructs to prioritize that would have potential for improving care. This required the design of specific involvement activities tailored for this purpose.

3.1.2. STUDY II

In early 2019, a new first of its kind Danish PRO diabetes questionnaire and clinical PRO tool was finalized. Content and functionality were new, and the tool had not been evaluated in Denmark previously. A formative pilot feasibility study was required to examine basic appropriateness, acceptability, feasibility, fidelity and collect preliminary insights about perceptions of the tool in routine care [170]. Specifically, the theorized benefit of the PRO questionnaire on PWDs' level of active participation and perceived dialogue quality was applied as hypotheses to be preliminarily evaluated using mixed-methods research. We used qualitative insights from workshops, focus groups and clinical user testing of early digital prototypes to design the study materials. PWD gave input to the study aims, study design and wording as well as Likert-scale evaluation questions.

3.1.3. STUDY III:

As part of the Danish Health Data Authority's procedure for development of national PRO questionnaires, a qualitative pilot test was planned to evaluate the practical experiences with use of the PRO diabetes questionnaire and its potential for implementation. The initial scope was not to undertake a scientific evaluation. In line with the aim to apply systematic patient involvement in all phases of the PRO diabetes questionnaire program, Study III was designed to complement the national pilot test through systematic collection of subjective experiences from PWD and HCP and participating centers. These data would allow for scientific analyses of acceptability and development and initial testing of hypotheses in line with the program theory. This study was the first evaluation of the acceptability, perceived value, implementation and public health potential of a national PRO diabetes tool in Denmark.

We did not identify previously psychometrically validated PRO evaluation questionnaires suitable for completion in busy routine care settings by PWD and HCP which would address the research questions identified as important by PWD and the national PRO diabetes working group. The rationale for the study was to obtain detailed quantitative insights into how PWD experienced the process of completing the questionnaire and use of their PRO data during their visit, and how they perceived the use of PRO affected their role in care, their diabetes care and their self-management. The study aimed to establish a pragmatic research data collection protocol that would piggy back on the planned practical pilot testing to generate unique insights about acceptability and perceived value of the PRO diabetes tool in a large and diverse sample of people with type 1 and type 2 diabetes treated for diabetes across three different health care settings [3]. An additional aim of the study was to develop and psychometrically evaluate Likert-based PRO evaluation questionnaires to be used also in the future for comparative evaluation of PWD and HCP's experiences of PRO tools in different settings [3].

3.2. METHODS

3.2.1. STUDY I

The study design was aligned with general steps for design of core outcome sets [87] and principles for patient involvement in research [181] and methods for qualitative analysis to augment the process [323]. The study was designed in two main parts: 1) A structured set of patient involvement activities supported by qualitative analysis pertaining to the perspective of PWD in Denmark on selection of core outcomes and 2) A stepwise consensus facilitation process for a multi-stakeholder expert group to prioritize and define a core set of clinical and PRO outcome constructs.

The choice of method was driven by the primary aim to solicit insights about the specific perspectives of PWD regarding what outcome constructs should be included in a future solution to integrate outcomes evaluation in their routine care. The health outcomes hierarchy model of the value based health care (VBHC) model provided the methodological framework [196].

Through input from a panel of PWD, a purposive theory-based sampling approach was defined [324] to optimize representation of factors identified as theoretically relevant including type of diabetes, diabetes duration, gender, therapy, age, and disease burden [1]. A group of 21 PWD and 5 FM were recruited in accordance with the pre-defined criteria.

Detailed advance planning of patient involvement activities using multiple methods for engaging PWD as either advisors and collaborators as relevant for each research question and phase was undertaken [181]. A combination of individual surveys, focus groups, workshops and plenary discussions were designed to match each research question to the most suitable research method as deemed feasible within the time and resource constraints of this phase of the value-based diabetes project.

The data generated from this work was consolidated using a pragmatic approach to combining different involvement methods to achieve the optimal research outcome [166,325]. Workshop design and qualitative analysis was designed to achieve saturation as it was an important aim to identify a core set of outcomes which could be considered comprehensive by the representative group of PWD [162].

A proposed candidate list, which reflected the priorities of PWD, was qualified using literature review and was used as a starting point for the work of a national value-based diabetes care expert panel with the mandate to select a final core set of patient-important outcome domains for use for value-based diabetes care in Denmark [1]. The process for consensus was facilitated by using a candidate outcome list which

reflected both patient and clinician ratings of importance and using pre-defined criteria for the selection and prioritization of outcome domains.

3.2.2. STUDY II

A single arm feasibility and acceptability pilot study design was applied as the primary purpose of the study was to establish basic feasibility, acceptability, and perceived utility of the first functional version of the digital tool, *DiaProfil*, which at the time had not yet been tried in routine care visits. The underlying hypotheses, as defined in the PRO diabetes program theory, pertained mainly to the impact of the use of PRO on patient engagement and quality of the dialogue as well as to underlying assumptions about the mechanism of action developed during the participatory design that would be preliminarily evaluated using descriptive and qualitative analyses. The design was further guided by the aim to use the study for formative evaluation as part of iterative testing and refinement of the PRO questionnaire and digital tool. Since this was the first test of the Danish PRO tool in a routine setting the author included an exploratory component to prompt for any unintended or unexpected challenges, impacts and adverse events.

Theoretical purposive sampling [324] was defined with input from PWD who helped define which attributes were most important to have representation of to adequately reflect the breadth of experiences related to acceptability and value of PRO. We recruited PWD attending regular scheduled diabetes visits at the outpatient diabetes clinic of Aalborg University Hospital.

A pragmatic planned mixed-method design was used because it was deemed of significant value to triangulate data and thereby potentially strengthen the credibility of findings. Mixed-methods was chosen as method because it was believed that combination of the different data sources would strengthen the credibility of the findings especially considering the small sample size [164,326].

The research questions were based on the initial program theory (table 5), hypothesized benefits of the PRO tool, input from PWD and guided by qualitative data from ongoing user testing. The benefits related to improved patient participation may be analyzed in context of several theoretical frameworks and models, including patient activation [327,328], empowerment [45,58], self-determination [205] and social cognition theory [289].

All evaluation tools and final qualitative analyses and synthesis were developed by the author with input from the PWD, multi-disciplinary clinical care team and medical students involved in coding consultation transcripts.

3.2.3. STUDY III

The design of the M-PRODIA study protocol was guided by input from PWD and qualitative data collected during the PRO diabetes development process and aligned with the program theory for the PRO diabetes tool. The rationale for the design of brief Likert scale PRO evaluation questionnaires was that valid brief questionnaires were required, which could be completed by PWD and HCP as part of routine care even in study sites with very limited resources for collection of research data. A digital user-friendly system was needed with minimal responder burden [93].
Protocol acceptability and feasibility was optimized through co-design with PWD and HCP at each site and local tailoring of procedures as needed for each site. The aim was to minimize noise and interference caused by data collection as much as possible. As a key goal of the study was to generate data to guide future implementation of the PRO diabetes tool, the RE-AIM framework [153] was used to guide data collection and analysis plans.
The study design reflected the realization that both qualitative and quantitative data was required to capture and analyze the complexity of real-world usage and effectiveness of clinical PRO tools [329]. The PRO evaluation questionnaires were designed to quantitatively evaluate feasibility, acceptability, validity, relevance, implementation, and perceived effectiveness in line with the hypothesized benefits. Wording and content were prioritized in collaboration with people type 1 and type 2 diabetes.

3.3. KEY FINDINGS

3.3.1. STUDY I

This study revealed that PWD found both objective clinical indicators as well as subjective indicators of life impact and care experience to be highly relevant and important to include in planned future efforts to evaluate diabetes outcomes.
The study found the following areas to be required for comprehensive outcome evaluation: self-rated health, psychological well-being, diabetes related quality of life and diabetes-specific emotional distress, medical treatment experience and burden, blood sugar regulation and burden of hypoglycemia, confidence in diabetes self-management, symptom distress related to neuropathic pain, cardiovascular symptoms, sexual dysfunction, sleep and fatigue and gastro-intestinal symptoms and access to person-centered diabetes care, support and required technology [1]. The core constructs were identified as relevant to both type 1 and type 2 diabetes whereas issues pertaining to hypoglycemia and blood sugar fluctuations were only relevant depending on the

use of insulin therapy and methods for blood sugar measurement. PWD agreed that all outcome areas were relevant for all PWD as a lifespan outcome set, with the exception of insulin-related treatment burden, since needs of PWD change over time [17].

3.3.2. STUDY II

All PWD regardless of type of diabetes, diabetes duration, age, treatment modality, and burden of disease found it manageable and acceptable to complete the diabetes PRO questionnaire from home using *DiaProfil* in connection with their scheduled regular visit. PWD found the questionnaire to be relevant with comprehensive coverage of relevant topics and no one reported major concerns or problems related to the questionnaire or its use. This was confirmed by combining semi-structured interviews, Likert-scale questionnaires, audio-recording of consultations and debriefing workshops with health professionals.
Both PWD and HCP reported that the use of the PRO results using the digital PRO diabetes tool was feasible, acceptable and helped improve the quality of the dialogue. PWD were positive about the opportunity to fill out the questionnaire in advance and many expressed it made them better prepared. They felt reassured that they would get to talk about their priority topics at their next visit [2].

3.3.3. STUDY III

A complete set of data collection tools and evaluation questionnaires were finalized and successfully implemented in all three healthcare settings as part of study III. The evaluation questionnaires evaluated subjective experience of PWD of the PRO questionnaire's content, format and purpose and perceptions of impact as well as HCP's subjective evaluations of use of PRO in line with RE-AIM framework constructs [330].
In March 2021 field work was completed by the main study sites: Two ambulatory diabetes care clinics at Frederiksberg-Bispebjerg Hospital (Denmark) and Aalborg University Hospital (Denmark), five Danish municipal diabetes education centers and one primary care clinic. Consolidation of the study database is ongoing at the time of submission of this thesis so approximate numbers from the database are provided. An interim database was analyzed with data from 560 PWD who had completed informed consent and the PRO diabetes questionnaire and 501 PWD who had completed the PRO-EVAL-PWD questionnaire which evaluated their experience of the PRO questionnaire itself. 31 HCP had completed the PRO-CON-EVAL-HCP evaluation questionnaire after a total of 481 diabetes visits using PRO which resulted in detailed

data regarding perceived visit quality, clinical validity of PRO data and scoring algorithms, utility of the digital dashboard and overall impacts of PRO on the dialogue and care quality and the role of the PWD. In the interim database 301 PWD had completed the PRO-CON-EVAL-PWD questionnaire to evaluate their experience of use of the digital PRO tool during their diabetes visit. 40% of PWD in the study were women, approximately 30% were type 1 diabetes, mean age was 57 years. A total of 4 doctors, 25 nurses, 5 dietitians and 8 physiotherapists took part in the evaluation.

Distribution and missing value analysis, internal consistency reliability analyses, factor analyses and construct validity testing confirmed that the PRO and PRO evaluation questionnaire data were usable for protocolized statistical analysis. 55 semi-structured interviews of PWD were audio-recorded, transcribed and registered in NVivo for initial coding and analysis with questionnaire data as part of the M-PRODIA study. 10 multi-disciplinary evaluation team workshops involving 31 HCPs were transcribed and transcriptions were coded and prepared for thematic analysis in Nvivo 12. The statistical analysis of final study results is scheduled to be done April-June 2021 and the main interim results are accepted for congress presentations end of June 2021. While the results of study III will be presented and published separately through formal future presentations and are not as part of this thesis, some specific examples of interim results are provided in this section to illustrate the acquirement of substantial useful data using the study protocol developed in study III.

Examining the interim evaluation data from PWD in the M-PRODIA study, more than 90% of PWD who evaluated the use of PRO after their visit reported the PRO dashboard gave a good representation of their diabetes situation whereas less than 2.5% did not. 86% of PWD felt that completing the PRO diabetes questionnaire made them feel better prepared for the visit whereas 1% indicated feeling less prepared. About 95% of PWD reported that the use of their PRO diabetes data in the visit resulted in better focus on the topics that were most important to them to talk about. 99 % of PWD reported they had no unpleasant or uncomfortable experiences related to the use of PRO diabetes for their diabetes visit. The majority of PWD reported a perception that the PRO diabetes tool had a positive impact on their own diabetes management as well as on the ability of their HCP to give better quality diabetes care.

The qualitative data from the semi-structured interviews of PWD after the PWD had participated in a routine diabetes visit which included the use of their PRO data in the dialogue were initially analyzed and coded by multiple coders to obtain an initial quantification of PWD's experiences relating to acceptance, comprehension, feasibility and perceived value. The initial coding of PWD's experiences based on interviews showed very high concordance with PWD's responses to the PRO-EVAL and PRO-CON-EVAL questionnaires. A full analysis of inter-rater reliability and

reliability of the evaluation questionnaires is pending completion of a comprehensive coding of all interviews. Analyses of the interview data identified that a subset of PWD experienced the process of completing the questionnaire as very positive due to the self-reflection process that was prompted. The positive aspects of self-reflection were related to a perception that the PRO questionnaire prompted 1) healthy consideration of own efforts to manage diabetes and 2) identification of specific difficult topics that were important for the PWD to discuss but which the person might not have brought up had it not been for the PRO tool. A positive experience was also associated with the PWD's appraisal that the questionnaire was relevant, comprehensive, and person-centered [2]. These initial findings directly support the initial results of study II and quantitative analyses are ongoing to examine which patient characteristics are associated with perceived benefits related to questionnaire completion and self-reflection. PWD who participated in study III expressed the benefits of completing the PRO questionnaire in different ways which is illustrated by the following quotes from five different PWD: "the questions are good and sets the thoughts in motion", "you are forced to think about your situation", "I think more about the importance about taking charge of my diabetes", "it makes me think about how it is actually going [with my diabetes]", "I got to reflect about the positive aspects – I thought about the fact that it is good that my diabetes is well regulated".

A contribution of this study is the granular assessment of individual experiences of use and value of the PRO diabetes tool which revealed major individual variation in personal benefits of using the PRO tool. The PRO questionnaire did not appear to benefit PWD who had a high degree of disease mastery as much. Even so, many of these PWD still found it valuable to complete the PRO questionnaire because they felt it led to a more productive diabetes visit.

The extent to which PWD had problems related to their diabetes was also see to affect their experience and what kind of benefits they experienced as a result of the PRO tool.

DiaProfil is a flexible user-friendly PRO data collection app which allows the PWD to choose between mobile, tablet or computer interfaces for self-completion and additional features were included based on user testing to decrease cognitive burden and improve reliability of measurements. Using different modalities however raise methodological challenges regarding congruence and comparability of data obtained from different user interfaces. Psychometric analyses will therefore be undertaken to examine validity, reliability, and measurement errors across platforms. One brief example of initial psychometric analysis to examine data quality is shared here for illustration. The interim data for the WHO-5 Well-being Index [143] from 560 PWD were analyzed in order to psychometrically compare data collected via the Danish

PRO diabetes *DiaProfil* tool with previously collected population data using both paper and web-based forms. The internal consistency of the scale was adequate (Cronbach $\alpha = 0.83$), the mean score in the diabetes population was 60.0 (SD=21, score range:0-100) which was in line with expectations (The Danish population norm is approximately 70). 30% of PWD had moderate low well-being (WHO-5 score<50) and 14% had very low well-being indicative of possible depression (WHO-5 score<28) which corresponded to other studies. Furthermore, as hypothesized, the WHO-5 well-being score was positively associated with self-rated health, daily life with diabetes, confidence with self-management and negatively associated with diabetes related emotional distress, symptom distress and having general life issues interfering with their diabetes management [143,309,331]. Overall, the psychometric characteristics of the WHO-5 index data were in line with previous WHO-5 diabetes research by the author of this thesis and others [7,62,143,331]. Approximately 20% of PWD exhibited signs of diabetes stress using the global items for distress in the Danish PRO diabetes questionnaire and the nature and levels of distress were concordant with results from a national Danish diabetes survey which had included items from the Danish PRO diabetes items alongside other items [194]. Initial analysis also confirmed that the diabetes distress items in the PRO diabetes questionnaire were able to discriminate between insulin and non-insulin users and people with type 1 diabetes and type 2 insulin which was also anticipated. About half of the PWD who exhibited signs of diabetes distress had reduced psychological well-being. 9.7% of PWD in the national M-PRODIA study sample were indicated to have likely depression according to the two-item depression screener (MDI-2 [209]) in the PRO diabetes questionnaire. The relevance of somatic symptom distress was supported by the finding that 19-38% of PWD in the national pilot study (interim data) indicated high somatic distress with pain (35%), sleep difficulties (38%), gastro-intestinal symptoms (31%) and sexual dysfunction (29%) being most commonly indicated. The value of assessment of sexual dysfunction was highlighted both by PWD and by HCP and by study sites. In some pilot sites the care for sexual dysfunction was markedly improved during the pilot testing of the PRO diabetes tool because its use highlighted the need for systematic improvements in HCP's ability to provide counselling and referrals for PWD with sexual dysfunction.

31 HCP (nurses, physiotherapists, dietitians and doctors) participated in the MPRODIA study (study III) and completed both baseline and end-of-study questionnaire evaluations as well as evaluations of use of PRO diabetes after individual care visits. More than 95% of HCP expressed confidence in their ability to use the PRO diabetes tool in their diabetes visits which increased significantly during the pilot study. The mean confidence score was 4.4 (SD=0.7) on a Likert scale from

1-5 with 5 representing high confidence. Initial analysis of qualitative data (free text evaluations and transcriptions of HCP evaluation workshops) suggests confidence is both related to confidence in ability to interpret the PRO data and to use of the data in a good person-centered way during the care visit with the PWD. More than half of HCP developed a more positive attitude about the PRO diabetes tool during the period of pilot testing and only one HCP reported a slightly negative attitude. At least 85% of HCPs experienced that the use of the PRO diabetes tool improved their work satisfaction related to caring for PWD, and none reported that it decreased their work satisfaction. The perceived impact on work satisfaction was related to feeling better prepared for visits and to experiencing a more meaningful and productive dialogue. About 1 in 5 of HCP reported some increase in work stress related to usage of PRO which appeared to be mainly related to time constraints especially regarding instances where the PRO dashboard highlighted many problem areas for the PWD. All HCP in the study expressed very strong interest in continuing to use PRO diabetes in their care and willingness to recommend the use of tool to other diabetes HCPs. 2 out of 3 believed it would be essential that HCP receive training in use of PRO in the dialogue prior to implementation whereas one third did not believe it was required. Initial qualitative analyses found that the perceived requirements for use of the PRO diabetes and approaches to use depends on the HCPs care style, diabetes care training and experience, specialization, and context of care.

3.4. METHODOLOGICAL CONSIDERATIONS

3.4.1. STUDY I

The context and resource frame for the study necessitated a narrow focus on program deliverables rather than research depth, which resulted in the adaption of a pragmatic approach to the choice of scope and methodology. The scope was limited to identifying broadly defined outcome constructs as following phases of the program would focus on measurement. It was not feasible to undertake a preference survey involving a larger group of the population as it was out of scope of the study to go into detail about patient prioritization of clinical and physiological outcome indicators. It was also out of scope of this study to involve different diabetes stakeholders in a more in-depth way when it came to the prioritization of outcomes for the purpose of identifying more operational outcomes beyond what was possible during one working meeting.

3.4.2. STUDY II

The use of convergent mixed-methods was useful to strengthen the robustness of the results, clinical relevance, and interpretability of the study results. It was also useful to support the content validity of the Likert-scale PRO evaluation questionnaires. A limitation of the study was that there was only one qualitative analysist involved in coding and analyzing the data as the HCPs were unable to access the qualitative data since patient participants had been explicitly promised their results would not be shared with the HCPs (only the author, as a non-HCP qualitative researcher, had access to this information). This was done as part of the efforts to minimize bias related to social desirability. The study results should be considered in light of its pragmatic design and limited scope with focus on feasibility and acceptability testing and formative evaluation to provide a basis for the design of the larger study III.

3.4.3. STUDY III

The real-world piggy-back study design has important strengths and limitations. A key strength is the systematic collection of both quality and quantitative data which detail the experiences of PWD and HCP related to use of PRO in care. This experiential data fills important gaps in our current understanding regarding the drivers of acceptance and adoption of PRO in practice from the patient perspective and the causal pathways by which PRO tools may impact distal diabetes outcomes.
An important strength of this study is the systematic collection of matching data from both PWD and HCP for several hundred diabetes care visits which allows for testing of interrater reliability and hypotheses derived from both the PRO tool's program theory and study II. The use of multi-informant data provides for a more robust evaluation of perceived impacts of the PRO diabetes tool on patient participation and quality of the dialogue [3]. Another strength is the use of brief digital evaluation questionnaires integrated into the PRO tool and minimally disruptive procedures to mimic real-world care as much as possible. It was not in scope for this study to document if any concrete changes were made in relation to the individual priorities of each PWD based on the use of the PRO diabetes tool. Due to the great individual variance in how the PRO tool impacts a PWD, such evaluation requires a comprehensive follow-up design which takes into account individual care goals. Limitations of the study design include the lack of an attention control group, comparison to other PRO tools, longitudinal follow-up and use of objective measures for outcome evaluation. These limitations need to be addressed in future research.

3.5. DISCUSSION AND CONCLUSIONS

3.5.1. STUDY I

To our knowledge this was the first study at the time to identify a patient-prioritized list of core outcome constructs for diabetes outcomes assessment in Denmark using systematic methods for patient involvement and a value-based health outcomes framework.

The finding that the identified priority outcome constructs of general health, psychological well-being, perceived life impact of diabetes, symptom distress, treatment burden, self-efficacy and access to person-centered diabetes care are important to PWD and are relevant to measure psychometrically is supported by other research [7]. The previous DAWN2 study established a global core set of population level indicators of person-centered diabetes care and outcomes through a participatory multi-stakeholder process with PWD as partners which was used in a multi-national diabetes benchmarking study [7,12]. The following patient-important outcomes were identified both in DAWN2 and study I: self-rated health, psychological well-being, impact of diabetes on life quality, diabetes-related emotional distress, confidence in self-management and perceived access to person-centered diabetes care. The DAWN study also included measures of empowerment as well as non-professional and professional support for healthy coping and self-management as well as a measure of perceived discrimination due to diabetes [7]. The perception of discrimination was not selected as a stand-alone priority outcome construct in study I which may be explained by a relatively lower rate of discrimination in Denmark [7,332]. PWD did however highlight challenges related to lack of knowledge about diabetes among their friends and the public. The factors related to empowerment and specific sources of support outside of the healthcare system were also identified by PWD in study I but were not prioritized as stand-alone outcomes. These issues may therefore still be deemed relevant for incorporation in future efforts to develop outcome measurement models.

The national Swedish PRO diabetes questionnaire program [263,333] conducted extensive qualitative research to establish a national PROM for use to measure patient-centered diabetes outcomes in diabetes care. The finalized Swedish diabetes questionnaire measures several constructs which correspond to a large extent with the constructs identified in study III to be relevant in Denmark: General well-being, depression, diabetes related stress, perceived limitations due to diabetes symptoms, worries of hypo- and hyperglycemia, confidence in self-management, sleep quality, satisfaction with medicine and technology, and support from and access to HCP [263,333]. The

similarity of findings is important as Denmark and Sweden would be expected to have comparable conditions for managing and living with diabetes. The Swedish diabetes questionnaire does not include symptom distress related to neuropathy, sexual dysfunction, and gastrointestinal symptoms and hypoglycemia unawareness, which were identified as relevant for both PWD and HCP in Denmark in study I-III.

The project to define a global diabetes outcomes measurement standard set of the International Consortium for Health Outcomes Measurement (ICHOM) which was co-authored by the author of this thesis identified many of the same outcome constructs as we found in study I as patient-important outcomes. This included well-being, depression, diabetes related distress, treatment burden, hypoglycemia and self-management. The scope and aims of the ICHOM program differed from both the Danish and Swedish programs as ICHOM's aim was to define outcome tools for global use with focus on passive use of outcome data to monitor and benchmark quality of diabetes care and with limited focus on the clinical dialogue. Due to pragmatic requirements for selection of questionnaires with global accessibility and usability, the WHO-5 Index [143], PHQ-9 [304], and PAID [126] were selected as the 3 PROMs to be included in the global ICHOM standard set [86]. These PROMs measure psychological well-being, depression, and diabetes related emotional distress, respectively. While the 20-item PAID questionnaire covers issues that are relevant to PWD and their clinical care [126,334], it does not include several constructs that were identified as important to PWD in our study such as daily life with diabetes, confidence with self-management, treatment satisfaction, subjective evaluations of blood sugar regulation and somatic symptom distress. The PAID questionnaire measures severity of problems and does not provide options for PWD to indicate positive experiences related to daily life with diabetes, self-management, support, and treatment satisfaction. Findings from our patient involvement process suggests that the PAID as a standalone tool does not provide sufficiently broad coverage of the outcome constructs that are important to PWD in Denmark. The ICHOM working group identified the relevance of additional outcome constructs in the design process including those identified in our study and encouraged consideration of supplemental PRO assessments if relevant. Our study identified a core set of outcome constructs of importance to PWD which are supported by the wider literature as relevant for clinical use. The research team identified the following as the most useful strategies for patient involvement in study III: 1) the involvement of PWD in the early planning and design of the patient involvement activities, 2) the use of theoretical purposive sampling, 3) the pragmatic use of qualitative research methods to augment use of data and 4) the consideration of best practice principles to ensure a good process experience. The high level of concordance between the diabetes outcome constructs identified as important

by PWD and the resulting core set determined by the multi-stakeholder consensus process suggests that the research project was responsive to the patient perspectives and priorities [1]. While a formal scientific evaluation of the impact of the patient involvement was not undertaken specifically for study III the research team found that the use of systematic methods facilitated transferability, credibility and impact of the patient involvement process.

3.5.2. **STUDY II**

The qualitative data indicated that completion of the questionnaire may be a positive reflective experience for a subset of PWD which can facilitate active participation in care independent of effects of use of PRO diabetes by the HCP in the visit. The study suggests that the positive experiences reported by some PWD related to completing the PRO questionnaire may be related to key user friendly, person-centered features of the questionnaire which were defined by PWD in the development process. PWD praised the user friendliness, the wording of items, the absence of questions that can be perceived as "pointed fingers", and expressed they felt all main topics were well covered by the questionnaire. These were all factors that had been explicitly addressed as a result of the systematic approach to patient involvement in the design of the PRO questionnaire. It is hypothesized that the perceived positive experience related to completing the PRO questionnaire is partly due to questionnaire qualities resulting from patient involvement in the design: person-centered language, patient-perceived relevance, comprehensive topic coverage, balance of negatively and positively worded items and consideration of both problems, resources and action options. Some PWD reported a positive experience from completion whereas others did not and it appeared that the individual situation of the PWD, e.g. level of current mastery of the disease, was a key determinant. Furthermore data suggested that the extent to which the PWD understood the intended use of the PRO questionnaire (e.g. to improve the quality of the dialogue by focusing on what matters most to the PWD) had a major impact on the potential for the PWD to have a positive reflective experience.

Optimizing the patient experience related to filling out the PRO questionnaire is important not only from a therapeutic perspective but as a way to motivate PWD to attend visits and participate in care and to improve the care experience for PWD. The latter is of high importance since PWD undergo treatment across their lifespan and it was shown in study I that the experience of person-centered, respectful and emphatic diabetes care is a priority outcome for PWD in its own right.

The study showed that the use of the PRO diabetes tool affected the content of the dialogue and directed the focus of the dialogue to the topics highlighted by the PWD

in advance as most important. The qualitative results provide a basis for hypothesizing that the use of the PRO diabetes dialogue tool in the visit increases the proportion of time during the dialogue which focuses on what is of greatest diabetes-specific importance to the PWD [58].

It was an important finding that many broader health-related constructs were actively and concretely used to support the dialogue, including general life issues impacting diabetes (economy, co-morbidity, stress), general social support, self-efficacy and confidence in access to care. While some of these constructs are not directly modifiable by HCP action, our study supported the potential importance of their inclusion for facilitating health-related empowerment [45], self-efficacy [204], and potential adoption of a whole person approach [328]. The importance of a broad coverage of topics is also supported by research demonstrating the value of considering the complex interactions between biological, psychological and social factors as perceived by PWD in order to support healthy coping with diabetes [335] .

The effective use of the question on general life situation issues impacting diabetes provided initial indications that these constructs function well as part of a broader approach to diabetes care based on a social ecological model[2]. Many PWD reported that they had general life situation issues (e.g. work, economy, other health problems) which had a moderate (51%) and major (9%) negative impact on their ability to manage their diabetes. HCPs reported the item was useful and relevant in the dialogue. The specific wording had been adjusted during user testing in dialogue with PWD and HCP to ensure it captured the right construct. Initial results suggest that the incorporation of broader health constructs including social determinants may be beneficial for optimizing the use of PRO tools within a person-centered and whole person care model [63]. The evaluation of use of each PRO construct by PWD and HCP in this study is only exemplified here. The analyses provide initial proof-of-concept for their usefulness to prompt topics in the dialogue and contribute to the overall review of the PWD's diabetes situation. Our findings are line with other research showing positive impacts of use of digital PRO tools on the patient's experience of person-centered care [4,328].

Several PRO diabetes tools provide stand-alone assessment of the individual's mental health [27,29,137,208,336] and diabetes related distress [86,337] in order to ensure early detection and treatment of mental health disorders and improved care for emotional problems related to diabetes[27,61]. The Danish PRO diabetes tool includes items that measure psychological well-being [7,143,149,208], depression [209], diabetes related distress [18,19,137,217–222], and aspects of diabetes-related impact on life [19,223] as elements of a broader assessment of a range of health-related constructs. Our study results suggest that the

nesting of these items within a broader set of constructs and items provided an effective and helpful context for detecting and prompting depressive symptoms and diabetes-related distress when this was relevant.

The PRO diabetes tool evaluated confidence with self-management and priorities for self-management support using the theoretical model for measurement of self-efficacy as the basis [67,69,227–236]. The study results suggest the measurement of confidence with self-management is helpful as a part of the dialogue about individual diabetes education needs as also indicated by other research [65,192,231]. The study supported the potential clinical utility and relevance of diabetes-related somatic symptom distress [237,238,309] which was included in concordance with study I [1] and in line with other research supporting clinical relevance and measurability of pain [239–241], gastrointestinal symptoms [19,242–246], cardiovascular symptoms [238], sexual dysfunction distress [19,247–250], sleep difficulties [130,251–256] and foot problems [260–262]. Burden of hypoglycemia and challenges with blood sugar regulation were identified and discussed using the PRO diabetes tool in the study and the broad usage was further corroborated in study III confirming high relevance and utility especially in PWD using insulin. The relevance of measurements of patient experiences related to blood sugar regulation and hypoglycemia was established in study I [1], during the participatory PRO tool development process and is supported by related research[7,13,18,20,21,222,234,250,256,287–293].

It was a general observation in this study that the specific content and format features of the PRO diabetes tool which were a result of the involvement of patients in the design stage were positively evaluated by PWD during the pilot testing. This related to both the constructs and wording of questions. For example, PWD expressed appreciation of the fact that the questionnaire did not raise “pointed fingers” and balanced neutral and negatively focused questions, which were specifically emphasized by PWD during the design phase. All PWD found the questionnaire’s coverage of topics relevant and comprehensive. Further assessment of this will be undertaken as part of a systematic analysis of positive and potentially negative effects of patient involvement across all stages of the PRO diabetes questionnaire program.

3.5.3. STUDY III

The M-PRODIA study protocol was designed to collect new structured quantitative and qualitative data to allow for testing and further development of the program theory (table 5) and conceptual working models for use in different care settings. A simplified conceptual working model defined based on study II, the participatory PRO diabetes tool design process and related research [4,156,290,338] is shown in figure 2.

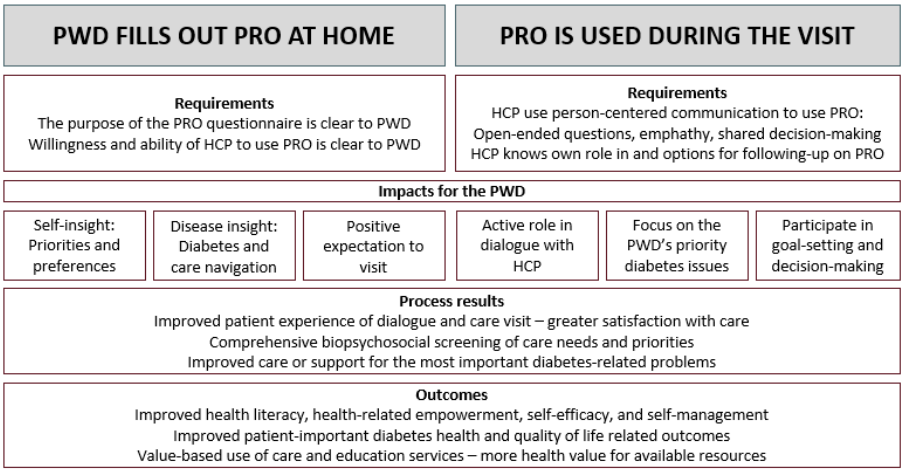

Figure 2. Simplified conceptual working model for the PRO diabetes tool.

The interim results of study III provide initial corroboration of results from study II which suggest that some of the benefits of the PRO diabetes tool experienced by PWD may be mediated by self-reflection (self-insight and disease insight), motivation and active participation in diabetes care. Interim study results were used to begin to define hypotheses for how the PRO diabetes tool may support each of four key steps[68,69] of patient empowerment. Table 8 shows examples of hypotheses that are based on initial results from study II and III pertaining to the value of reflection. The significance of the reflective process and the utility of this in the dialogue process has been described as part of a model for person-centered care and guided self-determination [56]. It may be hypothesized that the use of the PRO diabetes questionnaire can facilitate the PWD's autonomous re-assessment of own care needs and options [58]. The initial hypothesis pertaining to the potential benefit related to the fourth element of empowerment listed in table 8 is based on tentative data from study III which showed that PWD were motivated and enthusiastic about the ability of the PRO diabetes tool to help track their personal progress on the measured patient-important PRO outcomes.

Element of empowerment	Examples of hypothesized impacts of PRO diabetes on aspects of empowerment for PWD.
1) Understanding the personal	The self-completion of the Danish PRO diabetes questionnaire increases the PWD's self-awareness and understanding of personal biological, psychological and

experience of impact of diabetes.	social impacts of diabetes and related personal support needs.
2) Understanding preferences for own role in diabetes care.	The self-completion of the Danish PRO diabetes questionnaire makes PWD more aware of their own role in their care and their preferences for how they would like to be involved in their own care. The PRO diabetes tool exerts its effect by inviting the PWD to set the agenda and signaling respect for and acknowledgement of the role of the PWD as the central person in the person's care.
3) Understanding and communicating personal priorities, goals and needs	PWD gain self-insight regarding own self-management practices and priority goals for self-management through the self-completion of the PRO diabetes questionnaire. This enables the PWD to more actively communicate personal self-management goals and support needs and more actively take part in collaborative care planning.
4) Use of trial and error to find better individual strategies for living well with diabetes.	The introduction of dynamic monitoring of patient-important outcomes engages PWD to continuously explore, evaluate and improve personal strategies for diabetes self-management.

Table 8. Examples of hypothesized links between the PRO diabetes tool and empowerment.

The combined results of study II and III provided detailed insights into the experienced impacts of use of PRO on the quality of the dialogue. The impacts on the dialogue appeared to differ depending on the characteristics of the care setting, the format of the visit, and individual characteristics of both the HCP and PWD.

The potential for improvement of both self-insight and disease insight resulting from PRO diabetes to facilitate active participation shown in study II was confirmed in study III.

Study II and III provided data to help identify individual and organizational factors that may influence adoption[196] of the PRO diabetes solution by HCP in routine care. In line with behavior change theory, HCP adoption may be expected to be predicted at the individual level by self-efficacy, motivation and perception of

barriers/opportunity related to use of PRO diabetes [161]. The finding that all HCPs were highly confident in own ability to use the PRO diabetes tool in study III and that confidence increased over time suggests confidence may contribute to high level of adoption. High confidence is hypothesized to be mediated by HCP's ability to use PRO diabetes for person-centered priority-setting and care planning, clear roles and responsibilities regarding how to use and follow-up on PRO results, and simplicity, user-friendliness, relevance and appropriateness of the PRO dashboard. The HCP in study III were highly motivated to continue using the PRO diabetes tool after the pilot study. High motivation is hypothesized to be partly caused by the improved work satisfaction experienced as a result of PRO diabetes. Qualitative data suggest that improved work satisfaction relates to the perception of improved meaningfulness and effectiveness of the dialogue with PWD, improved interpersonal relations with PWD and PWD's experience of satisfaction with the encounter. Our findings regarding the impact of PRO on HCP's work satisfaction represent a new important field of research which can now be analyzed further. The relevance of the well-being and satisfaction of the HCP who provide diabetes is highlighted by emerging research describing diabetes stress among HCP [339].

Adoption of the use of the PRO dashboard in care visits also requires that the HCP has the practical opportunity to adopt PRO diabetes in practice and that specific barriers can be identified and overcome. This means that adequate PRO practice facilitation [340] which helps each clinic or care team to identify and address local barriers to integration of PRO diabetes in routine care is important [192].

3.6. STUDY IMPLICATIONS AND NEXT STEPS

3.6.1. STUDY I

Study I involved PWD in the scoping phase of the national value based diabetes program [181]. The study identified the importance of measuring mental health, diabetes impact on quality of life, treatment burden, somatic symptom distress, confidence in self-management, and experience of person-centered relationship-centered diabetes care using a social ecological framework [5,96]. The implications of the study is that the agreed patient-important outcome constructs need to be operationalized so they can be standardized and harmonized nationally and potentially internationally[96]. As diabetes language, culture and treatments change, many existing PRO diabetes questionnaires become outdated raising the demand for harmonization at the level of latent diabetes outcome constructs. While it is widely agreed that measurement of positive psychological well-being can be done with e.g. the WHO-5 Index [143], precise

definitions of latent constructs to be measured in relation to diabetes-related quality of life [78,96], diabetes-related emotional distress [22,341], and other PRO constructs [79] are lacking. Our study emphasizes the importance of further research with involvement of PWD as partners to establish theoretically grounded and carefully defined latent outcome constructs to be used for diabetes outcome measurement which takes into account a social ecological approach and personal resources [70,96].

3.6.2. STUDY II

Methodological research is needed to evaluate and further document the usability of the pragmatic multi-informant methods applied to examine clinical validity, utility and person-centered impacts of PRO in clinical practice. Development of standard methods to integrate qualitative and quantitative evaluation data for clinical PRO testing as done in this study could benefit future clinical PRO research [342].

The study provided initial support for face validity and clinical utility of the PRO diabetes tool. Given the broad topic coverage of the questionnaire and use of branching logic, clinical testing of the full PRO diabetes questionnaire requires a study with a larger population as was undertaken in study III.

The findings of study II suggest that using a PRO questionnaire which covers all main topic areas perceived as important by PWD may be beneficial for PWD due to the value of the reflective process. It may be hypothesized that the perceived benefit by PWD is partly dependent on the comprehensiveness of the PRO diabetes questionnaire coverage.

Future research could compare how completing different PRO diabetes questionnaires (different topic coverage and length) impact PWD's experience of benefits related to self-reflection and overall impact their preferences. Further research is needed to examine which individual PWD characteristics predict if the PRO questionnaire is perceived as valuable due to self-reflection. This can be tested using study III data.

3.6.3. STUDY III

Given the highly positive interim results for study III controlled research studies are warranted and could potentially use a stepped wedge[343] effectiveness study design to evaluate the clinical, PRO and health economic impacts of the PRO diabetes tool across healthcare sectors. This will create the needed evidence to guide future policy decisions regarding expansion and ongoing improvement of the program.

3.6.4. PAPER IV

The results of the paper highlights a need for development of a broader theoretical and methodological framework for the use of PRO to improve aspects of person-centered diabetes care. There is a need to reconcile the many different models for use of PRO in clinical practice and develop a methodological framework which can facilitate international harmonization and collaboration. Systematic patient involvement and strategies for contextual and participatory learning [182] as well as mixed-methods research [159] will be important methodological approaches to incorporate in ongoing psychometric clinical PRO diabetes research.

CHAPTER 4. PRACTICAL AND RESEARCH IMPLICATIONS

4.1. CONTRIBUTIONS TO DIABETES CARE AND OUTCOMES

The research in this thesis contributed significantly to the development of the first nationally agreed upon Danish PRO diabetes questionnaire and a new clinical digital PRO tool, *DiaProfil*. The use of the PRO diabetes tool has been shown to be highly acceptable for use in routine care by both PWD and HCP and is now available and approved for use nationally to improve the quality of diabetes care in both hospital and municipality care settings. Initial data from the research studies in this thesis and unpublished data support the findings of the national health data authority's evaluation report 2021, which shows that using the PRO tool results in PWD feeling better prepared for their visit and leads to diabetes visits becoming more meaningful and relevant as they focus more on the most important issues for the PWD. Importantly, the national PRO diabetes pilot study indicates that integration of the PRO diabetes tool in standard care within existing health care resources is feasible.

The newly developed digital PRO diabetes tool, *DiaProfil* is a result of this research, and introduces a new important functionality that may improve diabetes care in the future. The *DiaProfil* solution provides the HCP with one-click access to concrete, locally relevant information about relevant follow-up options for each PRO topic which is intended to facilitate improvements in the way HCP help PWD navigate their full range of support options across the care continuum. The strategic adoption of this functionality by the health authorities across health systems holds the potential to significantly increase the appropriate use of the full range of diabetes care, education, community, technology, social and public service offerings available to PWD. Such an effort could be potentially based on the nationally standardized assessment of needs of PWD introduced by the PRO diabetes tool. Linking referrals and care pathways more directly to PRO could help minimize waste, monitor value, and strengthen the role of HCP as gate keepers of resources from a whole-person care approach.

While it is an important value contribution in its own right that PWD experience that the PRO tool is helpful to them and improves the quality of their dialogue with their HCP, it is a necessity to pursue detailed assessment of causal relationships between use of the PRO diabetes tool and factors such as satisfaction, health-related empowerment, self-management, quality of medical care and education and health and quality of life outcomes now. This will help guide future investments to ensure

the appropriate and evidence-based use of PRO tools in the future. A multi-disciplinary health services research platform is required in Denmark which is designed for the complex task of quality assurance and evaluating the effectiveness of PRO within and across diseases.

Many of the hypothesized or intended benefits of the PRO diabetes tool rely on the implementation of supportive strategies which may or may not be implemented. It is therefore important that future PRO evaluation research in Denmark adopts a systemwide view on the role PRO tools can play in achieving patient-orientated objectives. As an example, the PRO diabetes tool incorporates screening questions for depression and diabetes-related distress in line with evidence-based recommendations [27]. Improving screening and early detection in routine care has the potential to improve mental health, psychosocial as well as clinical and health outcomes [27,344] but only if implemented as part of a coordinated strategy that ensures that adequate psychosocial care, support, and resources are available [61,345]. The development of PRO evaluation methods for use in real-world settings in this thesis provide one starting point for defining viable models for ongoing evaluation of PRO.

The Danish PRO diabetes tool was created as a result of a creative co-learning process involving PWD, FM, HCP, researchers, and other health stakeholders and constitutes a new innovative intervention model for use of PRO in routine care in Denmark.

This means that we are presently at the bottom of a steep learning curve in terms of understanding the tool's full potential, its advantages and disadvantages, and the main facilitators and barriers to effective implementation.

The national implementation of the PRO diabetes tool in Denmark may result in general improvements to participation of PWD in care and dialogue quality in Denmark. Furthermore, if national efforts are undertaken to ensure implementation of the PRO diabetes tool in close coordination with other person-centered care policies, it is possible that several derived benefits may be achieved from introducing the tool. Possible additional benefits that may be achieved by implementing PRO on a national scale in a systematic manner might include:

1) Positive shifts in public awareness and attitudes about the role of PWD in care.

2) Improved multi-disciplinary cross-sector collaboration for person-centered care based on relationships established in the PRO diabetes development program [4,39,42]. This assumes continued involvement of stakeholders in the implementation [63,176].

3) Improvements in person-centered diabetes communication [54] between PWD, between PWD and FM, between PWD and HCP, and between HCP and HCP as a result of the introduction of a new "vocabulary" for patient-important diabetes constructs by PRO diabetes.

4) Normalization and destigmatization of mental health and psychosocial problems

related to having diabetes and improved integration of these aspects in health promotion, prevention and care strategies across the care continuum.
5) Increased use of local and national PRO data to identify gaps between patient needs and available services to guide quality improvement and service development.
6) Implementation of value-based diabetes care to generate more health value by continuously identifying what care generates most value.

Figure 3 shows a simplified logic model for how the PRO diabetes model may influence health care and care outcomes through both passive and active uses of PRO data. Future efforts to implement the PRO diabetes tool for different purposes should always continue to be done in a participatory manner with PWD as equal partners. As supported by this thesis, patient involvement is a critical component in all aspects of diabetes care research, intervention design, ongoing quality assurance and care improvement.

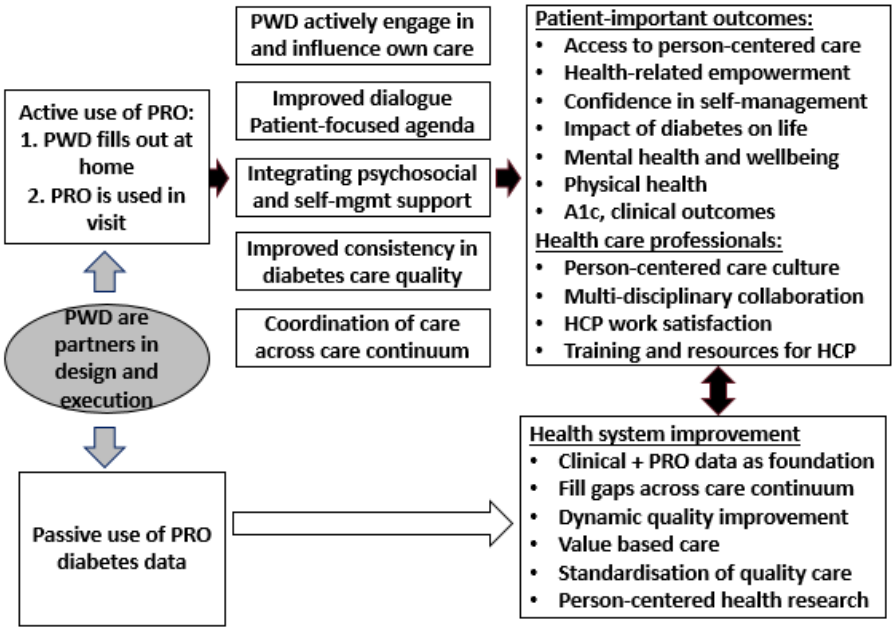

Figure 3. General logic model for potential benefits of the PRO diabetes program. Active use of PRO refers to use of individual PRO data in the individual care for the PWD. Passive use of PRO refers to the analytical use of aggregated PRO data.

4.2. IMPLICATIONS FOR CLINICAL PRO RESEARCH

The research in this thesis was pragmatically designed to guide the development of a new national PRO diabetes questionnaire and a new digital dialogue tool, *DiaProfil*, for routine clinical use through use of patient involvement and stakeholder participation. The result is a final PRO diabetes tool which is now being implemented in routine ambulatory diabetes care at the Aalborg University Hospital.

The collection of structured PRO and PRO evaluation data allows for quantitative testing of hypotheses identified during the design and formative evaluation research phases [3]. Both quantitative and qualitative research can now be used to test hypotheses and begin to build causal models and develop the conceptual model.

The main hypothesis generated by the research in this thesis is that PRO diabetes improves the quality of the PWD-HCP dialogue by helping both PWD and HCP to be better prepared and facilitates person-centered priority setting. It is furthermore hypothesized that the PRO diabetes tool will specifically improve detection and person-centered consideration of psychosocial and behavioral challenges of PWD as an integral part of their care. If detection of psychosocial problems is adequately followed up by systematic referrals and psychosocial support services, improvements in mental health, diabetes-related quality of life, health outcomes, and costs related to diabetes may be achieved. Furthermore, it is hypothesized that the PRO diabetes tool can facilitate a positive shift in HCP attitudes, skills and care practices related to treating the whole person with diabetes by using person-centered communication strategies and shared decision-making which may benefit patient empowerment, health and quality of life of PWD.

It is hypothesized that the PRO diabetes tool engages PWD to become more actively engaged in their own care as a result of multiple influences. It is also hypothesized that a significant subset of PWD benefits from self-reflection regarding diabetes resulting from completing the PRO questionnaire. This effect is hypothesized to depend on the individual characteristics of the PWD and be facilitated by the unique comprehensiveness and patient-centered wording of the PRO questionnaire. It is hypothesized that increased patient participation is also facilitated by the way the PRO diabetes tool legitimizes that the PWD contributes with detailed input prior to the visit.

The studies demonstrate ways by which systematic patient involvement in each stage of development of a PRO tool for clinical use appear to benefit the research process and propose specific methods to improve person-centered design of clinical PRO tools. The conceptual model for involvement of patients in the design of PRO tools assumes that the benefits of patient involvement (research relevance and quality, cost-efficiency and potential impact on patient-centered outcomes) is derived from the

active use of patients' experiences, perspectives, and co-learning across stakeholders at each research stage [176].

The collection of data from patient involvement activities across all steps of development and systematic coding and analysis of these using Nvivo allows for testing of specific hypotheses regarding how patient involvement benefits each phase of clinical PRO tool design [176,346,347].

4.3. RECOMMENDATIONS FOR PATIENT INVOLVEMENT IN DESIGN OF CLINICAL PRO TOOLS

The scientific analysis of benefits of patient involvement at each stage of the development of the Danish PRO diabetes tool will be initiated in April 2021 upon the completion of the final patient workshops. The results of this research will be used to define evidence-based recommendations for patient involvement in the design of PRO tool for clinical use. The key methods for systematic patient involvement that were developed and applied in this thesis are summarized in table 9. Initial results, including ongoing feedback from participants and interim results from study III suggest that this overall approach to patient involvement was helpful and effective.

It is recommended to adopt best practices for patient involvement in research[4,176,181], and apply relevant evidence-based strategies for use of qualitative research[333,348]. It is also recommended that multi-stakeholder participation in research [167,170,171], psychometric PRO design [128], health intervention design [202], behavioral and health psychology research [63], and public health research [349] methods be prioritized.

Recommendation	**Methods used in relation to the Danish PRO diabetes tool and this thesis**
Define a patient-orientated outcome goal for the PRO design process	The adoption of patient-important measurable goals from outset (project aims) (table 5).
Use quality guidance for patient involvement from project start [161,181,350].	The adoption of the 7 quality criteria for patient involvement [181] in this thesis (table 3).
Pragmatic use of qualitative and mixed-method research methods (reflexivity, design, analysis and reporting methods) to augment patient involvement [351]	The use of qualitative methods to support credibility, transferability, reporting and impact of patient involvement in PRO research (studies I-III).

Plan patient involvement for each distinct phase of clinical PRO tool design	Use of patient-involvement activities tailored to the key steps of clinical PRO tool design (table 2).
Ensure multi-stakeholder participation augments impact of patient involvement	The strategies used for multi-stakeholder participation in this thesis (table 4).
Develop conceptual PRO model which aligns with available empirical evidence and theoretical frameworks for disease-specific person-centered care.	Use a conceptual model for the PROM which is aligned with a disease-specific person-centered care model [5] and reflects the wider evidence base for patient-important outcomes [1,7,86]. Apply a measurement model which aligns with the PRO tools' program theory.
Develop the PRO tool for optimal sustainable, public health impact.	Adoption of the RE-AIM framework to consider public health impact of the PRO tool in both design and evaluation (study III)[63].

Table 9. Systematic approaches to patient involvement in clinical PRO tool design.

On a practical level, PRO researchers may consider the following questions when selecting PRO tools for use in clinical care to promote person-centered care:

- How were patients involved in conceiving, designing, evaluating, implementing and confirming quality assurance of the PRO tool?
- What are the patient-important measurable goals with the use of the PRO tool?
- What are the hypothesized mechanisms of action for the PRO tool?
- Does the conceptual model for the PRO tool align with a broadly accepted empirically based framework for person-centered care for the given disease?
- How was it established that the PRO tool has comprehensive coverage of the topics that are considered essential and important to patients?
- What steps were taken to ensure the PRO questionnaire uses language that reflect the lived experience and facilitates respectful, collaborative person-centered care?
- How was it evaluated if the PRO questionnaire is acceptable to patients and benefits patients?

4.4. RECOMMENDATIONS FOR FUTURE RESEARCH

While preliminary results from the MPRODIA study support the acceptability and utility of the PRO diabetes tool, controlled studies are needed to quantify the effect of the PRO tool on care quality, clinical, quality of life, and health economic outcomes. Quantitative analyses are also needed to fully detail its psychometric characteristics.
Both controlled and comparative study designs need to be undertaken to demonstrate effectiveness in terms of health and cost outcomes and delineate the most active components in order to continuously improve the tool and its implementation [176].
It is important to examine the "dose-response" relationship, i.e. the relative effectiveness of small vs larger PRO tools.
Mixed-method research[155] is needed to do exploratory research and to test the hypotheses regarding the impacts and the mechanisms of action of the PRO diabetes tool which have been defined in this thesis based on initial data.
Future PRO research should be multi-disciplinary and acknowledge the need of drawing on several different theoretical frameworks to fully evaluate all facets and multi-level impacts of the PRO diabetes tool. Psychosocial support in diabetes [27,352], individualized self-management and goal-setting [65], diabetes self-management education and behavior change [295], person-centered diabetes care[5,23], person-centered outcomes measurement [86,132], personalized care[25], patient empowerment [45], a whole-of-society model of care [29,39,49] and a sustainable public health [153] approach to diabetes care improvement are all research fields with important contributions to the future research on PRO diabetes.
Psychometric analysis of the content validity, reliability, interpretability, and responsiveness of each item, scale, latent construct and the overall measurement model using large quantitative datasets is required in order to enable the analytical use of PRO diabetes data for value-based care and quality of care monitoring [86,99]. This involves detailed analysis of the comparability of local conditions for questionnaire administration and a range of potential contextual and individual sources of measurement bias which needs to be investigated. The incorporation of PRO data into the patient's electronic patient record for multi-disciplinary care team use, and the experience of patients that the HCP follows up on individual PRO results in accordance with certain thresholds comprise potential new sources of measurement bias compared to the anonymized administration of PROMs for research purposes. As the PRO diabetes tool is implemented, ongoing measurement reliability research is needed with systematic patient involvement to examine the level of measurement bias caused by factors such as expectations to care and use of PRO data and previous experiences. PWDs' use of both mobile, tablet and PC interfaces to complete the PRO

questionnaire and the use of different IT methods by different care settings pose significant measurement challenges yet to be researched and documented in detail as data is not yet available to document measurement equivalence [353].

Future research should examine the reach of the PRO diabetes intervention to vulnerable populations with specific consideration of equity and overall public health impact potential. This involves working with representatives of vulnerable communities to understand barriers to using the PRO diabetes intervention and strategies for ensuring all people with diabetes can achieve equal benefit of the principles of the intervention. It is important to define the optimal target group and realistic targets for the PRO diabetes intervention and define suitable alternative strategies for providing similar benefits to hard-to-reach populations.

Many interventions have been developed to support patient activation and aspects of person-centered diabetes care over the past decades, but the majority have failed to become an integral part of standard diabetes care. Two possible reasons for this are 1) Development of the tool in a research environment which is unattached from the realities of routine clinical care, and 2) Overreliance on a single theoretical model or methodological framework which does not reflect the complexities involved with designing a tool for standardized use across health care settings on a national scale.

In light of the results of this thesis, it is proposed that future research aimed at developing and evaluating PRO tools for use in clinical practice should adopt an inter-disciplinary research framework which is theoretically grounded in the principles of patient involvement and participatory research in health care design. To meet the requirements of creating a PRO tool that is feasible and value-adding in diverse health care settings a broad research framework is required which allows for the integration of multiple theories related to the many facets of person-centered diabetes care, health outcomes measurement, behavior change, health services research, and public health.

CHAPTER 5. CONCLUSIONS

Study I found that to evaluate outcomes of diabetes care in Denmark in a way that reflects the priorities and perspectives of people living with diabetes, clinical outcome indicators should be complemented by self-reported health status, psychological well-being, and perceptions of impact of diabetes on quality of life, diabetes related emotional stress, treatment burden, confidence in self-management and access to person-centered quality diabetes care and support. Study II demonstrated that the PRO diabetes intervention was feasible and acceptable to use in routinely scheduled diabetes care visits. PWD felt better prepared as a result of completing the questionnaire and the use of the digital PRO tool helped improve the quality of the dialogue by facilitating identification of and focus on diabetes related issues which were most important for PWD. Study III comprised of the design of a national study protocol for examining patient and HCP experiences of PRO using the RE-AIM framework. Digital Likert-scale evaluation questionnaires were developed to facilitate quantitative testing of hypotheses generated from the program theory for the PRO diabetes tool and study II. Initial results from study III confirm high acceptability, feasibility and perceived benefit of the PRO diabetes tool. The finding that all HCP were confident in their ability to use the PRO tool in a good way in routine diabetes visits with limited or no additional resources and almost all PWD reported a positive experience suggests that the PRO diabetes tool may have a high potential for large outreach and public health impact. It may thereby provide important benefits compared to more specialized tools for person-centered diabetes communication which require extensive HCP training and experience-based learning.

As implementation proceeds, it is essential that PWD and HCP continue to be involved as equal partners to help ensure that the PRO tool is used optimally and continuously optimized to improve care practices and patient outcomes. Patient involvement needs to continue and be systematic at all levels[5,29] to ensure HCP training, reorganization of care pathways, community and peer support resources, diabetes care policies, national PRO policies, and IT strategies are sustainable.

The aim of the research presented in this thesis was to involve PWD as partners in developing a novel value-based digital PRO tool for routine person-centered diabetes care for large scale implementation. Initial data supports that the PRO diabetes tool can deliver the intended benefits and has the potential for high reach and adoption in the Danish health care system. In addition, the thesis has generated new methodological approaches and tools for collection and analysis of quantitative and qualitative data. The results of the thesis provide the foundation for the future

establishment of a broader theoretical foundation and generic methodological framework for person-centered design of PROs for use in routine care for chronic diseases.

It is important to emphasize that the PRO diabetes tool is only "a tool". To realize its full potential, it needs to be implemented as an integral part of a broader sustained multi-stakeholder effort for value-based person-centered diabetes care.
It is my hope that this thesis will inspire future theoretical and methodological work aimed at improving patient involvement in the development and implementation of digital PRO tools for use in routine care settings across disease areas.

And it is my hope that the results of this research will help enable people with diabetes in Denmark to increase their control over, and to improve, their health and quality of life in the years to come.

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APPENDICES

Study I

Skovlund, S.E., Troelsen, L, Klim, L., Jakobsen, P.E., Ejskjær, N.

The development of a national core set of person-centered diabetes outcome constructs for use in routine diabetes care across healthcare sectors.

Submitted to BMC Patient Research Involvement and Engagement Journal. February 2021.

Study II

Skovlund, S.E., Troelsen, L, Noergaard, L.M., Pietraszek, A., Jakobsen, P.E., Ejskjaer, N.

Feasibility and Acceptability of a Digital Patient Reported Outcomes (PRO) Tool in Routine Outpatient Diabetes Care: A Mixed-Method Formative Pilot Study. *Submitted to* JMIR Formative Research Journal, March 2021.

Study III

Skovlund, S.E., Nicolucci, A., Balk-Møller, N.C., Berthelsen, D.B., Glümer, C, Perrild, H, Nørgaard, L.M., Troelsen, L., Kjær, P., Pietraszek, A., Hessler, D. Kaplan, S., Ejskjaer, N.

Perceived Benefits, Barriers and Facilitators of a Digital Patient Reported Outcomes (PRO) Tool in Routine Diabetes Care: A National Multi-Center Mixed-Method Pilot Study (M-PRODIA). *Submitted* to JMIR Journal of Research Protocols, March 2021.

Paper IV

Skovlund, S. E., Lichtenberg, TH., Hessler, D. Jakobsen, P.E., Ejskjær, N.,

Can the Routine Use of Patient-Reported Outcome Measures Improve the Delivery of Person-Centered Diabetes Care? A Review of Recent Developments and a Case Study. Published in Current Diabetes Reports. 19, 9, 18 s., 84. 2019.

https://doi.org/10.1007/s11892-019-1190-x

SUMMARY

The thesis consists of 3 studies which make up a key part of the scientific development of the national Danish Patient Reported Outcome (PRO) diabetes questionnaire and the digital PRO diabetes tool, DiaProfil, for use in routine diabetes care. The thesis focuses on the use of systematic patient involvement in the development of the PRO diabetes tool. The first study concluded that self-reported health and psychological well-being, diabetes related quality of life and distress, medical treatment experience, symptom distress, confidence in self-management and in access to person-centered diabetes care and support are important constructs to measure in order to evaluate outcomes of diabetes care which reflect the priorities and perspectives of those living with the condition. The second study showed that the Danish PRO diabetes tool was feasible and acceptable to use in routine ambulatory diabetes visits and improved the care experience for people with diabetes and their health care professionals. The third study involved the design of a national multi-center study to evaluate the benefits of the tool in 7 diabetes care centers involving more than 550 people with diabetes and 30 health professionals. Interim results from this study confirm that the PRO diabetes tool facilitates active participation of people with diabetes and improves care by focusing on what matters most to the individual. The thesis describes the development and value of new methods and tools for systematic patient involvement in the design of PRO tools for clinical care. The national Danish PRO diabetes tool, co-developed with people with diabetes and health professionals is now approved for use in Denmark and implementation is ongoing.

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