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BY
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ENGLISH SUMMARY

Background and objectives
Patient-reported outcomes (PROs) have transformed from merely being paper-based questionnaires used for drug testing and research to increasingly being applied within clinical practice through digital solutions. With the integration of PROs in the new and complex context of clinical practice, different perceptions, purposes and functionalities of PROs have emerged. In a Danish context, PROs' patient-oriented potential pertaining to patient participation and patient empowerment has been emphasised. These are PRO features and expectations resulting from the increased digitalisation of the tools. Thus, PROs can be considered a technological innovation that enables systematic patient-centred healthcare, which has been a focus area in political healthcare strategies for the last 20–30 years. Due to PROs' change in digital mediation and application in new and different contexts, we can reasonably assume that the expectations and perceptions of PRO substance, functionalities and purposes have changed. This development raises new research questions concerning PROs; hence, the focus of this PhD project has been to

Objective 1: Scrutinise the association between PROs and patient participation in chronic care based on a scoping review of the extensive literature. This is a study meant to show how these two phenomena are connected in terms of chronic care, to qualify discussions on PROs' influence on patient participation, elucidate how patient participation is required for PROs to function as intended in healthcare and to identify gaps in current research within the field (Paper I).

Objective 2: Examine the purpose and functionality of PROs on national and international levels when digitalised and as part of clinical practice. This subject field has been investigated through ethnographic studies entailing participation in different arenas on national, regional and hospital levels. The fieldwork has improved my pre-understanding and paved way for expert interviews with people having substantial knowledge of PROs. Hence, Paper II in this PhD project concerns Danish experts' perception of PROs' substance, purposes and functionalities. Furthermore, two document analyses on PROs' functionalities and purposes are conducted. The third paper identifies PROs' functionalities in connection to different stakeholders and after the digitalisation of tools (Paper III), and the fourth paper examines the purposes of PROs, which have resulted in an interdisciplinary reconceptualisation of PROs (Paper IV).

Objective 3: To create a concept map of the elements constituting a PRO *(PRO Elements*) in clinical practice. Hence, a third document analysis is conducted to identify the main elements shaping a PRO. The different purposes and the increase in functionalities mean that PROs are now being used in different contexts, across disease areas, in various ways and by several new users. Therefore, assuming that a

PRO, as other technologies, is shaped through actions and context of use, it becomes relevant to identify and map the elements constituting a PRO as part of clinical practice. The concept map aims to improve new as well as experienced users' understanding of what constitutes a PRO, potentially enhancing the collaboration across sectors, disciplines and disease areas and allowing stakeholders to meaningfully engage in discussions when developing, implementing, applying and evaluating a PRO (Paper V).

Objective 4: To study how newly diagnosed citizens with type 2 diabetes practically experience the use of PRO questionnaires and PRO data in a municipal setting. The aim is to elucidate how this specific group of citizens experienced the newly developed national diabetes PRO questionnaire, which was developed by observing consultations and subsequently interviewing the participants (Paper VI).

Methods and scientific approach

The project takes an eclectic approach methodologically and scientifically, meaning that various methods and scientific approaches are applied in this project. Scientifically, the project is a mix of phenomenological, hermeneutic, pragmatic, post-phenomenological and critical approaches. Methodologically, ethnographic and qualitative methods constitute the research design, where the specific methods include a scoping review; 17 semi-structured interviews with PRO experts and citizens having type 2 diabetes; fieldwork and participant observation in a municipality, in a hospital setting, on a regional level and in national PRO development workshops.

Findings

Objective 1: The association between a PRO and patient participation is dialectic. In chronic care, PROs and patient participation are connected in the development process, in the completion of the questionnaires, when used during consultation for communication and decision-making, in the display of data and when used as an empowerment or a self-management tool. This association is affected by organisational and attitudinal elements. The link between the two phenomena can be split into three phases—*Pre*, *Present* and *Post*—indicating the phases' temporal connection to the patient–clinician consultation. Research concerning the pre and present phases is common, whereas the post phase requires more attention in future studies (Paper I).

Objective 2: Based on the literature, the overall purposes of PRO fall into five categories: a) Research and drug testing tool, b) Quality and economy instrument, c) Enhancement of patient-centred care, d) Politicisation and democratisation of healthcare and e) Cultural and organisational transition (Paper IV). The third study discloses 33 different functionalities of PROs, 11 existing before and 22 existing after the digitalisation of PROs. The growth and change in functionalities reveal that PROs have gradually moved from being a clinician and research tool to a more patient-centred tool (Paper III). Danish experts perceive PROs as nine different things, which can be divided into the following categories: population PRO and individual PRO, passive PRO and active PRO and PRO as a quality improvement tool within healthcare. The experts disagree on whether PRO data are usable for value-based healthcare (VBHC) and as an economic efficiency tool. Moreover, they emphasise a PRO as patient-centred care; as a specific approach in clinical practice; as a digitally mediated tool used for visitation, monitoring and coordination and as a contextual tool shaped according to the disease areas of application (Paper II). In this context, the fieldwork conducted during the PhD project is particularly valuable as it confirms and nuances PROs' complexity in terms of functionality and purpose.

Objective 3: In the creation of a concept map on *PRO Elements*, eight main elements are identified and categorised as *validated questionnaires*, underscoring that PRO questionnaires need to be psychometrically validated and contextually adapted; *developers*, emphasising various developers and their importance in the development process; *content*, outlining examples of a PRO's content; *measure*, containing the types of measures constructing a PRO; *mediation*, concerning the distribution and mediation of PROs, which are either paper-based or digital; *respondent*, indicating that, in practice, different types of respondents exist; *data*, illustrating that data are applicable on both an individual and a population level and *outcome*, implying that PROs not only elicit subjective outcomes but are also used to produce *objective outcomes*. How these elements are combined determines the type of PROs at hand. Hence, a concept map is intended to improve the development, implementation, application and evaluation of PROs (Paper V).

Objective 4: The last study concerns how newly diagnosed citizens with type 2 diabetes experience the national PRO questionnaire within a municipal setting. The findings indicate that the citizens, in general, consider the PRO questionnaire to be a beneficial solution; however, they do stress that the questionnaire requires modification to match their needs as newly diagnosed citizens with type 2 diabetes. Most citizens find the analytical categories and interpretation of PRO data easy and intuitive. The application of PRO data in the consultations have several advantages as it structures the conversation, discloses issues relevant to the citizens, functions as a preparation and a memo tool, ensures a common starting point and improves the effectiveness of the conversations (Paper VI).

Conclusion

Based on the literature reviewed in this project, it is concluded that

- There is a dialectic association between PROs and patient participation in at least seven different areas. PROs' connection to patient participation before and during a consultation has been extensively examined; however, as part of citizens' everyday life, where PROs are supposed to function as a self-management tool, this connection needs to be further studied.

- PROs, according to the literature, ethnographic findings and expert perceptions, have several purposes and functionalities when digitalised and applied as part of clinical practice. The functionalities concerning patients, healthcare professionals (HCPs) and management have become increasingly important.

- PROs in clinical practice consist of many different elements as illustrated by *PRO Elements*. This is a concept map that might improve stakeholders' understanding of a PRO's essentials; enhances collaboration across disciplines, sectors and disease areas and facilitates the development, implementation, application and evaluation of PRO tools.

- Newly diagnosed citizens with type 2 diabetes approve the use of the national diabetes PRO questionnaire but encourage modifications of the questionnaire to better match the needs of newly diagnosed citizens with type 2 diabetes.

DANSK RESUME

Baggrund og delmål

Patient-Reported Outcomes (PROs) er gået fra at være papirbaserede spørgeskemaer anvendt i lægemiddeltestning og forskning til nu i højere grad at være en del af klinisk praksis via digitale løsninger. PROs integration i klinisk praksis, en ny og kompleks kontekst, har ændret forståelsen af deres indhold, formål og funktionalitet. I en dansk sammenhæng er især PROs potentiale som et patientdeltagelses- og empowermentværktøj centralt, hvilket er forbundet med og muliggjort af den øgede digitalisering af PRO. Således kan PRO i nogen grad betragtes som den teknologiske innovation, der potentielt realiserer et systematisk patient-centreret sundhedsvæsen, hvilket har været et fokusmområde i politiske strategier gennem de sidste 20-30 år. I betragtning af PROs øgede digitalisering og anvendelse i klinisk praksis er det relevant at granske hvilke forståelser der eksisterer af PROs indhold, funktionalitet og formål, hvilket har været med til at forme forskningsspørgsmålene i Ph.d.-projektet og konkret givet anledning til at:

Delmål 1: Undersøge sammenhængen mellem PRO og patientdeltagelse inden for kronikkerområdet via et scoping review baseret på relevant forskningslitteratur. Et studie, der viser hvorledes de to fænomener er forbundet, kvalificerer diskussioner vedrørende PROs indflydelse på patiendeltagelse, belyser hvorledes patientdeltagelse er nødvendig for at PRO kan fungere som tiltænkt i sundhedsvæsenet og identificerer videnshuller i nuværende forskning inden for området (artikel I).

Delmål 2: Identificere PROs formål og funktionalitet på nationalt og internationalt niveau i tilfælde hvor PRO er digitaliseret og anvendes i klinisk praksis. Genstandsfeltet er undersøgt gennem etnografiske studier, hvilket indebar deltagelse i diverse areaner på et nationalt, regionalt og hospitalsniveau. Feltarbejdet styrkede min forforståelse og banede vejen for interviews med eksperter, der har en betydelig viden omkring PRO. Således omhandler den anden artikel i Ph.d.-projektet danske eksperters forståelse af PROs indhold, formål og funktionaliteter (artikel II). Endvidere blev der foretaget to dokumentanalyser vedrørende henholdsvis PROs funktionalitet og formål. I den tredje artikel identificeres PROs funktionaliteter, hvilke relateres til forskellige interessenter og PROs digitalisering (artikel III), mens PROs formål undersøges i den fjerde artikel, resulterende i en interdisciplinær rekonceptualisering af PRO (artikel IV).

Delmål 3: Skabe et konceptkort indeholdende de elementer, der udgør en PRO i klinisk praksis (*PRO Elements*). Således blev en tredje dokumentanalyse udført for at identificere de hovedelementer, som former en PRO. De forskellige formål og væksten i antallet af funktionaliteter betyder at PRO nu anvendes i diverse kontekster på tværs af sygdomsområder, på forskellig vis og af flere nye brugere. PRO betragtet som en teknologi, der formes gennem handlinger og brugskontekst, betyder at det er relevant at identificere og kortlægge de elementer der udgør en PRO i klinisk praksis. Formålet med konceptkortet er at forbedre nye såvel som erfarne brugeres forståelse af hvad der udgør en PRO, hvilket potentielt kan styrke samarbejde på tværs af sektorer, discipliner og sygdomsområder og muliggøre at interessenter meningsuldt kan indgå i samtaler og samarbejder omkring en PROs udvikling, implementering, applicering og evaluering (artikel V).

Delmål 4: belyse hvorledes nydiagnosticerede borgere med type 2 diabetes oplever brugen af PRO-spørgeskemaer og PRO data i kommunal praksis. Formålet er at belyse hvordan denne specifikke gruppe af borgere oplevede det nyligt og nationalt udviklede diabetes PRO-spørgeskema, hvilket blev gjort ved at observere konsultationer og efterfølgende interviewe deltagerne (artikel VI).

Metoder og videnskabelig tilgang

Projektet har en eklektisk tilgang metodisk og videnskabeligt, hvilket betyder at en række forskellige metoder og videnskabsteoretiske tilgange anvendes. Således er projektets videnskabsteoretiske fundament et mix imellem fænomenologi, hermeneutik, pragmatisme, postfænomenologi og kritisk teori. Metodisk er forskningsdesignet rodfæstet i etnografiske og kvalitative metoder, hvilket inkluderer: et scoping review, 17 semistrukturerede interviews med PRO-eksperter og borgere med type 2 diabetes, feltarbejde og deltagerobservation på nationalt, regionalt, kommunalt og hospitalsniveau.

Resultater

Delmål 1: Sammenhængen mellem PRO og patientdeltagelse er dialektisk. Inden for kronikerområdet er PRO og patientdeltagelse forbundet i udviklingsprocessen, ved besvarelse af spørgeskemaerne, ved anvendelse i konsultationen som et kommunikativt og beslutningsstøtte værktøj, ved fremvisning af PRO data og som et empowerment og egenhåndteringsværktøj. Sammenhængen påvirkes af organisatoriske faktorer og brugernes holdninger. Sammenhængen mellem de to fænomener kan opdeles i tre faser: *Pre* (Før), *Present* (Under) og *Post* (Efter), kategorier der indikerer fasernes tidsmæssige relation til patient-kliniker konsultationen. Studier vedrørende PROs egenskaber i de to førstnævnte faser er relativt udbredt mens flere undersøgelser af PROs potentiale i den sidstnævnte fase er påkrævet i fremtidige studier (artikel I).

Delmål 2: Baseret på forskningslitteratur kan PROs overordnede formål kategoriseres som: a) Forskning og lægemiddeltestning, b) Kvalitets- og økonomiinstrument c) Forbedring af patientcentreret sundhedspraksis, d) Politisering og demokratisering af sundhedsvæsenet, e) Kulturel og organisatorisk omstilling (artikel IV). Det tredje studie afslørede 33 forskellige funktionaliteter af PRO, 11 eksisterede før digitaliseringen af PRO og 22 opstod med digitaliseringen af PRO. Væksten og ændringen i funktionaliteter indikerer at PRO er gået fra primært at være et kliniker-og forskningsværktøj, til nu at være et mere patient-centreret værktøj (artikel III). Danske eksperter betragter overordnet PRO som værende ni forskelige ting. Eksperterne er enige om at PRO kan inddeles i de følgende kategorier: *Populations PRO* og *Individ PRO*; *Passiv PRO* og *Aktiv PRO*; og ses som et kvalitetsforbedringsværktøj. Eksperterne er uenige om PRO kan anvendes som en del af værdibaseret sundhed (VBS) og vedrørende PROs økonomiske potentiale. Desuden fremhæver eksperterne at PRO fremmer patient-centreret sundhedspraksis, som et digitalt medieret værktøj der blandt andet kan anvendes til visitation, monitorering og koordinering, og PRO kan betragtes som et kontekstuelt værktøj, der formes af det sygdomsområde hvor det appliceres (artikel II). Feltarbejdet udført i løbet af Ph.d.-projektet var især værdifuldt i forhold til disse temaer, eftersom feltarbejdet bekræftede og nuancerede PROs kompleksitet i formål og funktionalitet.

Delmål 3: Konceptkortet (*PRO Elements*) er baseret på identifikationen af otte konstituerende elementer, hvilke kategoriseres som: *validated questionnaires*, der hentyder til vigtigheden af at PRO-spørgeskemaer er psykometrisk validerede og kontekstuelt tilpassede, *developers*, hvilken fremhæver relevansen af en række forskellige udviklere i en udviklingsproces, *content*, der opstiller eksempler på indholdet i en PRO; *measure*, omhandlende de forskellige måleredskaber der indeholdes i en PRO, *mediation*, der vedrører distribueringen og medieringen af PRO-spørgeskemaer, hvilket foregår enten papir-baseret eller digitalt, *respondent*, som fremhæver at forskellige typer af respondenter besvarer PRO-spørgeskemaer ved anvendelse i klinisk praksis, *data*, hvor det illustreres at data kan benyttes på såvel individniveau som på populationsniveau, og *outcome*, der antyder at PRO kan producere subjektive og/eller objektive outcomes. Hvorledes elementerne er kombineret varierer i relation til den enkelte PRO. Således et konceptkort, der er tiltænkt anvendelse i udviklings-, implementerings-, applicerings- og evalueringsprocesser af PRO-værktøjer (artikel V).

Delmål 4: Det sidste studie omhandler hvorledes nydiagnosticerede borgere med type 2 diabetes oplever og opfatter det nationale diabetes PRO-spørgeskema når det anvendes i en kommunal kontekst. Empirien indikerer at PRO-spørgeskemaet af borgerne generelt betragtes som en fordelagtig og brugbar løsning, men på samme tid understreger de vigtigheden af at spørgeskemaet ændres til i større grad at matche de behov man har som nydiagnosticeret borger med type 2 diabetes. Størstedelen af borgerne fandt de analytiskekategorier og fortolkningen af PRO-data nem og intuitiv. Brugen af PRO-data i konsultationerne havde en række fordele eftersom det strukturerede samtalerne, belyste borgerrelevante emner, forberedte deltagerne før samtalen, fungerede som en huskeliste under samtalerne, sikrede et fællesudgangspunkt og muliggjorde mere effektive samtaler (artikel VI).

Konklusion

Baseret på studierne, der udgør Ph.d-projektet konkluderes det at:

- Der er identificeret en dialektisk sammenhæng mellem PRO og patientdeltagelse. Desuden er det påvist at PRO og patiendeltagelse er forbundet indenfor for mindst syv forskellige områder. PROs sammenhæng med patientdeltagelse er i relativ stor grad undersøgt i faserne før (*pre*) og under konsultationerne mellem patient og sundhedsprofessionel (*present*), mens sammenhængen i den tredje fase stort set er ubelyst (*post*), hvilken angår borgernes brug af PRO data i deres hverdag, altså den fase hvor PROs egenskaber som et egenhåndteringsværktøj udfoldes, hvorfor fremtidige studier inden for dette område er påkrævet.

- I forbindelse med digitaliseringen og integrationen af PRO i klinisk praksis er en række af PROs funktionaliteter og formål identificeret baseret på forskningslitteratur, etnografiske studier og ekspertforståelser. Specielt de patient-orienterede, de klinisk relevante og de funktionaliteter, der er anvendelige på ledelsesniveau er kommet mere i fokus.

- PRO i klinisk praksis er sammensat af en række forskellige elementer, hvilket illustreres i *PRO Elements*. Et konceptkort der potentielt kan anvendes til at give interessenter en bedre forståelse af PROs essentielle elementer, forbedre samarbejde på tværs af sektorer, discipliner og sygdomsområder samt anvendes i udviklings-, implementerings-, applicerings- og evalueringprocesser af PRO-værktøjer.

- Nydiagnosticerede borgere med type 2 diabetes påskønner i hovedtræk brugen af det nationale PRO-spørgeskema, men opfordrer til at fremtidige versioner af skemaet i højere grad tilpasses nydiagnosticeredes behov.

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I owe thanks and appreciation to all people who allowed me to take on and get through with this project and provided me with the room and encouragement to stay on track continuously.

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Jeppe Eriksen

Aalborg, 2021

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LIST OF TABLES, FIGURES AND ABBREVIATIONS

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Abbreviations

Abbreviation	**Full word**
PRO	Patient-Reported Outcome
ePROs	electronic Patient-Reported Outcomes
PROM	Patient-Reported Outcome Measure
PREM	Patient-Reported Experience Measure
HRQOL	Health-Related Quality of Life
QOL	Quality of Life

AAU	Aalborg University
DaCHI	Danish Centre for Health Informatics
ViBIS	Knowledge Center for User Involvement
WHO	The World Health Organization
FDA	U.S. Food and Drug Administration
ISOQOL	The International Society for Quality of Life Research
VBHC	Value-Based Healthcare
EBM	Evidence-Based Medicine
RCT	Randomised Controlled Trial
PLO	The General Practitioners Organization
GP(s)	General Practitioners
SDS	The Danish Health Data Authority
HCP(s)	Healthcare Professional(s)
SDM	Shared decision-making
CAT	Computer Adaptive Testing
DDKM	The Danish Healthcare Quality Programme
DR	Danish Regions
KL	Local Government Denmark
SM	The Ministry of Health
FM	The Ministry of Finance

VIVE	The Danish Center for Social Science Research
TAPAR	Techno-anthropology & Participation
TAN	Techno-anthropology
RSI	The Regions Health it
RKKP	The National Clinical Registries
DRG	The Diagnosis-related group system
SS	The Danish Health Authority
CPG	Clinical practice guidelines
CfD	Center for Diabetes
AAUH	Aalborg University Hospital

LIST OF PAPERS

The present thesis is based on six papers. Throughout the thesis, papers are referred to by their roman numerical.

Paper I:
The association between Patient-Reported Outcomes (PROs) and patient participation in chronic care – A scoping review, Patient Education and Counseling (PEC), (in 2nd review – after revision) [1]

Paper II:
Experts Perception of Patient-Reported Outcomes (PROs) in a Danish Context, Linköping University Electronic Press, SHI (2019), https://ep.liu.se/ecp/article.asp?issue=161&article=027&volume [2]

Paper III:
The Digital Transformation of Patient-Reported Outcomes' (PROs') Functionality within Healthcare, IOS Press, (MIE 2020), https://ebooks.iospress.nl/publication/54324 [3]

Paper IV:
The purpose of Patient-Reported Outcome (PRO) post its digitalization and integration into clinical practice: An interdisciplinary redefinition resembling PROs theoretical and practical evolvement, Applied Sciences, https://www.mdpi.com/2076-3417/10/21/7507 [4]

Paper V:
Exploring, describing, and mapping the constitutive elements of Patient-Reported Outcomes (PROs) used in clinical practice, BMC Health Services Research, (in 2nd review – after revision) [5]

Paper VI:
The Experience of Citizens with Newly Diagnosed Type 2 Diabetes with the use of Patient-Reported Outcomes (PROs) in a Municipal setting, DIGITAL HEALTH (Submitted) [6]

STRUCTURE

The thesis consists of eight chapters divided into three parts. In the first part (chapters 1–4), the background, scientific approach, methods, context, concepts and theory are introduced. This part provides relevant background knowledge, displays the research questions and explains the scientific and methodological character of the project; in other words, it provides the reasoning behind the studies conducted in the PhD project. The second part concerns the study findings (chapter 5); findings from the six studies comprising the PhD project and findings from the field studies are outlined. The third part (chapters 5–8) entails a discussion on the project findings, relating them to key concepts and theories, and a conclusion summarising the essentials of the PhD project and its potential impact, scientifically and in clinical practice.

The focus of the project and the thesis concerns how digital PROs in clinical practice are associated with patient participation, patient empowerment and recognition. Hence, these concepts, their association and PRO as a technology are the main pillars in the project and have provided methodological and analytical guidance and helped delimit the scope of the project.

CHAPTER 1. BACKGROUND

Problems worthy of attack prove their worth by hitting back.

(Piet Hein)

In this chapter, the concept of PRO is introduced. Then, it is explained why and where PROs are used. This chapter focuses on a PRO in a Danish context: how the tools have been integrated in clinical practice, highlighting various stakeholders; the political expectations associated with PROs; in what disease areas and sectors PROs are applied and examples of clinical experiences with PROs. Hence, the chapter presents examples of current international knowledge regarding the use of PROs in clinical practice. At the end of the chapter, the research questions are outlined.

The contents of particular PRO instruments are not included in this chapter. If interested in a detailed understanding of particular PRO questionnaires, please refer to the five-item World Health Organization Well-Being Index (WHO-5) and the Short Form-36 (SF-36) described in Paper IV [4]; the instruments constituting the diabetes PRO tool evaluated in Paper VI are described by the PRO secretariat in their evaluation report [7][1].

1.1.1. WHY PRO IN DANISH HEALTHCARE?

In the report *Fem megatrends der udfordrer fremtidens sundhedsvæsen* [8] (Five Megatrends Challenging the Future Healthcare System), authored by the Danish Center for Social Science Research (VIVE), the main challenges that Danish healthcare is expected to face in the coming years are elaborated upon.

The report explains that a consequence of the five megatrends is that patients today and henceforth, to a greater extent, are responsible for their health and treatment, as the public healthcare system lacks the necessary resources. This is focal when trying to describe the current state of the Danish healthcare system. The healthcare system lacks resources, and the solution so far has been to place an increased responsibility on the shoulders of the citizens, who are held accountable for their health and treatment. The five challenges referred to as megatrends are presented as follows:

- Challenge 1 – An ageing population: The number of elderly citizens is increasing due to healthier lifestyles and the ageing of the huge birth cohorts after World War II. Hence, it is estimated that by 2036, the number of citizens aged above 80 years will be doubled. This is a demographic alteration, which is a challenge in a tax-based welfare system like the Danish,

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[1] If interested in a broader variety of PRO tools, https://www.healthmeasures.net/ might be useful.

as this model requires that those who are active in the labour market finance those outside the labour market. The ratio between labour-active and retired citizens was 4.3 in 2000 and 3.2 in 2016; it is estimated to be 2.2 in 2042.

- Challenge 2 – The increasing number of citizens suffering from chronic conditions: Citizens diagnosed with one or more chronic conditions are increasing. This is a development caused by an increasing number of elderly, improved living conditions, technological and medical improvements, increased screening and diagnoses of citizens and enhanced treatments.
- Challenge 3 – The information revolution: The increased amount and use of data, AI and digital solutions are currently transforming the healthcare system. Consequently, healthcare is accessible through new channels, such as healthcare apps, wearables, telemedicine and video consultations. This makes citizens' health data accessible to health practitioners, enabling an increasingly automated practice. Regarding technology, telemedicine does not necessarily lead to a more efficient healthcare system. Systematic validation and regulation of healthcare apps are needed. The methods such as deep learning and big data are being increasingly used to identify correlations in healthcare, which increases the amount of data, subsequently requiring complex and adequate IT infrastructure to facilitate their distribution, access and use. Note that it is not sufficient to implement and apply new technologies as the contextual use varies, which determines the actual impact on healthcare.
- Challenge 4 – The blessing and curse of healthcare technology: Gene technology and molecular biology are transforming healthcare, especially when the human genome is linked to healthcare data that allow tailored and individualised treatment of citizens and extended forms of preventive healthcare. This is a healthcare practice (i.e. raising ethical questions) that concerns the degree of information citizens should receive on potential health issues based on their genome. Another consideration is resource allocation, which will be different in a healthcare system based on preventive interventions. These are relevant considerations, as the future healthcare system will be based more extensively on proactive and preventive actions, in contrast to the traditional treatment paradigm.
- Challenge 5 – The new healthcare user: In the future, citizens will expect better treatments, sufficient information and increased participation in healthcare-related issues. Similarly, citizens will be expected to participate actively and, to a greater extent, self-manage their health and treatment. Facilitated by digital healthcare solutions, increased patient participation might improve the treatment quality and the healthcare system, potentially making it more efficient. Even though it is assumed that citizens, in general, are interested in increased responsibility, not all patients are interested in or are able to take on such a responsibility. Therefore, if increased participation is mandatory, the exclusion of certain patient groups is a future attention point; subsequently, individualised treatment and communication are

> warranted. In this section, a PRO is described as a tool that enables citizens to democratically influence the healthcare system through VBHC. The increased patient participation and self-management means that patients become experts in their disease situation; subsequently, their relationships with HCPs gradually move closer to a partnership.

Additionally, health expenditures are increasing due to citizens' ageing, proximity to death, number of chronic conditions and survivability. Health expenditures are 11 times bigger if a citizen suffers from three or more chronic conditions compared to someone suffering from none, and the chances of readmission are 12 times higher among these patients. Chronic conditions are also an economic and individual problem, as they result in less productive years as part of the labour market. On a societal level, the information revolution means that traditional job functions are handled by new technological innovations, and some segments of the population have access to private health technology solutions. Consequently, the development potentially has negative consequences for unskilled labour and less resourceful patients, as it might increase inequity in healthcare. However, in general, it is difficult to foresee how technological development, digitalization and increased patient participation will influence inequity in health. On one hand, healthcare has become more easily accessible and resources are allocated to those who are most in need, as self-managing citizens require less attention. On the other hand, some patients might not be able to use the technological solutions offered in the future [8].

1.1.2. ARE PROS EVEN FEASIBLE?

Traditionally, PROs have been applied in randomised controlled trials (RCTs) and as part of drug testing [4]. However, integrating PROs into clinical practice generates several other questions, one of which concerns the feasibility of PROs in clinical practice. Several studies have examined this subject and established PRO feasibility in clinical practice [9–13].

As an example, in the paper *Patient Satisfaction with Collection of Patient-Reported Outcome Measures in Routine Care*, Recinos et al. [14] examined exactly what the title of the paper states: patient satisfaction with PROs. The results of a survey containing 323 responses from patients showed that 92.3% patients strongly agreed or agreed that the questionnaire system is easy to use, 87.6% strongly agreed or agreed that the questionnaire is of an appropriate length and 77.3% strongly agreed or agreed that their care overall benefits from the use of PROs. Hence, their study indicated that a systematic collection of electronic patient-reported outcome measure (PROM) questionnaires is feasible and that most patients are satisfied with such a solution [14].

1.1.3. AMBUFLEX

In a Danish context, AmbuFlex, which is part of the VestKronik system and a widely used PRO developer, is a great example of the bottom-up movement. The VestKronik system was established by Niels Henrik Hjøllund, who, as a physician, has been working with PRO questionnaires. Initially, the system was used in minor projects; however, in 2008, Hospitalsenheden Vest decided to integrate the system as part of clinical practice and AmbuFlex was established. Today, AmbuFlex is a major developer and distributor of PROs in a Danish context, offering solutions in the following disease areas:

- Cancer diseases
- Cardiac diseases
- Diabetes diseases
- Infectious diseases
- Lung diseases
- Neurological diseases
- Others (various condition-specific questionnaires)
- Palliative care
- Psychiatry
- Rheumatic diseases
- Women's diseases [15,16]

1.1.4. INTERNATIONAL SOURCES OF INSPIRATION

The top–down integration of PROs in Denmark is related to different developments. First, it is reasonable to assume that the regional use and growth of, for example, AmbuFlex has inspired national actors. Second, PROs' potential has been promoted by theoreticians and practical experiences from other Western countries. In this context, the FDA report *Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims* [17], making the use of PROs mandatory when testing drugs, is a pivotal document as it contains the most common definition of a PRO. Hence, a PRO is defined as

'Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' [17, p. 2].

This is an interpretation of PROs embedded in an industrial and drug testing context, where they are mainly referred to as measuring instruments; consequently, PROs are also often referred to as PROMs in an international context [18–22]. The definition is quite flexible as it refers to a PRO as *any report of a patient's health condition*; therefore, requirements are limited as the report merely needs to concern patients' health condition and come from patients themselves. On one hand, a flexible interpretation makes the definition applicable in most settings, and on the other hand, this coining of the concept makes it difficult to understand what a PRO implies in detail.

In the same year, 2009, the National Health Service (NHS) in the United Kingdom initiated a routine collection of PROs for specific elective procedures (i.e. knee, hip, groin hernia or varicose vein surgeries) [23]. Simultaneously, with a systematic top–down integration of PROs in the United Kingdom, Michael Moore published the paper *What Is Value in Health Care?* [24], elaborating on the idea of a PRO-based VBHC.

‘Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent. This goal is what matters for patients and unites the interests of all actors in the system. If value improves, patients, payers, suppliers can all benefit while the economic sustainability of the health care system increases’ [24, p. 1].

Thus, PROs are supposed to create an economically efficient healthcare system and improve patient outcomes. The mission is to establish a healthcare system in which providers are evaluated on patient outcomes (value) and not utterly on the volume of services delivered [24].

1.1.5. PA CONSULTING REPORT

In a Danish context, an inquiry was initiated by PA Consulting in 2014, resulting in a report the subsequent year, named *Analyse af Patientrapporterede Oplysninger (PRO) – Hovedrapport* [25] (Analysis of Patient-Reported Outcomes (PROs) – Main report). The results in the report indicate several prerequisites; for example, patients should complete the questionnaire at home before the patient-provider consultation, the PRO should be supported locally by clinicians and management and patients should only be invited to patient–clinician consultations if deemed necessary by the build-in algorithms and other minor issues. These results were based on a literature study and insights provided by the use of PROs within AmbuFlex projects in the following disease areas: asthma, epilepsy, chemotherapy, kidney failure, prostate cancer and rheumatoid arthritis. Based on the business case in the report, it was concluded that the economic gains achieved when using PROs are approximately between 67 and 102 million DKK. These findings are based on the assumptions that the application of a PRO leads to a reduction in patient transportation, a decrease in the number of physical consultations and more effective use of medicine. The report points out that there are no decisive technological or organisational barriers concerning PRO implementation from a national level, and that economic gains increase as PROs are standardised and widely spread across sectors. The qualitative findings in the report suggest that a PRO ensures more engaged patients and that patients have a higher influence on their treatment, better patient-provider dialogues and more effective conversations. However, the patients need to be active and responsible caretakers of their health. The report mirrors the complexity of the benefits and barriers pertaining to the application of PROs in clinical practice, which depends on several factors. Therefore, it is also peculiar that the report finds zero barriers on a technological or organisational level. The PRO analysis by PA Consulting is focal, as this report shows, based on doubtful conclusions, that PROs might have a positive economic impact on the Danish healthcare sector [25].

1.1.6. PATIENT ASSOCIATIONS AND PROGRAM PRO

In 2013, Danish Patients, which is an umbrella organisation representing 102 patients and relatives associations in Denmark, published a short report titled *Patientcentrerede kvalitetsmål* [26] (Patient-centred Measures of Quality). This report deals with how to use patient-centred outcome measures to improve quality in chronic care, which is a focal area as 80% of healthcare expenditure is allocated to chronic care. The report emphasises using different and fitting measures in chronic care, as the traditional measures applied in acute care are inadequate. According to Danish Patients, there is a paradigm shift in the approach to achieving quality improvements in the healthcare sector, through the use of PRO measures that create a healthcare system based on patients' needs and perceptions, in contrast to the traditional system, which is based on HCPs and administrator preferences. Thus, patients' subjective understanding of their health status and quality of life (QoL) are considered essential benchmarks when assessing quality improvements. This is a paradigm shift that Danish Patients recognises as a cultural challenge for HCPs and the management level. Note that PROs are meant to complement and not substitute for traditional quality measures. According to Danish Patients, PROs can elucidate patients' QoL and functional level and be used as a measure of effectiveness. Therefore, Danish Patients suggests that PROs be used systematically to evaluate and improve healthcare quality across regions, sectors and disease areas and to assess the quality of patient pathways. Based on PROs' capabilities, Danish Patients suggests, two years ahead of the PA Consulting report, initiating PRO projects on a national level to improve the quality of healthcare. The report explains how patient knowledge is an unexploited resource that should be exploited to improve patient pathways, enable tailored treatment of citizens suffering from chronic conditions, secure better treatment, prevent mistakes and build a more effective healthcare system [26].

In 2015, TrygFonden and Knowledge Center for User Involvement (ViBIS), a subsection of Danish Patients, started a collaboration, which resulted in the so-called *Program PRO* [27]: a report compiled by 29 experts, chaired by professor Mogens Hørder. This report explains what PROs are and how they are best implemented and used as part of clinical practice and as quality assurance and improvement tools. According to the authors, the driving force behind *Program PRO* is the desire to integrate PRO data into clinical practice and quality development work in a Danish context, subsequently leading to increased patient involvement and thereby fulfilling the vision of a patient-centred healthcare system where patients are partners and not just passive receivers of healthcare. Hence, a PRO is supposed to benefit individual patients and the healthcare system as a whole [27]. It is reasonable to claim that this report is one of the most central documents on PROs in a Danish context due to not only the amount of relevant information it contains but also because it is the go-to document when implementing PROs in clinical practice. This report explains that

- Patients are citizens who need the healthcare system to support them in managing their health condition.

- Patients wish to contribute to an improved healthcare system.
- The healthcare system should use patient preferences, needs and resources.
- PRO data should improve dialogues between patients and HCPs.
- PROs should be a flexible tool adaptable to individual patients.
- PROs need to be meaningful for all stakeholders.
- The usage of PRO data should result in improved patient pathways, potentially decreasing hospital admissions and outpatient visits [27].

Furthermore, the report contains the following alternative interpretation of PROs (translated from Danish):

'PRO-data (Patient Reported Outcome Data) is data about the patient's health condition such as physical and mental health, symptoms, health-related QoL and functional ability, PRO-data is reported directly by the patient' [27, p. 16].

This is an alternative definition accentuating PROs as data, indicating the healthcare system and clinical practice as the contexts of use. Similar to the FDA's interpretation of a PRO, completion of questionnaires is still done by patients; however, this definition explains, in detail, the type of content constituting a PRO tool. A comparison of FDA and ViBIS interpretation highlights two important points: The usage of PROs has moved from one context to another and different perceptions of PROs' essentials exist. This is one of the reasons this thesis concerns PROs' purpose, functionality and reconceptualisation. Even though it is not apparent in the two definitions of PROs, the reports explain how the collection of *any report/data* is based on validated PRO questionnaires. Figure 1, borrowed from *Program PRO*, describes how PROs are a specific type of patient-reported data.

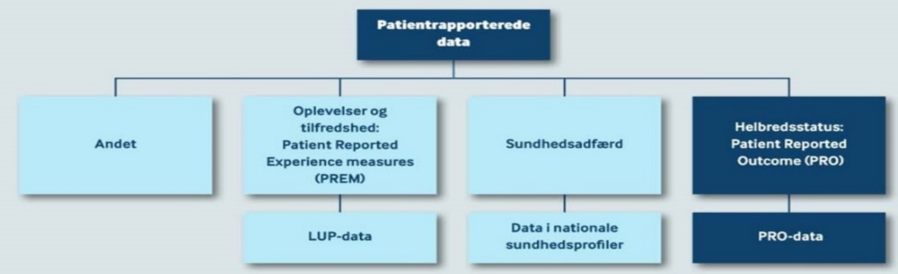

Figure 1. Types of patient-reported data [27]

As Figure 1 illustrates, other examples of patient-reported data include systematic surveys and patient-reported experience measures (PREMs). Especially, PREMs and PROMs have been compared in the international literature to scrutinise the differences between the measures [28]. A common distinction, as the figure illustrates, is that PRO(M)s concern patients' health status, whereas PREMs disclose their experiences and satisfaction level [27]. The figure presents another interesting point concerning PRO conceptualisation in a Danish context, which is revealed through the fieldwork conducted in the PhD project. Being in the field made me aware of how actors confuse PRO data and patient-reported data, referring to them as synonyms, which, according to the figure, is a misinterpretation. PRO data represent a particular subgroup of patient-reported data. The first substantial point is that discussions on PRO are based on relatively common perceptions of a PRO to avoid its arbitrary and less productive innovations and applications in clinical practice. The second point is related to the mixing of PROs that are validated measures with types of patient-reported measures not necessarily being valid measures, which potentially devaluate or diminish HCPs' confidence in PRO data. This is underscored by HCPs' attitudes on PRO measures and data disclosed in Paper I [1].

The report distinguishes, analogue to Greenhalgh [29], between the use of PROs on an individual level and those on a population level. The former concerns the use of an individual's PRO data in treatment and care, whereas the latter refers to research, storage of PRO data in clinical databases, systematic quality development and as a way to compare individual data with population data in clinical practice. A dichotomy, familiar to another conceptual division introduced in *Program PRO* between *active PRO* and *passive PRO*, refers to whether PRO data are actively used in clinical practice or stored in databases used for other purposes. The application of PROs in clinical practice potentially results in a more structured and systematised working practice for HCPs. In this context, it is crucial that patients receive feedback based on their PRO answers by actively referring to their PRO data during the patient–clinician consultation. A focal goal is to promote a genuine partnership between patients and HCPs [27]. Importantly, the aggregated data constituting PROs on a population level are also applicable in clinical practice as a decision-making tool on treatments during consultations, where it, for example, provides information on the probability of outcomes of health interventions [29]. Hence, analytically, the distinction between individual and population PROs and *active PRO* and *passive PRO* might be beneficial, but in practice, the picture is a bit more complex.

According to *Program PRO*, challenges regarding PRO use in clinical practice concern adequate response rates; the burden of extra tasks on the clinical personal; economic expenditures linked to PRO use; patient burden; handling of sensitive patient data; representation and participation issues in development workshops; the fact that some patients are unable to complete PRO questionnaires and therefore assisted by a proxy; health literacy issues creating awareness on the potential exclusion of certain patient groups; coordination and integration of PRO tools across sectors; ownership among patients, management and HCPs and PRO integration into current infrastructure and quality systems [27]. Concerns related to sufficient patient participation and inequity in healthcare underscore the relevance of the approach in the present PhD project.

In contrast to the findings of the PA Consulting report, the authors of *Program PRO* are slightly more hesitant regarding indicating PROs' economic impact on healthcare, as knowledge in the area is sparse. Thus, it takes a year for an investment in a PRO solution to recover its value, assuming that the implementation leads to an expenditure reduction of approximately 37 million DKK. However, based on these conservative calculations compared to the PA Consulting report, the authors of *Program PRO* deem a PRO to be a reasonable investment as well. Similar to other sources, this report elaborates on the possibility of using PROs as part of a VBHC system, where reimbursement is additionally based on the value it creates for patients and less on the production volume [27].

The findings of the report facilitates the establishment of the PRO secretariat, whose job is to handle PRO development on a national level, to coordinate PRO initiatives and to create a common national platform for future PRO work [30].

1.1.7. ANNUAL ECONOMIC AGREEMENTS

In October 2015, the Economic Agreement between the Government and Danish Regions (DR) was established for 2016. This is an annual agreement deciding the number of resources the regions are allotted and how these are allocated to different areas. This agreement accentuates that quality improvements in healthcare must be based on a few but ambitious goals concerning systematic patient involvement, strong leadership, systematic use of timely data and increased transparency. It is stated that quality improvements must be based on positive patient effects and results and not just process indicators; therefore, tentative models of a VBHC system must be developed and tested. Similar to other Danish healthcare strategies, the slogan *patienten i centrum* (focus on the patient) is part of the agreement; however, what is interesting in the 2016 annual agreement is that PROs take a central position, as it is assumed that their systematic use enables patient-centred care by offering knowledge on what matters to the patient, promotes shared decision-making (SDM) in clinical practice and facilitates competence development. Therefore, PROs were to be implemented within three disease areas by the end of 2019 [31].

In the economic agreement the following year (2017), a new task force was formed on a national level to oversee the standardisation of PROs across sectors and to share knowledge on the use of PROs in clinical practice and for quality improvements [32]. This initiative led to the formation of the National Steering Group and the PRO secretariat [30]. This agreement focuses on reductions in hospital admissions, a more coherent healthcare sector, more efficient handling of the increasing number of patients with chronic conditions and improved digital collaboration on complex patient pathways [32]. Thus, this is an agreement revealing the expectations linked to PROs' potential.

1.1.8. PRO AND HEALTH POLICIES ON A NATIONAL LEVEL

In the report *Fælles Offentlig Strategi for Digital Velfærd 2013-2020 - Digital Velfærd en Lettere Hverdag [33]* (Joint Public Strategy on Digital Welfare 2013-2020 – Digital Welfare an Easier Everyday Life), the Local Government Denmark (KL), DR and the government underscore that digital solutions support citizens' active involvement in their care, subsequently improving individual and societal welfare through more efficient use of resources. This report states that, at this point, little is known concerning PROs on a national level; therefore, more knowledge on the systematic use of PROs is required [33].

In the report *A Coherent and Trustworthy Health Network for All - Digital Health Strategy 2018-2022* [34], authored by The Ministry of Health (SM), The Ministry of Finance (FM), DR and KL, the following five focus areas are highlighted:

1) Proactive involvement in everyday life—and more self-service
2) Knowledge on time
3) Prevention
4) Trustworthy and secure data
5) Progress and common building blocks [34]

The first focus area concerns how digital solutions need to facilitate increased patient involvement in handling their disease and treatment. For this to happen, an increased responsibility is placed on individuals; thus, patients are, to a larger degree, expected to manage their disease and treatment. If patients have the necessary access to data concerning patient pathways and their diseases, they will be able to self-manage their disease from a homely environment. A PRO is mentioned in this context, as a PRO, according to the report, entails increased patient involvement and allows a systematic integration of the patient perspective. Hence, by using patients' knowledge, an individualised approach in healthcare is made possible. The visitation functionality based on algorithms and PROs is emphasised in this report, as it ensures that only patients in need are invited for a check-up at the hospital [34], a functionality explained in more detail in Figure 6. The focus on this exact functionality, which potentially leads to a more efficient use of resources, resembles PRO interpretations in the other included reports; hence, this is a dominant interpretation on the political level where PROs are considered tools that pave way for an efficient healthcare system based on increased patient participation. Even though PROs, in the report, are not explicitly mentioned as part of the section *Knowledge on Time* and *Prevention* [34], findings from this PhD project reveal that these areas are linked to PROs [3]. Knowledge on time and access to data is important in clinical practice to use the potential of health data. The use of digital data might make patient pathways more effective and reduce the patient burden, as digital solutions are meant to prevent scenarios in which patients have to answer the same questions multiple times. Digital solutions are also advantageous in preventive healthcare, as interventions based on continuous data become more timely. The sections *Trustworthy and secure data* and *Progress and common building blocks [34]* concern preconditions in the establishment of a data-driven and patient-centred healthcare system. Hence, an adequate digital infrastructure, a system that benefits patients and HCPs and secure digital systems, are central preconditions when striving for a healthcare system based on digital solutions. Especially, proper handling of citizens' health data is important if patients are to have confidence in the digitalised healthcare system [34]. In this context, note that the concept of *digitalisation* linked to PROs in the present PhD project does not refer to digitisation, ‘the conversion from analogue to digital’ [35, p. 15], but to digitalisation, ‘the process of using digital technology and the impact it has’ [35. p. 15] or digital transformation defined as ‘new ways of doing things that generate new sources of value’ [35. p. 15].

In 2017, Denmark’s central government, KL and DR launched an ambitious political agreement, *Nationale Mål for Sundhedsvæsenet* [36] (National Targets for the Danish Healthcare System). This agreement aimed to ensure that all sectors of the health system—hospitals, municipalities and general practitioners (GPs)—pursue clear and common goals to improve the quality of healthcare.

Figure 2. National targets for the Danish healthcare system [36]

As illustrated in Figure 2, the healthcare system is facing several challenges. Interestingly, most listed topics here are areas in which a PRO is supposed to have an impact [3].

As mirrored by the political documents, the attention on and use of PROs have accelerated in a Danish context. This is a development, as indicated by the establishment of the PRO secretariat and National Steering Group, which has institutionalised PROs on a national level (Figure 3). The following are the members of the National Steering Group:

- The Danish Ministry of Health (SM)
- Danish Regions (DR)
- Loal Government Denmark (KL)
- Danish Patients
- General Practitioners Organization (PLO)
- The Danish Cancer Society
- The Brain Injury Association
- The Danish Health Authority (SS)
- The Danish Health Data Authority (SDS).
- The Region of Southern Denmark
- The Capital Region of Denmark
- The Municipality of Aalborg
- The Municipality of Copenhagen
- Mogens Hørder (the chair of *Program PRO*) and national advisor [30]

This is a group comprising some of the most influential actors and institutions in the Danish healthcare system, confirming the relevance of PROs.

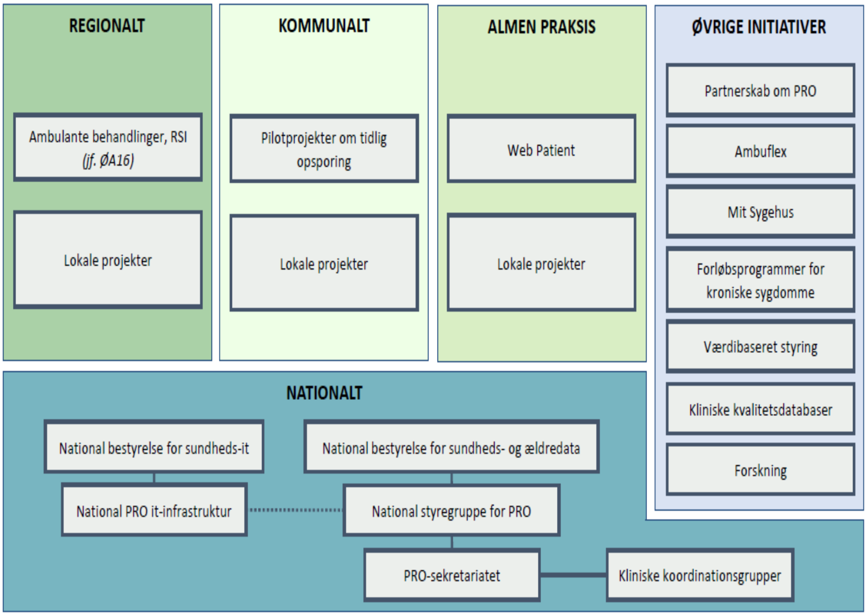

Figure 3. PRO initiatives on different organisational levels [30]

Figure 3 illustrates how the PRO secretariat refers to the National Steering Group and visualises how several other PRO initiatives and solutions are in progress in a Danish context, on local, municipal and regional levels, underscoring the extensive character of PRO initiatives and the current relevance of PROs in Danish healthcare. The figure also shows how the initial PRO projects on a regional level focused on outpatient visits, whereas PRO projects in a municipal setting regarded PROs' preventive potential. The column to the right, listing additional initiatives, indicates the multifaceted use of PROs in a Danish context as the projects focus on PROs' applications in science, VBHC, clinical practice, quality improvement work, enhancement of patient pathways, the Danish Clinical Quality Program and as part of the AmbuFlex system [30].

The PRO secretariat is an important actor as it hosts workshops and handles PRO development on a national level in collaboration with clinical coordination groups and patients. Thus, the PRO secretariat is meant to facilitate the development of three new PRO questionnaires every half a year, which so far has resulted in the creation of PRO questionnaires in the following areas (some are still under development):

- Apoplexy

- Cardiac rehabilitation
- COVID-19
- Diabetes
- Early detection of depression
- Hip and knee arthritis
- Palliative care
- Pneumokok
- Pregnancy and maternity
- Psoriasis
- Rehabilitation [30]

As the list shows, PRO questionnaires on a national level cover various disease areas. In the present PhD project, the workshops within diabetes and cardiac rehabilitation are particularly relevant, as part of the fieldwork has been conducted in these settings.

According to the PRO secretariat, PRO can be used as a tool for

- Screening
- Dialogue support
- Decision-making
- Local quality improvements
- Healthcare solutions based on aggregated data
- Management, benchmarking and transparency [30]

Functionalities are also identified in the present PhD project [3]. Figure 4, created by the Danish Ministry of Health, displays an alternative explanation of how a PRO works on a national level. Hence, the figure displays how the PRO flow is a six-step iterative process, starting with the development of a PRO questionnaire and the attached decision algorithm, followed by its integration into the local system, questionnaires being sent to patients for completion, PRO answers being assessed and used for decision-making by an HCP and PRO data being made accessible through the IT infrastructure [37]. A simple illustration of a PRO flow, providing a useful overview of a PRO's journey on a national level, is presented in the figure.

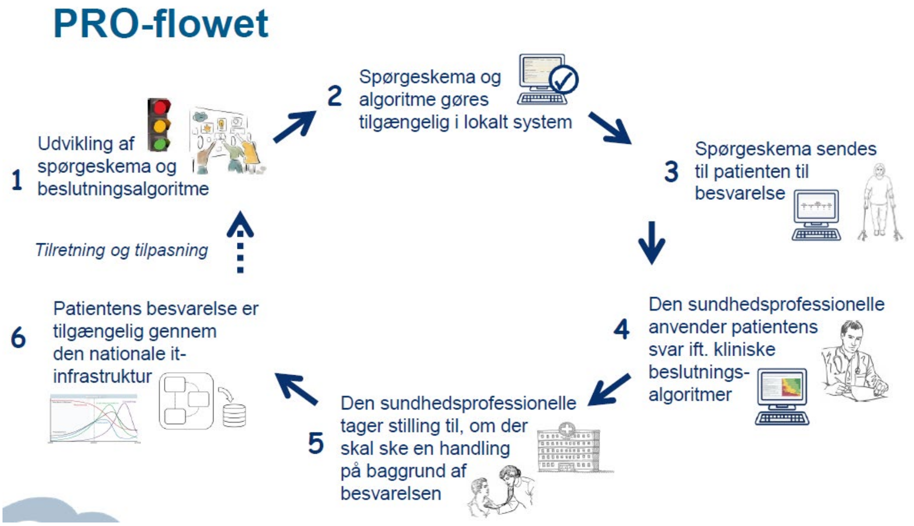

Figure 4. Iterative flow of a PRO from development to data [37]

Figure 4 illustrates only one type of scenario; however, in a Danish context, other PRO flows are also possible, which is a logical consequence, considering the different types of PROs that exist and the numerous PRO functionalities [3,5]. Hence, a more patient-oriented description of the PRO flow would have been a different story. Note that the development and application of PRO solutions are considered an iterative process, which arguably will require a continuous allocation of resources to the area and ensure that PRO tools stay valid and clinically relevant. Furthermore, it is noticeable how PROs, on a national level, are considered part of digital and technological solutions.

Figure 5 explains how the national IT infrastructure enables the use and sharing of PRO data. The box to the left represents the collection of all specific PRO solutions that are distributed to citizens. After completion of the questionnaires, answers are accumulated in the XDS repository, which is a standard system for cataloguing and sharing patient data across health institutions. Data are then sent to the National Service Platform (NSP), which accumulates various national registers; hence, it is from NSP that the PRO data are made available to hospitals, municipalities, GPs and Sundhed.dk[2] (the national health portal). In this way, HCPs, citizens and other users can access and use PRO data [38].

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[2] Sundhed.dk is used by patients and HCPs as it contains the patients' EHR, the corona passport and several other apps and solutions that are useful in healthcare: https://www.sundhed.dk/

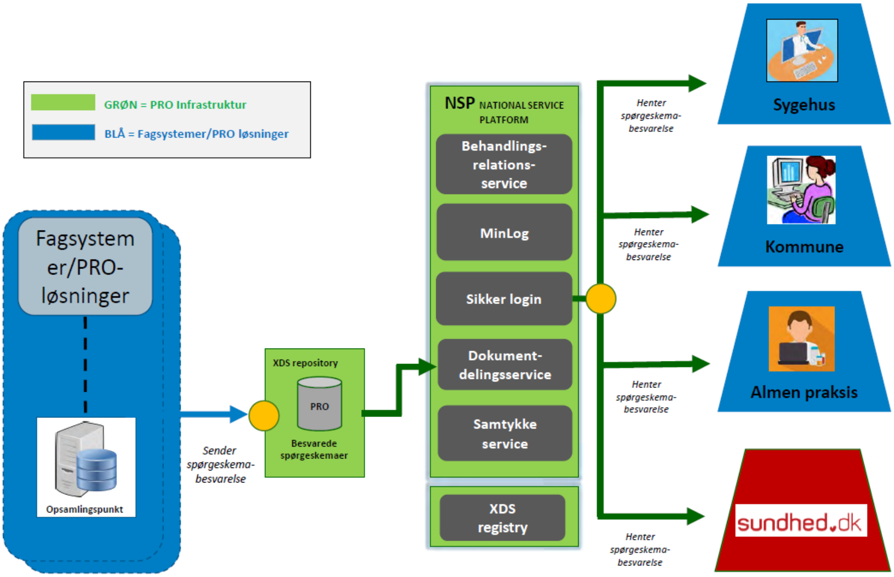

Figure 5. Technological infrastructure allowing the use and sharing of PRO data [38]

1.1.9. PRO AND HEALTH POLICIES ON A REGIONAL LEVEL

In 2015, DRs published the healthcare strategy *Plan for Borgernes Sundhedsvæsen - vores Sundhedsvæsen* [39] (A plan for citizens' Healthcare System – Our Healthcare System), with the following focus areas:

a) A new patient-centred culture
b) Enhanced quality
c) Improved patient pathways
d) Increased patient participation
e) Shared decision-making
f) Integration of the patients' perspective, knowledge, preferences and needs
g) Shared ownership
h) Debureaucratisation and efficiency

The word *active participation* is central in the report as changes can only be passed if the management, HCPs and patients act as active participants. Hence, a cultural change is required to promote awareness of patients' individual treatment and health responsibility. This is achievable if patients are informed and equipped with the necessary knowledge to handle and manage their disease and health situation. Moreover, enhanced cooperation between healthcare institutions is a precondition for realising the intentions in the strategy. To establish a patient-centred culture, the practice of patient participation is essential; hence, participatory methods and practices are focal in HCP education. According to the citizens' inputs included in the strategy development process, the following are necessary: improved communication, dialogue and information, increased participation and decision power, focus on patient needs, coherent patient pathways, individual patient responsibility and adequate support systems, facilitating citizens' self-management of their health. Citizens have different qualifications and capabilities, which determine their ability to actively participate and handle their disease situation. Nonetheless, *the active patient* is idealised and praised based on the assumption that the systematic inclusion of patient perspectives in clinical practice improves equality in health. In this report, PROs are described as measures, aligned with the ViBIS definition, and perceived as tools that disclose patients' utility of course of treatment and are used to improve the quality of the healthcare system. Thus, PRO measures enable VBHC and a systematic application of patient-centred healthcare. The idea is that the traditional volume-based system must be complemented by a quality-focused reimbursement system measuring the effect and value patients gain from treatments, which subsequently improves quality assurance and improvement work. Hence, PRO data should be collected systematically and used to create a transparent system based on benchmarking and public access to data. In other words, improvements in treatment, patient pathways, coherence, communication and quality of care should be rooted in citizens' experiences, needs and preferences, where PRO and patient participation are considered the main tools [39].

The same year (2015), DRs also published the report *Handleplan for Bedre Brug af Sundhedsdata i Regionerne* [40] (A Plan of Action to Make Better Use of Healthcare Data in the Regions). In the quest to use healthcare data better, the DRs focused on the following factors:

a) Citizens' use of healthcare data
b) Healthcare systems' use of healthcare data
c) Scientific use of healthcare data
d) Public–private innovation
e) Security and transparency
f) Transparency and efficiency

Once again, citizens are considered focal actors. Hence, it is important that citizens feel safe when sharing their healthcare data and have access to and actively use their healthcare data in treatment and preventive healthcare. If these criteria are fulfilled, healthcare data might instigate patient participation and empower patients. The HCPs also benefit from the healthcare data, as they provide them with timely data applicable in decision-making, potentially resulting in better treatment. In this context, appropriate IT infrastructure is highlighted as an important prerequisite. At an organisational level, the use of health data might create a more coherent, transparent and efficient system and enhance preventive healthcare interventions, improving healthcare quality. The strive for a more transparent healthcare system concerns citizens' access to their results and data displaying comparative benchmarking results of healthcare institutions. Therefore, healthcare data are considered both patient and management tools. From a development perspective, healthcare data might facilitate the creation of innovative solutions based on citizens' and HCPs' knowledge, which are alternative solutions needed considering the increased demand on healthcare services. In this report, PROs are described as a patient-centred tool that facilitates that facilitate patient participation and increased ownership, supporting patients in their disease management. Moreover, PROs can improve diagnosis and treatment and be utilised in research and quality improvement in healthcare through their integration in the National Clinical Registries (RKKP) [40].

After the economic agreement (2016) between DRs and the government, the regions were asked to initiate PRO development within the first three disease areas on a national level. Therefore, Regions Health IT (RSI) developed PRO instruments for epilepsy, prostate cancer and breast cancer (chemo patients). After the initial three development workshops, the development and distribution of PROs were placed at the PRO secretariat; the implementation task is still located on regional and local levels [41]. The RSI inputs are relevant, as the scope and conceptual framing of PROs at these workshops subsequently formed the workshops hosted by the PRO secretariat [42]. The RSI report states that a PRO is a tool used for outpatient visits and that the purpose of the projects is to promote the use of a PRO as part of clinical practice. PROs must enhance patient–clinician dialogues, promote patient participation in decision-making and ensure that the most fitting health interventions are chosen as they provide maximum value for patients and the system. Moreover, PRO data can be used for research, quality improvements and to improve patient pathways. This report links the use of PROs on a national level directly to the findings in the PA Consulting report and to the presented healthcare strategy *Den Offentlige Strategi for Digital Velfærd 2013-2020*. Similar to *Program PRO*, the RSI project revises down some of the economic gains identified in the business case conducted by PA Consulting and estimates that the use of PROs in the RSI project results in an annual economic surplus of approximately 6.4 million DKK. Hence, the extent of economic gains is doubtful, but a decrease in the number of outpatient visits is expected, which is a focal consequence on a regional level as it enables more efficient use of resources. In the evaluation of RSI projects, PROs' ability to improve patient satisfaction and the instruments' capacity to influence treatment decisions are key parameters. The RSI project outlines relevant requirements; hence, for PROs to function in clinical practice, they need to be easy to use and applied through an automated process; moreover, PRO solutions should be as time-effective as possible [41]. These points indicate that a PRO is supposed to function as a technology ensuring increased effectiveness in healthcare. Moreover, how the interpretation and display of PRO data and the integration of PRO into patients' electronic health records (EHRs) are best achieved need to be carefully considered, especially when the interpretation of PRO answers and the improvement of decision-making are based on algorithms [41].

Later in 2016, RSI workshops on the development of PRO instruments within epilepsy, prostate cancer and breast cancer (chemo patients) began. The development process in each disease area comprised three clinical workshops. The scope of the first workshop was to agree on the aims and purposes of a PRO. In the second workshop, an initial form of the PRO questionnaire was created, and the types of questions and relevant areas were decided. The third workshop concerned the verification of prior agreements from the two former workshops, and questions were discussed in more detail in connection to how scores were to be interpreted by the algorithms. This RSI approach to PRO development is described as almost the same approach as that used by the PRO secretariat in the national workshops I participated in. However, there are also differences between the initial and subsequent workshop formats, as the approach used by the PRO secretariat additionally entailed separate patient workshops and a broader variety of participants (PRO secretariat and workshops). The clinical workshops comprised a chairperson, one patient, a physician and a nurse from each of the five regions and representatives from RKKP and the Organization of Danish Medical Societies. The business case analysis conducted by PA Consulting was also discussed in these workshops. The participants found it questionable whether the use of PROs leads to economic gains, as the handling of PRO responses in clinical practice demands new and time-consuming workflows. In addition, according to the report, triage-based PRO systems lead to an over-representation of complex patients at the outpatient clinic, increasing the time required for a consultation. Therefore, according to the RSI workshop participants, the use of a PRO does not necessarily result in cost-savings but might enable more effective use and allocation of resources. In the three initial RSI workshops, PROs were portrayed as tools that might improve decision-making, SDM, patient–clinician dialogue and treatment [43]. Moreover, PROs as part of an algorithm-based triage system were described as illustrated in Figure 6.

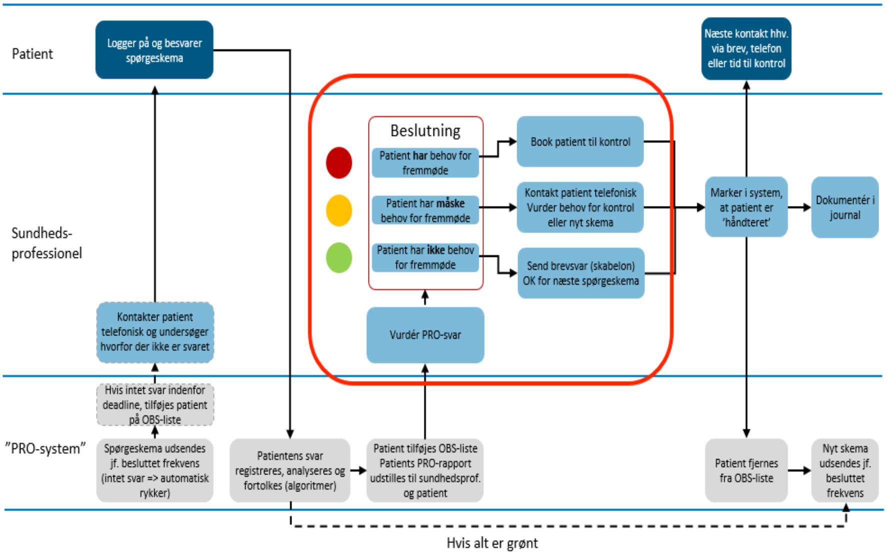

Figure 6. Example of an algorithm-based PRO triage system (visitation system) [43]

In other words, PROs might allow increased patient influence in patient–clinician consultations, improve the quality of healthcare interventions, ensure more efficient use of resources and improve patients' self-management. As indicated in this chapter, a PRO's functionality as a visitation tool is central in a Danish context, which is why this functionality is displayed in Figure 6. The idea with this functionality is to make sure that only patients in need are invited to patient–clinician consultations at outpatient clinics. In practice, there are different variations of the exact workflow; however, the figure explains the basic elements of the system. First, the patient receives digital PRO questionnaires for completion. Second, the patient completes the questionnaires. Third, algorithms are used to analyse and sort responses into green, yellow and red categories, based on the patients' health status. Fourth, *green patients* automatically skip consultation, *yellow patients* are further assessed through phone conversations with nurses and *red patients* are automatically invited to the outpatient clinic. Some *green patients* might still prefer to consult a physician, which is an option if required [43]. In the context of chronic diseases, this system is an iterative process.

EXPERIENCE WITH PRO IN CLINICAL PRACTICE

As shown so far, there are several reasons why PROs might be an attractive tool in Danish healthcare on a political level and in clinical practice. Therefore, based on the selected scientific evidence, the known effects of using a PRO in clinical practice are presented in this section. Several of the Danish studies conducted within the area are outlined in the papers comprising the PhD project, which is why only a single case from Denmark is included here. The studies in this section are included, as they provide scientific background, and to some extent, justify the focus of the current PhD project. All the studies concerned the use of PROs as part of clinical practice.

In 2013, Chen et al. published *A systematic review of the impact of routine collection of patient-reported outcome measures on patients, providers and health organisations in an oncologic setting* [44], to elucidate the effects of routine use of PROs within cancer care. Based on 27 studies assessed on 12 outcome indicators, the review shows that the positive effects on patient-provider communication are the most common, as it occurred in 21 of the 27 studies. The PRO application showed strong or modest effects on monitoring of treatment (11 studies), detection of unrecognised problems (15 studies), patient management (13 studies) and patient satisfaction (13). Based on the strength of the empirical evidence provided by the included studies, Chen et al. concluded that PROs primarily affect patient-provider communication and patient satisfaction and secondarily facilitate the monitoring of treatment and identification of unrecognised problems [44].

In the systematic review in the paper *Patient-reported outcome use in oncology: A systematic review of the impact on patient-clinician communication* Yang et al. [45] examined how PROs influence patient–clinician communication when used in consultations with adult oncology patients. The systematic review indicated that the use of PROs increases awareness of symptoms and how often symptoms are discussed; helps patients recall and verbalise relevant symptoms and other complex issues and ensures that patients' and clinicians' understanding of symptoms are more aligned. In particular, patient care, treatment plans, emotional function and patients' health-related quality of life (HRQoL) are more frequently discussed due to PRO use. Thus, PROs facilitate an enhanced and more holistic understanding of patients' health conditions, leaving room for discussions on more complex issues while making conversations more effective. These are the outcomes of PRO usage that are promoted by clinicians' explicit and positive reference to PROs during consultation. When a PRO has no or low effects on communication, it is often due to either ceiling effects, indicating that the communication is already of high quality before the PRO intervention or clinicians' attitudes, as some of the clinicians refuse to use PROs because of scepticism targeting the validity of the instruments [45].

In the article *What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcomes in Cancer Care? A Systematic Review of Controlled Trials* Kotronoulas et al. [46] examined PROMs' effect on patient care as part of clinical practice. According to the authors, a necessary inquiry related to the costs of PROM collection needs to be justified in comparison to potential patient outcomes, health service outcomes and effects on processes of care; hence, the study aims to make this relation more transparent when PROMs are used in clinical trials. Statistically, the study findings are vague and the effect sizes are on the lower end. However, in clinical practice, the findings indicate that PROMs increase discussions on patient outcomes, supportive care measures, symptom control and patient satisfaction. Of the 24 studies included in the review, 21 concerned patient outcomes and 19 included processes of care, whereas the results on health service outcomes were inconclusive due to a lack of studies. The studies on patient outcomes indicated positive effects on physical symptoms through lower symptom prevalence (7 studies). QoL measures showed that the patients had fewer post-intervention effects (9 studies). The study did not identify effects on psychological symptoms (anxiety and depression), and results concerning supportive care were unclear due to inconsistent results. Findings on processes of care, in general, lacked statistical significance. However, the studies showed effects on medical decision treatment, referrals and advice; patient–physician consultations were more frequently patient outcome-based when scores revealed alarming health problems or when emotional, social or sexual problems were disclosed through PRO scores and patient satisfaction was, in general, positive in most studies (80%). Furthermore, 83% of patients considered the content of PROMs important, whereas 93% were supportive of questions regarding emotional well-being during patient–physician consultations. Conclusively, PROMs' effects on quality of care within clinical trials across chronic conditions are vague and lack statistical evidence. However, PROMs are best used to increase patient satisfaction concerning emotional and communicative issues and to elucidate patient outcome concerns during patient–physician consultation, subsequently enhancing patient satisfaction, symptom control and supportive care measures [46].

In 2014, Boyce et al. [47] scrutinised *The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research.* The review comprised 16 qualitative studies and was conducted based on former heterogeneous findings on PROMs' effects on quality of healthcare and patient care. The review findings showed that the increased workload on HCPs caused by PROMs is a focal barrier. Relevant enabler concerns improved guidelines on data collection and data interpretation, which should be combined with training and educative measures; referrals and treatments based on PRO answers; improved collegial collaboration and awareness of how PROMs affect HCPs' work burden unequally and transparent leadership recognising the extra work burden associated with the use of PROMs. Note that HCPs consider the role of technology as being double-sided; when functioning smoothly, it is perceived as a facilitator, and when it affects the collection and use of data negatively, it is perceived as a barrier. Therefore, the objectives for collection must be transparent and organisational and technical structures and support must be established and function properly. HCPs are generally satisfied with graphic presentations of PRO data but prefer detailed and clinically relevant feedback. Likewise, the validity and sensitivity of PRO data are other issues that are important to HCPs. PRO effects on patient care are multidimensional; on one hand, HCPs believe that PROs can enhance communication, patient education, joint decision-making, screening, monitoring, care planning and patient confidence, and on the other hand, PROs might have no impact and value in clinical practice or negative effects on clinical workflows, damaging the patient–clinician relation. Moreover, PROs might narrow the focus in the patient–clinician consultations, help manage patient expectations and make patients responsible for their health. According to Boyce et al., HCPs' attitudes on PRO, as examined in this study, are essential, as they determine the success of PROs in clinical practice; hence, it is relevant to identify sources of resistance and negative attitudes [47].

In *A systematic review of randomised controlled trials evaluating the use of patient-reported outcome measures (PROMs)*, Ishaque et al. [48] examined PROs' effects when applied in clinical practice. Based on 22 studies and 25 comparisons, the findings indicated that PROs have a positive effect and have value in clinical practice. However, further research providing stronger evidence is required. Important barriers/enablers concerning the use of PROs in clinical practice are valid and reliable measures, and enhanced training and education of patients and physicians are required to improve the interpretation of PRO data. The review revealed that PRO use significantly increases the inclusion of HRQoL issues in patient–clinician consultations and significantly improves patients' HRQoL and psychosocial health. Conversely, some of the included studies showed no evidence of the effect of PRO use, according to clinicians and/or in comparison to standard care. Ishaque et al. emphasised that the included studies are based on methods focusing on statistically significant results, which do not necessarily disclose whether the use of a PRO is clinically meaningful [48].

Philpot et al. [49] examined *Barriers and Benefits to the Use of Patient-Reported Outcome Measures in Routine Clinical Care: A Qualitative Study*. Through the use of semi-structured interviews and focus groups involving 10 patients, 8 providers and 11 administrators, the authors identified several barriers and benefits to the use of PROs. General challenges in PRO use include adequate infrastructure, time and resources, sufficient patient participation, how to integrate PROs in quality improvement work and how to avoid data misuse. The patients found the following barriers to be more or less equally important:

- The length of the PRO questionnaires: the surveys must not be too long.
- The complexity of the survey: the difficulty in reading and understanding the PRO questionnaires must be considered.
- PROs' influence on patient–provider consultations, directing attention to PRO data and reducing the interaction between the patients and HCPs.
- The structured format of PROs, making it difficult to raise concerns not contained in the questionnaires.
- Data security issues: who will have access to patients' personal health information?

According to the patients, the two most important benefits are PROs' ability to track disease progression and changes in symptoms over time and to enable providers to focus on the problems that matter the most to patients. The providers identify two main barriers that concern the number of resources required in the collection and processing of PRO data and providers' lack of use of PRO data in clinical practice. They highlight PROs' ability to improve the quality of care and monitor patients' disease progression and symptoms over time as relevant benefits. The administrators believe that two issues particularly function as barriers: patients' health literacy and the patient burden/fatigue caused by the use of PROs. According to them, PROs might enhance disease control, improve clinical outcomes and generate a standardisation of data and care, which are considered beneficial impacts of PROs on healthcare [49].

In 2015, Howell et al. [21] published the paper *Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors*. The aim was to examine the outcomes of the use of PROs in cancer clinical practice and describe relevant issues influencing the implementation of PROs within this context. The study found that PROs, in general, are useable in routine cancer clinical practice, as they are acceptable to patients. Positive outcomes linked to PRO use concern improved patient–clinician communication and earlier detection of symptoms. In detail, the review found that the use of PROs insignificantly improved patient satisfaction; improved the quality of care to a minor degree; significantly improved patient outcomes in one study and had a non-significant effect in four other studies; improved symptom management and self-management; strengthened patient–clinician communication by ensuring increased awareness of emotional functioning, HRQoL and other sensitive issues and enabled better detection and monitoring of symptoms and potentially improved clinical decision-making. The authors underscored that the effect of PROs on patients' health outcomes is still quite unclear and requires further investigation. The study also identified barriers and enablers when implementing PROs. Enablers concerned high acceptability of PROs among HCPs and patients; adequate guidelines on the use of PRO in clinical practice; flagging systems indicating clinically relevant PRO scores in the short and long terms and a healthcare service based on service-user perspectives. The barriers included lack of time and training; uncertainty on the interpretation of PRO data; transparency concerning the value of PRO in clinical practice; liability issues in cases in which PRO data are reported between visits; the intrusive nature of PROs and the cultural clash with current healthcare it entails; the length and complexity of PROs and patients' ability to handle the technical systems mediating PROs. Moreover, PRO tools used across healthcare providers need to be standardised and used systematically to generate quality improvements within cancer care [21].

In 2016, the Danish Cancer Society published a report named *Klinisk anvendelse af Patient Reported Outcome Measures (PROM) – evalueringsrapport* [50] (Use of Patient-Reported Outcome Measures (PROMs) in clinical practice—an evaluation report), focusing on PROs' potential in routine use in clinical cancer care. In this project, PROs were used as dialogue tools for lung and prostate cancer and as a visitation tool within prostate cancer. The results indicated that in the implementation phase, it is important to:

- Have a visible leadership, who makes the purpose of PRO clear, motivates HCPs, ensures that attitudes towards PRO and patient participation are positive and support the project with adequate resources.
- Have dedicated project managers, who motivate colleagues, function as role models and manage the project.
- Have HCPs, who take ownership and responsibility of the project, divide new tasks and responsibility reasonably among themselves and perceive PROs as clinically meaningful.
- Ensure that the IT infrastructure is adapted to the routine use of PROs.

The economic effect when using a PRO as a visitation tool is uncertain; however, the implementation of PROs means that nurses take over some of the tasks formerly handled by physicians. For example, when patients are allowed to skip consultations, they will only be in contact with a nurse who handles the assessment of and contact with the patient. In general, the electronic distribution method in the project was acceptable to patients, even though completion at the site was problematic due to technical problems. Hence, patients typically preferred to answer the PRO questionnaire at home. In this context, the main barriers concerning non-response were HCPs' lack of trust in patients' ability to complete the PRO questionnaire and the agility of the PRO system when used by HCPs. When used as a dialogue tool, a PRO

- Provides an overview of patients' health status, QoL and disease progression over time.
- Enhances the focus on patients' primary problems.
- Enables the patients to open up and discuss sensitive topics.
- Supports HCPs in decision-making and patient management.
- Improves communication and patient participation.
- Prepares patients before the consultation and functions as a memo during the consultation.
- Offers patients an improved understanding of their health and makes them more active in handling their course of treatment.
- Facilitates health-related talks between patients and relatives.

As a visitation tool, the use of PROs

- Increases nurses' job satisfaction due to the new tasks.
- Improves the quality of nursing care.
- Results in more effective courses of treatment.
- Allows patients to skip unnecessary consultations and spend less time on transportation and waiting at the hospital.

When a PRO is used as a dialogue tool, one problem is how time-consuming the implementation process and technical issues are. Even though participants, in general, are satisfied, patients and clinicians indicate that the questionnaire used as a dialogue tool should be more specific and require improvements. When used as a visitation tool, the allocated resources do not match the time required for tasks appointed to the nurses; hence, the work with PROs is considered as too time-consuming. Subsequently, inadvertent actions and delays in patient pathways are potential risks. The limited representation of patients' disease situations, which a PRO displays, is also problematic as relevant problems are potentially overlooked and neglected. Patients point out that HCPs' lack of use of PRO data during consultations is a problem that negatively affects PROs' potential to increase patient participation. The purposes of PROs also need to be clearer to the patients. Patients appreciate how PROs function as a starting point in the consultation, how they prepare patients before consultations, PROs' potential to focus on the problems that matter the most to the patient and the questionnaires' educative potential [50].

RESEARCH QUESTIONS

As shown above, PROs are spreading horizontally and vertically across different sectors, organisational levels and disease areas in Denmark, increasing their use in clinical practice. This is a development linked to the digitalisation of PROs and the inherent belief that PROs might enhance patient participation. Hence, the present PhD project focuses on digitalised PROs in clinical practice, analysed from a patient participatory perspective. Specifically, the following research questions are scrutinized in this PhD project:

- How are PROs and patient participation associated?
- How do experts in a Danish context perceive PROs?
- What are the functionalities of a PRO?
- What are the purposes of a PRO?
- What elements constitute a PRO in clinical practice?
- How do newly diagnosed citizens with type 2 diabetes experience and perceive PROs when applied in practice in a municipal setting?

In Table 1 the research questions are displayed and linked to the four overall subjects and the research papers constituting the PhD project.

Table 1. Subjects, research questions and papers

Subjects	Research questions	Papers
1: The association between PROs and patient participation	How are PROs and patient participation associated?	*Paper I: The association between patient-reported outcomes (PROs) and patient participation in chronic care—A scoping review* [1].
2: The purpose and functionality of PROs	How do experts in a Danish context perceive PROs?	*Paper II: Experts' Perception of Patient-Reported Outcomes (PROs) in a Danish Context* [2].
	What are the functionalities of a PRO?	*Paper III: The Digital Transformation of Patient-Reported Outcomes' (PROs) Functionality within Healthcare* [3] .
	What are the purposes of a PRO?	*Paper IV: The purpose of Patient-Reported Outcome (PRO) post its digitalization and integration into clinical practice: A redefinition resembling PROs theoretical and practical evolvement* [4].
3: *PRO Elements* – a concept map of the elements constituting a PRO	What elements constitute a PRO in clinical practice?	*Paper V: Exploring, describing, and mapping the constitutive elements of Patient-Reported Outcomes (PROs) for use in clinical practice* [5].
4: Citizens' perspectives on and experiences with PROs	How do newly diagnosed citizens with type 2 diabetes experience and perceive PROs when applied in practice in a municipal setting?	*Paper VI: The Experience of Citizens with Newly Diagnosed Type 2 Diabetes with the use of Patient-Reported Outcomes (PROs) in a Municipal setting* [6].

As shown in Table 1, first, the connection between PROs and patient participation is scrutinised through a comprehensive scoping review. Second, the purpose and functionality of PROs are studied through the application of various methods, resulting in the reconceptualisation of PRO. Third, the elements constituting a PRO in clinical practice are identified and comprised in a concept map. Fourth, qualitative methods are used to uncover how newly diagnosed citizens with type 2 diabetes experience and perceive PROs when applied in practice. Patient participation, empowerment and recognition act as key concepts throughout the project.

CHAPTER 2. SCIENTIFIC APPROACH

What I'm looking at is only a shell. What's most important is invisible…

Antoine de Saint-Exupéry

The scientific position in this PhD project is characterised by its eclectic nature, meaning that the approach in the PhD project is best described through the combination of various scientific positions. This is a strategy used as each scientific position highlights and explains different features relevant in the present PhD project. Hence, the scientific foundation is based on phenomenology, hermeneutics, pragmatism, post-phenomenology and critical theory. These scientific positions are included as they enable me to answer the research questions from different perspectives. In the following section, the basics and relevance of each scientific position are presented.

2.1.1. PHENOMENOLOGY

The phenomenological approach is included in the present PhD project due to the useful concepts in qualitative science and because a focal aim has been to disclose PROs' purposes, functionalities and the elements that constitute a PRO in clinical practice, which are aligned with or closely connected to the essences of PROs. Edmund Husserl (1859–1938) is portrayed as the father of phenomenology [51], which is why the following description of phenomenology is based on his thoughts. Phenomenology concerns how we as humans perceive the phenomena outside our consciousness [52]; put differently, it concerns how a phenomenon appears to our consciousness [51]. Therefore, 'phenomenology aims to attain the eidetic and originary meanings of a phenomenon' [53, p. 2], to disclose how a phenomenon appears on its own [51]. Hence, phenomenology concerns *the teaching of what appears* [51]. Humans are active influencers of the world and not just passively sensing creatures [51]. This entails that the phenomenon is part of a whole, *the life world*, which provides meaning to the phenomenon; that the subject is a prerequisite for the phenomenon to appear and that the consciousness and body influence humans' ontological positions. In this context, *intentionality* is a focal concept in phenomenology, which concerns the idea that human consciousness is always is directed towards something [52]. The intentionality is directed towards various phenomena, hence the name phenomenology [51]. What is of interest in phenomenology is not merely what appears to the eye but how it appears and how the phenomenon is experienced and interpreted by the subject [52]. The purpose is to understand the world through human experience [51], which is why phenomenology is relevant in the studies on citizens and experts' experiences with and perceptions of PRO (Papers II and VI) [2,6]. The concept *horizon* is also important as it describes how an individual's consciousness and position make the experience of the phenomenon meaningful as part of a whole [52]. Hence, it is reasonable to claim that the *horizon* opens up and delimits an individual's perception and knowledge of the world. In a research context, it is important to understand the background of the participants and the researcher. Hence, parts of the research process, background and context are described in the current dissertation, allowing readers to grasp the aspects of the *horizon* on which the interpretations and conclusions are based. Another concept, the *lifeworld*, refers to the world or reality, which exists independent of perception or knowledge. According to phenomenology, the perception of a phenomenon is an individual matter based on a person's feelings, thoughts and wishes [51]. Therefore, when describing a phenomenon, concrete examples based on lived experiences and anecdotes are useful in providing a specific and detailed understanding of the phenomenon [53]. This is why qualitative and ethnographic methods that elicit the participants' perception and experience of PROs are applied in the PhD project. A phenomenon can be experience-based or categorical, which means that a phenomenon can appear through the senses or thinking. Moreover, a phenomenon can appear and be perceived in various shades or essences [52]. Hence, to understand the true essence of a phenomenon as thoroughly as possible, one should aim to uncover a magnitude of shades and essences of the phenomenon [51]. This explains why the understanding of a PRO in the present PhD project is based on a combination of methods: fieldwork, literature studies, interviews and observations, which is an approach providing a broader understanding of the essence of PROs. The ideal in phenomenology is to uncover and comprehend all essences or types of shades that the phenomenon appears in, resulting in an *evident* or *adequate* perception of the phenomenon [52]. It is a state in which the phenomenon as such and its perception become identical, which means that the true nature of the phenomenon in question has been discovered [52]. To get closer to this level of perception of PRO, additional inquiries complementing the studies comprising the current PhD are required. Another point in phenomenology is that scientists do not create new knowledge through interpretation but simply discovering and disclosing meanings and essences that already exist in the world; thus, it is the scientist's job to make them visible [51]. Husserl explained that one needs to look at a *thing-in-itself*, what is the essential aspect of the phenomenon. This process is referred to as *reduction*, in which the form of the phenomenon in all its complexity is experienced by the observer in an unprejudiced and intuitive manner and then reduced to a basic and essential idea of the phenomenon [51,52]. Thus, the ideas embedded in phenomenology have been useful both in the studies on PROs' purposes, functionalities and the elements that constitute a PRO in clinical practice [3–5] and when disclosing citizens' and experts' perceptions of PRO [2,6] .

2.1.2. HERMENEUTICS

The ontological and epistemological stance on which hermeneutics are based is useful in the current project as it makes it clear that the findings are based on my interpretations of the world and the empirical material, explaining how the study results have been generated. Within this approach, the ontology prescribes that the world is experienced through texts (e.g. documents, writings and laws), or in specific contexts through social and intersubjective relations, whereas the epistemological position means that the knowledge and understanding are based on human interpretation [52,54]. This means that the hermeneutic approach recognises the subjective and intersubjective nature of knowledge production. This is a distinctive feature-separating phenomenology from hermeneutics; hence, the question is whether the researcher should strive for an objective distance to the phenomenon and deliberately try to contain their pre-understanding, or whether the researcher's influence on the conducted research should be acknowledged and their pre-understanding should be transparent [51]. Additionally, the context (e.g. historical, social, cultural, political and economic circumstances) in which a study has been conducted should be considered [52,55]. In the present PhD project, the latter approach is chosen, which indicates why the descriptions of background, context and concepts are prioritised. The hermeneutic approach is useful in the present PhD project as PROs have been studied through the literature and document analyses and by disclosing citizens' and experts' perceptions of PROs. Therefore, hermeneutics is a natural choice that enables knowledge creation in collaboration with the participants and through interpretations of the included text materials. By acknowledging the subjective nature of science, hermeneutics accept that scientists, to some extent, shape data, making transparency essential [54,55]. Transparency allows others to follow and understand how data, coding and scientists' pre-understanding shape the whole research process and findings [56]. Therefore, the hermeneutical research process is affected by the researcher's subjectivity, which is an ever-changing element that should not be neutralised, but instead used actively and iteratively to constantly produce new knowledge [57]. In other words, there is a dialectic back-and-forth loop between the part and the whole, making the research process and the researcher's knowledge acquisition and evolvement more transparent, a process referred to as *the hermeneutic circle* [52]. This is a process ideally resulting in an enhanced understanding of the phenomenon in question [52]. The back-and-forth relation characterising the hermeneutic circle describes the research process in the present PhD project quite well and aligns with the typical explorative approach in qualitative and ethnographic studies. Thus, knowledge accumulation and creation in the present PhD study can be described as a continuously evolving process in which constant new knowledge has affected the research process and my understanding of PROs. The combination of a scientist's pre-understanding and contextual matters is conceptualised as *horizon*, which is quite similar to the concepts used in phenomenology, as it indicates how 'far' or how 'much' the scientist can 'see'. Hence, once again, *horizon* is considered a framework delimiting the potential vision of the world from a particular vantage point [54]. New horizons are generated when different horizons clash, as it instigates dialogue and discussions; consequently, individuals' horizons evolve [57]. In this project, the actors' *horizon* is relevant when the *horizons* of the participating experts and citizens are taken into account and when considering the impact of the concept map introduced in Paper V [5] on stakeholders *horizons*. Hence, the hermeneutic approach is included as it helps describe the PhD project's research process and to explain how the study findings are partly based on my interpretations as a researcher; thus, I acknowledge that the data in this project are constructions established in a process that resembles *the hermeneutic circle.*

2.1.3. PRAGMATISM

Pragmatism is relevant in the present PhD project, as one of the aims in this project is to produce knowledge useful to the stakeholders working with PROs, which is an intention that aligns with the pragmatic tradition. Pragmatism as a scientific approach, promoted by John Dewey and James Peirce, accentuates the importance of *action* when trying to grasp the connection among reality, science and knowledge. As a pragmatist, you are a resource and a pragmatic problem-solver of scientific and practical problems, facilitating the survival of humanity. Hence, it is a more active and action-oriented role, compared to scientific approaches in which observation and a distant position to the world are mandatory. This action-oriented engagement means that inquiries shape the subject field, and the subject field influences the inquiry. Pragmatists believe that problems and their solutions are embedded in reality, which explains their epistemological position, best described as *learn by doing*, underscoring that knowledge and learning are created and accumulated through practical experience. The abductive approach in which the aim is to come up with scientifically best explanations is typically used in pragmatism. In practice, working abductively means that the scientist makes a qualified guess to explain a phenomenon, generating tentative explanations and hypotheses that are then tested. Therefore, this approach implies that the formulation and occurrence of a problem are followed by a tentative explanation. The aim is not necessarily to find the truth but to solve real-world problems through rational, systematic and scientific inquiries, subsequently contributing to the progression of society and humanity. The implication is that inquiries and experiments should be related to reality, and it is the consequences of the scientific findings for real-world issues that matter. In this context, reality is what the scientific society agrees to be true in the long term. Consequently, valuable and valid knowledge is generated through competition and clashes with other ideas, where the winning idea/opinion is perceived as *knowledge*. This implies that a specific version of reality and knowledge will spread and constitute the most common understanding in society. The idea is that freedom of research functions as a means to ensure that the best scientific ideas prevail over inferior ideas and are recognised as *knowledge*. Hence, this perception of knowledge production aligns with the abductive research process in which the *best possible explanations* are accepted as knowledge. Rationality and pragmatism are closely linked. In the pragmatic approach, the interpretation of rationality is based on Weber's means-end rationality and instrumental rationality, meaning that different actions are considered in the pursuit of a specific outcome, where the most adequate and efficient mean is preferable. As a result, pragmatism entails a radically different interpretation of scientific validity compared to the traditional truth-seeking approaches. In pragmatism, the scientific value of an inquiry is assessed by comparing the required actions and subsequent consequences in practice. Hence, the best possible explanations while considering this trade-off are useful science. In other words, it is the degree of utility that an action or inquiry provides to the individual, society and humanity, which validates the value of a scientific study [52]. An approach to science embedded in Dewey's concept *warrants assertibility*, which emphasises the elusive and temporary character of *knowledge*; thus, knowledge does not need to be *true* but merely *assertable*, based on a thorough inquiry [58]. What matters is that findings are based on rational and systematic scientific studies; subsequently, theories are used to explain the implication of the scientific findings [52]. Importantly, the Aalborg University Strategy for 2016–2021 is called *Knowledge for the World*, a title accentuating the substance of the report, according to which the work conducted at AAU is supposed to have a societal impact [59]. Hence, pragmatism is an integrated part of the scientific approach at AAU, another reason why the pragmatic position is relevant in the present PhD project. Thus, a focal aim in this PhD project is to generate knowledge useable in clinical practice, applicable to problem-solving issues in real-life settings. Accordingly, the value of the scientific knowledge produced in the current project should be assessed and validated within pragmatic reasoning.

2.1.4. POST-PHENOMENOLOGY

The studies conducted in the PhD project are not rooted in post-phenomenological tradition. The reason why this scientific approach is briefly introduced is that the discussion on a PRO as technology is linked to post-phenomenological issues. Moreover, the ideas constituting post-phenomenology are closely aligned with techno-anthropological ideas; hence, it is a relevant branch of science considering my position as a researcher and teacher at techno-anthropology and participation (TAPAR). Don Ihde explained post-phenomenology as a merge between pragmatism and phenomenology mixed with technoscience, an approach perceiving science as embedded in and enabled and shaped by technology [60,61]. The advantage of the philosophy of technology is that it enables the analyses of technology relation and impact on social and cultural factors through contextual embedded and concrete empirical studies; hence, post-phenomenology provides a theoretical foundation that allows the scrutiny of technology in practice. Post-phenomenology concerns the relations between humans and technology where a focal assumption is that technology is not a neutral instrument merely used by humans. Humans and technology shape each other, determining the form of human life and the world, an inter-relational ontology embedded in human praxis. To determine the character of these relations, how technology and humans affect each other in practice, contextual investigations and analyses based on theories and concepts embedded in the post-phenomenological tradition are required. Note that technology is multistable, which indicates how technology takes shape and is used in different contexts, especially influenced by cultural elements [60,61]. Hence, the relevance of Don Ihde's elaboration of how technologies shape the lifeworld indicates that different worlds take shape through the use of technologies. This is a focus area in techno-anthropology (TAN) as well, where ethnographic methods are applied to achieve an authentic understanding of a specific technology in context and its interplay with humans in practice [62]. The aim is to generate tangible and useful interdisciplinary solutions in praxis and on a societal level. Thus, it is a useful approach in cases in which discrepancies related to a particular technology exist among professions, users, cultures and stakeholders, or when the consequences linked to the use of a certain technology are unknown [63]. In the present PhD project, the post-phenomenological approach is relevant in the discussion on the findings when considering a PRO as a technology. The conducted studies were based on qualitative and ethnographic methods and some were conducted under practical settings; hence, even though there are differences in focus and intentionality, the approach adopted in this project is aligned with the ideas constituting post-phenomenology and TAN.

2.1.5. CRITICAL THEORY

The dissertation includes various critical approaches used to discuss the findings of the PhD project. A stance included to ensure that the results are considered in a critical light forms an essential aspect of this research. The critical tradition is formed by several philosophers and scientists, making it difficult to provide a general overview; nonetheless, a short introduction to some of the main points is made here. According to the critical tradition scepticism, critical reflection is necessary when conducting science, as it makes the implications of the findings transparent and thereby legitimises the study findings. The point is that science, somewhat inevitable, is affected by researchers' normative standpoint, even in cases where researchers strive for objectivity and neutrality. Consequently, the truths and insights disclosed by science are conditional and contingent. The critical tradition has had as a purpose to counter some of the injustices and inequalities on a societal level, caused by technical and economic structures, implying an ontology based on social classes. The aim is to emancipate citizens from the oppressing structures and to positively affect the common good [52]. The present PhD project is influenced by the critical approach as it assesses PROs' capabilities and value in connection with patient participation. An intended normativity, as a PRO's ability to include/exclude groups of patients, especially the most vulnerable ones, is pivotal as these are most dependent on and in need of the healthcare system. Therefore, the association between PROs and patient participation is critically examined and assessed. The findings enable an improved understanding of who might benefit from a technology like PRO. In the dissertation, the critical approach is represented by Axel Honneth's theory on recognition [64]. Additionally, a PRO is discussed in connection with health inequity based on relevant insights obtained from Vallgårda [65]. The focal position of the empowerment concept, which stems from the critical tradition, also exemplifies the integration of this approach in the present PhD project. Thus, the critical approach is in different ways part of the PhD project.

In summary, each scientific approach is included in the phD project for different reasons and has influenced its character in various ways. Therefore, the scientific approaches are considered complementary, making an eclectic approach relevant and useful.

CHAPTER 3. METHODS AND RESEARCH PROCESS

...as designers and users of models methods and artefacts, i.e. technology, we have to meet the world and get acquainted with use, environment and tradition in the context.

Lars Botin

This chapter concerns the methods and research design applied in the PhD study, revealing the type of knowledge that the PhD project has been able to produce. Several of the methods are already described in the research papers constituting the PhD project; this chapter mainly focuses on issues related to the fieldwork and methodological implications not already explained in the research papers. Hence, this chapter covers two elements of the PhD project: the initial research process describing the conducted fieldwork, which strengthened my pre-understanding of the area, and the methods applied when conducting the six studies. The application of various methods and analytical approaches was continuously reconsidered throughout the research process. Hence, the research process and continuous knowledge acquisition reflect how the hermeneutic approach and the back-and-forth in the hermeneutic circle have been at play. In addition to research, several other activities were carried out during the PhD project, such as teaching, supervising, PhD courses and dissemination of the research results through participation in conferences and seminars. Even though these activities affected my development as a researcher, this chapter focuses on the applied methods and research design.

3.1.1. ETHNOGRAPHIC AND QUALITATIVE APPROACH

The studies conducted in the PhD project are based on a qualitative and ethnographic research design. Ethnography has no standard definition but concerns ‘first-hand empirical investigation and the theoretical and comparative interpretation of social organization and culture’ [66, p. 1], which in practice means that the researcher examines the study subjects and human practice over a period under natural settings within a specific field. According to Hammersley and Atkinson, the purpose of ethnographic research is simply to produce valid knowledge, which preferably challenges the status quo [66]. This is an interpretation of the purpose of science, which, to some extent, resembles the pragmatic approach. The characteristics of an ethnographic approach are as follows:

- The data are relatively unstructured.
- Analytical categories emerge during the research process.
- Knowledge is generated based on a few cases scrutinised in-depth.
- The generated knowledge is affected by the researcher conducting the study [66].

Hence, considering these methodological points and the scientific approaches applied in this project, there is a deliberate link between the two. What distinguishes ethnographic research from everyday life experiences and interactions is the reflective and systematic manner in which observations and interactions are conducted. When conducting ethnographic research, a pre-developed programmed approach is not an option; one needs to be ready to handle unexpected matters and adopt the research design accordingly. Therefore, initial and research problems are constantly changeable [66], a description resembling experiences in this PhD project. For example, an initial aim was to describe and analyse how citizens use PRO data as part of their daily lives; however, as data were not accessible to the citizens, such an inquiry was not an option. Consequently, other PRO-related research topics had to be considered, involving the formulation and reformulation of various research questions, which seems to be a common experience as a qualitative researcher [66]. Hammersley and Atkinson explained that ‘most ethnographic research, however, has been concerned with producing descriptions and explanations of particular phenomena, or with developing theories, rather than with testing existing hypotheses’ [66, p. 21]. This is a reason why an ethnographic approach is applied in this project, which scrutinises the phenomenon of a PRO and its association with patient participation and experts’ and citizens’ perceptions of a PRO. The methods applied in the current PhD project were fieldwork, participant observation, semi-structured interviews, scoping review and document analysis, which were chosen because of their ability to elucidate the research questions. The objectives of the PhD project were to achieve a deeper understanding of what constitutes PROs; their functionality and purpose; how a PRO is linked to patient participation and to study patients’ experiences with a PRO in clinical practice. This is a focus that makes the use of qualitative methods and an idiographic approach useful, as this enables a deeper and more nuanced understanding of a phenomenon [67,68]. Karpatschof described the characteristics of the qualitative research approach in contrast to the quantitative approach, where focal features in the qualitative approach pertain to contextuality, specificity and totality. In other words, a qualitative research design enables the researcher to examine a subject in its context (contextuality), makes it possible to examine a specific subject within an area of similar subjects (specificity) and allows the researcher to study the elements constituting a subject (totality). Applied in the present research project, a PRO has been examined contextually through field studies, participant observation and semi-structured interviews; a particular PRO was scrutinised through participant observation and semi-structured interviews, and its totality was studied through a scoping review and document analyses. Hence, all three pillars that, according to Karpatschof, constitute qualitative research were in play in the present PhD project [67]. Table 2 shows how the different methods were used to scrutinise the specific research questions.

Table 2. Subjects, research questions and applied methods

Subjects	**Research questions**	**Applied Methods**
Improved pre-understanding of the field and PRO	What is a PRO? How is a PRO perceived and used in different settings? What issues are faced in the implementation and application of a PRO?	Fieldwork and participant observations
1: The association between PROs and patient participation	How are PROs and patient participation associated?	Scoping review
2: The purpose and functionality of PRO	How do experts in a Danish context perceive PROs?	Semi-structured interviews
	What are the purposes of PROs?	Document analysis
	What are the functionalities of PROs?	Document analysis
3: *PRO Elements* – a concept map of the elements constituting a PRO	What elements constitute a PRO in clinical practice?	Document analysis
4: Citizens' perspectives on and experiences with a PRO	How do citizens experience and perceive PROs when applied in practice in a municipal setting?	Semi-structured interviews and participant observation

3.1.2. FIELDWORK AND PARTICIPANT OBSERVATION

The concepts of fieldwork and participant observation are closely linked conceptually and, based on experiences from the PhD project, in practice, which is why fieldwork and participant observation are described together in this section.

Fieldwork

When conducting fieldwork, one is interested in facts, experiences, narratives, institutions and ideas constituting a specific part of the world. The knowledge produced is shaped by the researcher's interpretations and their theoretical interest and position in the field [69]. Hence, in the execution of field studies, the researcher affects the study objects to some degree [69,70]. The strength of a field study is that it allows for the scrutinisation of a phenomenon in a so-called natural environment or an authentic setting [66,69]. Wadel presented the advantage of fieldwork through the expression *the spirit of flexible inquiry* (also referred to as *runddans*), which explains how theory, method and data continuously affect each other and allow a more flexible approach to the study [70]. As Hammersley and Atkinson stated, ‘It is expected that the initial interests and questions that motivated the research will be refined, and perhaps even transformed, over the course of the research; and that this may take considerable amount of time’ [66, p. 3]. This description mirrors the research process in this PhD project, in which the research questions on PRO have evolved throughout the process. Therefore, this approach requires considerable time and effort when analysing and processing data, which is an issue that needs to be and has been taken into account [66]. Although these results indicate that academic work always appears to take slightly longer than expected, a field study conducted in the real world is a complex matter requiring that the researcher has a specific focus. Hence, Hastrup indicated that knowledge is reductive and selective as the researcher in the field reduces and selects specific findings in the organisation of the acquired information [69], a point aligned with the phenomenological concept of intentionality. Hastrup distinguished between *felten* and *feltet*, which can be translated into *the narrow field* and *the broad field* in English. Essentially, the narrow field is a specific place or context, and the broad field is the entire field—all of which constitute the field [69]. In the present PhD project, there was a reciprocity connection between the two, as the *narrow field* was used to comprehend the *broad field*, and *the broad field* was used to obtain a better understanding of the *narrow field*. In other words, the engagement in different contexts and practices provided me with an improved praxis near PRO understanding, complementing the knowledge obtained through the scoping review and the document analyses, and vice versa. These scientific studies enabled me to better grasp the issues and challenges concerning PROs under local settings. This is an iterative process continuously leading to reinterpretations of the subject field [69], resembling the hermeneutic approach applied in the PhD project. Hastrup explained that the strength and validity of the knowledge produced through fieldwork stem from the participation and presence of the researcher in the situation experiencing the subject field in real life. Therefore, the researcher’s experience of tacit knowledge and actions in the field, combined with the subjects’ thinking, is what makes the knowledge generated through fieldwork useful and valid [69]. This is an approach mirroring the methodological approach in the current project, which enabled an enhanced understanding of PROs. Hastrup accentuated the value of moving between different areas of the field, as it allows the researcher to incorporate various perspectives [69]. In addition, this strategy was used in this PhD project, where fieldwork was deliberately conducted on different organisational levels and in different settings to achieve a multifaceted understanding of PROs.

Participant observation

Participant observation is part of the fieldwork and has been used in studying citizens’ experiences with PROs [6]. According to Szulevicz, participant observation refers to a situation in which a researcher observes an environment and engages somewhat socially with the humans and the field. Participant observation is particularly useful when we are interested in human experiences and different dimensions of social life [71]. Hence, the reason behind the use of patient participation in the present PhD project to scrutinise citizens' and experts' experiences with and perception of PROs. In Szulevicz's argumentation on the utility of patient participation, they referred to the following six points formulated by Bernard [71], according to which patient participation is useful because it

a) Opens up the field, allowing the researcher to attain insider knowledge.
b) Creates a relation with the observed actors in the field.
c) Enables the researcher to ask *the right questions* based on an enhanced understanding of the norms and culture.
d) Ensures that the researcher has an improved understanding of the data.
e) Allows the inclusion of empirical data that are inaccessible through other methods, giving the research an improved understanding of the problem at stake.
f) Makes it possible to create thick descriptions of praxis [71].

These points underscore the utility of the fieldwork and the participant observations conducted in the PhD project. Thus, the fieldwork and participant observation in various contexts provided me with insider knowledge of PRO and the knowledge unattainable through the conducted interviews, enhancing and extending my network. These were valuable experiences and knowledge to be used when preparing, conducting and analysing empirical data from the six conducted studies. A general challenge when using participant observation is the amount of time it requires [71]. However, in this PhD project, participant observation was limited by the specific contexts and situations in which it occurred. For example, in the study on citizens' experience of PROs, a short-term ethnographic approach was applied, meaning that the participant observation only occurred during the citizen–HCP consultation [6]. However, participant observation mainly functioned as a method to attain an improved understanding of PROs in various contexts to improve my pre-understanding before conducting the studies linked to the research questions. Thus, continuous engagement, over 2–3 years, on regional and hospital levels allowed me to stay in touch with the actors and networks working with PROs daily. Spradley's theoretical framework, which divides participant observations into the categories of *non-participation*, *passive*, *moderate*, *active* and *complete* [72], is another way of describing the participant observations conducted in the present study. The participant observations exercised during the national PRO development workshops are best described as moderate. *Moderate* is a position at which the researcher switches between being an insider and an outsider and participates moderately [72]. The primary task during the workshops was to listen to presentations and discussions and to observe without interfering. However, in the patient workshops, I was more involved and was, at times, delegated the role of the moderator. In both patient and clinical workshops, the participants were curious about my research project; hence, during lunch breaks, I engaged in several interesting conversations with them. The experiences from the hospital and regional levels were less systematically collected, as access to these forums relied on mutual trust and openness. Hence, notes were not taken during these meetings; instead, I actively engaged in conversations as a group member. Therefore, my role in these meetings can be best categorised as a*ctive*. According to Spradley, *active* participation is a situation in which the researcher participates in activities on equal terms as the study objects [72]. In both contexts, I started to participate incrementally in the meetings as a regular group member. This was a role undertaken in a respectful and relatively passive manner, as I wished to not influence the ongoing work in these settings too much. My role was not to influence processes in practice but to observe, learn and contribute when it seemed appropriate. The type of participant observation conducted during the study at the Center for Diabetes (CfD) is described in Paper VI [6] and is therefore omitted here.

Relation to the field and roles

The different fields on national, regional, municipal and hospital levels had commonalities, as they all are integrated parts of the healthcare system, meaning that certain values supporting the importance of evidence-based knowledge and economically efficient solutions were present in all settings. The different positions, responsibilities and tasks that were handled in the various settings and differences organisationally, in norms and cultural rules, made me aware of my role as a *stranger*. It was clear that I came from a different scientific environment; consequently, even though I had acquired a reasonable amount of scientific knowledge on PROs, a humble and reflective attitude was required to acknowledge and respect the complexity and uniqueness of the PRO matters being discussed in each context. This was a deliberate role I undertook, as it is important to consider the sort of impression one wishes to make in the field [66], which in this case was a kind, serious and humble impression. In other words, my knowledge of the norms, organisation, individual stakes, etc. was limited, meaning that my role as an *apprentice* and a *stranger* was most appropriate [66,70]. This was the position undertaken, as my impact on the processes in the different contexts should be as marginal as possible. This strategy was sometimes difficult to follow, for example, in situations where I possessed knowledge contradicting what was discussed and/or decided in a specific setting. Nonetheless, I remained passive in most cases, as my primary role was that of a researcher. Later on in the process, when my work and aim as a researcher were understood and acknowledged in some of the settings, I was, to a minor degree, involved as an advisor as well. This is a common development of the researcher's role during the fieldwork [70]. Thus, I had to be constantly aware of my role and position as a researcher. In this context, a known pitfall occurs if the researcher *goes native*, indicating that the researcher identifies too strongly with the field and the actors observed, making it challenging to produce valid interpretations that are not too heavily influenced by personal matters [71]. In contrast, a deeper relation might also be advantageous, as complete dedication and integration into the field allow the researcher to achieve a more authentic understanding of the field [71]. In this endeavour, my personal characteristics had to be considered as they might be relevant factors when conducting fieldwork [66]. During the national workshops, several participants were represented, and I undertook a *passive* role, meaning that the issues of personal characteristics were less important in this setting. On a regional level, the group I was part of exclusively consisted of women who had many years of experience within healthcare. Hence, I differentiated, in most cases, among gender, education and age, which was another reason why a *passive* role seemed most appropriate. The VBS PRO-DIA group was mainly composed of HCPs, women and men, doctors and nurses. In this setting, I was considered a techno-anthropologist whose role was to conduct techno-anthropological studies. Hence, there was an explicit difference between me and the rest of the participants concerning the approach to and perception of research and science. This was an educational experience as I understood how a PRO was perceived in this context and improved my knowledge of the types of methods and studies prioritised in this environment. When healthcare matters were discussed, I stayed passive and only contributed through my knowledge of PROs when relevant. Hence, in my experience, having a background in political science and pursuing a PhD within TAN is not a very strong position when working in the healthcare area. I am not an HCP, who normally is the one working with a PRO; my educational background is political science, hence a bureaucrat, which does not seem to be a particularly popular profession in this field. However, over time, as our relations became stronger and they got to know me better, this became an inferior matter in each setting. In particular, the good relation with *key informants* positively affected my role and provided increased access. According to Wadel, when conducting fieldwork in a foreign culture, one needs to try and abstract from one's cultural perceptions and be aware of how social constructions constitute the field of engagement [70]. However, as the researcher participates in a setting over a period, they gradually gain inside knowledge [66]. Hence, the continuous engagement in the different fields provided me with a deeper understanding of the topics being discussed, the underlying conditions and how PROs were perceived in specific contexts.

Handling of field notes

On one hand, if the researcher writes down field notes after participation in the field, it enables improved engagement in social activities in the field and ensures that the actors feel less observed (meaning that they act more naturally). On the other hand, the field notes taken during the engagement allow for more accurate and richer descriptions of the field [71]. In this regard, the findings are most valuable if the researcher prepares beforehand by writing down what might be of relevance; generalisations are advised against, while concrete and detailed descriptions of specific actions and situations are recommended [71]. Before participating in some of the first PRO development workshops on a national level, an observation guide containing potentially relevant categories was drafted beforehand, resembling the focus areas of the PhD project and my intentionality as a researcher. The notes taken were not thick descriptions of the social interactions but described various perceptions of PROs, as the aim of the participant observation in this context was to gain an improved understanding of PROs. In the other two settings, on hospital and regional levels, the purpose was largely the same, but the circumstances were different. There were fewer participants, relations were more intimate, observations occurred over a longer period and the issues discussed had a different value politically, professionally and practically, which in ethnographic terms is called *dangerous knowledge* [71]. This means that the groups had to feel assured that the matters being discussed stayed inside the group. For these reasons, notes were not taken during the meetings. Important information and considerations were noted afterwards and compared to the results obtained from the studies constituting the PhD project. In Hastrup's terms, in most of the fieldwork, I functioned as a participant instead of a reporter [69].

Ethical considerations

Maintaining a good relation with the actors engaged in the field has been a priority throughout the PhD project. Szulevicz emphasised that participants should not feel merely like research objects as the research project terminates [71], an issue deliberately focused on in the current project. The relation with the PRO secretariat and the PRO project group in the North Denmark Region has been and continues to be good, as indicated by my continuous contact with them, partly because of their investment and interest in my work. Hence, it is reasonable to consider it a mutually beneficial relation. On a hospital level, the relation with the VBS PRO-DIA group mostly had the character of a working agreement, a collaboration that unfortunately ended due to disagreements on scientific issues. Nonetheless, the relation ended on a friendly and professional note. Finally, my relation with the CfD was good, despite the scarce communication. The CfD provided me access and enabled me to conduct a study on patients' experience of PROs; therefore, a future presentation of the results at the CfD would be reasonable.

Access to the field

Getting access to the field can be a challenge [70]. It depends on gatekeepers and is something that needs to be continuously renegotiated and can take the form of a full-time occupation [66]. The fact that access to the field can be a challenge and requires substantial resources and time was a central experience in this PhD project. Access to the workshops hosted by the PRO secretariat was an unproblematic affair, as the SDS was invested in the PhD project as sponsors and therefore facilitated my access to the field. Sanne Jensen, whom I met at the beginning of March 2018 due to her leading role in the PRO secretariat, has functioned as an important gatekeeper. Throughout the PhD project, Sanne has been a great partner for discussions, especially on practical matters and regarding field access. The contact with the North Denmark Region was established not even a month into the PhD project, where Pernille Bertelsen and I met with Pernille Mejer Højholt, who introduced the regions' work on PRO. This initial meeting established continuous access to the quarterly project group meetings in the North Denmark Region held by the regional PRO project group, which are meetings I have been part of since the summer of 2018. During this process, Pernille Mejer Højholt got a new job, which meant that Stine Bangsted Lem Christensen and Vibeke Flytkjær took leadership of the group. Hereafter, Stine Bangsted Lem Christensen functioned as my primary gatekeeper on a regional level. The collaboration between Stine and the rest of the project group has been friendly, constructive and scientifically very useful throughout the PhD project. This was a professional forum where I had a chance to follow PRO development in the North Denmark Region and continuously challenge and validate the literature findings by comparing them with the practical experiences with PROs at this level. The project group could also benefit from my presence and knowledge, which sometimes happened when they were interested in scientific inputs on specific PRO issues. Access to both VBS PRO-DIA group and CfD could be achieved through my engagement in the national PRO development workshops on diabetes. Charlotte Glümer, who is in charge of the CfD, was appointed by the PRO secretariat as project manager for the PRO development workshops on diabetes. Hence, Charlotte Glümer and I met at the workshops, which probably made my access to the CfD a bit easier. The gatekeepers who coordinated my stay at the CfD were first Marie Papadaki and then Signe Hudtloff Nielsen, where particular efforts from the latter seemed to make a difference regarding my access to conduct studies at the CfD. Getting access was a long process because COVID-19 closed down Denmark the week before the initial studies were to be conducted, and the CfD was engaged in several other projects simultaneously; hence, to not overburden the employees at the CfD, the timing of my study had to be planned carefully. Thus, timewise contact was established during the national development workshops in 2018, a request to conduct the research study at the CfD was sent in the summer of 2019 and the studies were conducted at the end of 2020. At the PRO development workshops, contact with the leader of the VBS DIA-PRO group, Clinical Professor Niels Ejskjær, was initiated as well; he invited me to participate in their weekly meetings. This was a relevant opportunity as the VBS DIA-PRO group had developed substantial parts of the diabetes PRO questionnaire and the site was one of the few places where the PRO questionnaire was pilot-tested. Moreover, the stay allowed me to experience a very different research environment, which was relevant and interesting for me as a PhD student. Early in the process, I observed 10 patient–clinician consultations between Niels Ejskjær and citizens with diabetes, which gave me an impression of this practice without the use of PROs. Subsequently, I was supposed to observe PRO-based patient–clinician consultations. However, this never happened, and to this day, I am still not certain about the exact reason. What I do know is that this experience exemplified how access to the field can be troublesome. One answer to this question might come very close to the following quote by Hammersley and Atkinson: ‘the access negotiations can be construed as involving multiple views of what is profane and open to investigation vs what is sacred or taboo and closed to investigation...’ [66, p. 42]. The first meeting with Søren Skovlund, who was the acting PRO expert in the VBS PRO-DIA group, and Niels Ejskjær took place at the end of 2018, which resulted in several other meetings over the next half year. Right from the beginning, the aim of my PhD project was presented, and practical details were discussed. As the pilot tests conducted by the VBS PRO-DIA group at the AAUH concerned the PRO questionnaire developed on a national level hosted by the PRO Secretariat, a subunit under the SDS who sponsored my PhD project, I assumed that access to conduct my studies would be an unproblematic affair. Therefore, a bit into the process, my concerns regarded the design of my studies and not whether access would be a problem. However, the project leaders of the VBS PRO-DIA group insisted that the arrangement should take the form of a working agreement; hence, I was not allowed to conduct my studies without their interference. I accepted this demand, as a collaboration might produce valuable interdisciplinary research results. However, suddenly at the end of May 2019, I was contacted by Niels Ejskjær and Søren Skovlund, who wanted a meeting right away. I showed up the same day at the AAUH, where I was told that they were unable to see how my research project was relevant to them. This came as a shock and forced me to consider other locations for my studies. Therefore, I contacted Sanne Jensen, who in June 2019 helped me get in contact with Hans Jørgen Duckert Perrild from Bispebjerg Hospital and Charlotte Glümer from the CfD, who were both willing to help me out and provide access. The PRO questionnaire was also being pilot-tested at these sites, and I knew both gatekeepers from the national workshops. The challenge was that both institutions were located at the other end of the country, specifically in Copenhagen. In August 2019, I wrote to the project leaders of the VBS PRO-DIA group to thank them for our collaboration so far and to inform them that Bispebjerg Hospital and the CfD had allowed me to examine the PRO tool as part of their daily practices. Shortly after, Niels Ejskjær wrote a long and detailed email explaining that they were now very interested in my work and can grant me access. This put me in an awkward position because Bispebjerg Hospital had kindly granted me access, and now I was suddenly allowed to conduct my studies at AAUH as well, which is located in Aalborg in proximity to AAU. Even though this change of heart came as a surprise and caused some confusion, I chose to give it a chance, considering the geographical circumstances. Thereafter, I was regularly part of the meetings held in the VBS PRO-DIA group and participated in a workshop that was arranged by the group to assess temporary results from the sites that pilot-tested the national diabetes PRO questionnaire. Over the entire period, I participated in more than 40 arrangements with the VBS PRO-DIA group, another reason I assumed that access to conduct my studies, at least from this point onwards, would be unproblematic. Throughout the process, I provided, on demand, the project leaders with several study protocols, which, among other things, entailed a thorough description of the think-aloud method, which was never applied. I obtained an ethical approval of the research project from the Ethical Committee in the North Denmark Region, who afterwards explained that this was unnecessary due to the type of study. I drafted a detailed co-operation agreement as they required an official written agreement on the collaboration. All these efforts required considerable time and resources. I created the first draft of the co-operation agreement at the beginning of February 2020, just before the COVID-19 pandemic closed down Denmark during March 2020, which prevented access to patient–clinician consultations at AAUH. Half a year later, in the first half of September 2020, I received a response that did not respond to the initial draft but contained a completely new co-operation agreement. This agreement lacked some of the central points included in the first draft of the co-operation agreement, which is why the second version was forwarded to the contract unit at AAU, who are experts in such matters. In October 2020, the contract unit replied and suggested several revisions to the contract to ensure my freedom of research. This was a noticeable step backwards considering that the process at this point had been running for more than a year; hence, I was simply running out of time. Therefore, plans to conduct research at AAUH through the VBS PRO-DIA group were abandoned, and they were informed about it the same month. Thus, citizens' experiences with PROs when applied in clinical practice were only obtained at one site, the CfD, even though the plan was to examine patients at two different sites in two different contexts. This shows how difficult it can be to get access to the field, which I consider an important lesson learned as a researcher. As pointed out by Hammersley and Atkinson, one needs to consider

- Whether the initial research plan aligns with factors in the field.
- To what extent different ethical considerations are warranted.
- How transparent and detailed the research process needs to be to the site providing the access.
- Hanging about as it might provide further access (not in this case).
- How initial contact might be initiated in public settings influencing opportunities and research plans.
- The importance of helpful gatekeepers.
- Whether multiple gatekeepers might work counterproductive.
- How an organisation or a community strives to be presented in a favourable light.
- That the sponsors might be focal in the process of gaining access to the field.
- Whether hosts' expectations function as barriers or enablers [66].

These are all relevant considerations and potential reasons behind the success and failure in gaining access to the different fields in the present PhD project.

Description of the field

One of the locations where fieldwork was conducted was the national PRO development workshops on diabetes and cardiac rehabilitation, which are thoroughly described in the reports authored by the PRO secretariat [42]. Within each disease area, eight workshops were held, four *patient workshops*, comprising patients only, and four *clinical workshops*, comprising patients, clinicians, quality consultants, patient associations, regions, municipalities and state institutions. The locations of the workshops varied depending on their type and the disease area. The objective of the workshops was to create new PRO questionnaires, which, among others things, required that the purpose of the PRO and the integrated measures were identified and agreed upon [42]. I participated in six workshops, both in-patient and clinical. The meetings on a regional level took place at the locations where the participants were employed, which was either at one of the regional hospitals or the buildings of the North Denmark Region. The group comprised members representing different hospitals in the region and various disease areas. The group leaders were employed in administrative positions in the North Denmark Region. The meetings were held quarterly, took between 1.5 and 2 hours each and regarded how the spreading and implementation of PRO was progressing. Meetings in the VBS PRO-DIA group initially took place at AAUH; however, during the COVID-19 shutdown, meetings on a regional level and in the VBS PRO-DIA group were held online. Descriptions of the CfD are part of Paper VI [6] and therefore omitted here.

3.1.3. CASE STUDY

Hammersley and Atkinson explained that 'it is a matter of identifying the sorts of location that would be most appropriate for investigation of the research problem, as currently formulated' [66, p. 29], which is why fieldwork was conducted on various organisational levels in a Danish healthcare setting. As the aim was to attain an improved and broad understanding of PROs, engagement in different contexts was a deliberate strategy. However, case choices were not just based on rational decisions and my personal preferences; access also depended on the positions of the stakeholders and gatekeepers who were willing to help me. The scope of the fieldwork and the different locations meant that the time spent in each setting was limited, resembling a common trade-off between depth and breadth in ethnographic research, which is already elaborated upon slightly in this chapter. The fieldwork conducted in the different contexts was either in the form of meetings, consultations or workshops. These were limited by the people, context and time affecting the breadth of the inquiry, which are typical restraints when conducting an ethnographic study [66]. Nonetheless, the fieldwork that took place over a longer period enabled a deeper understanding of PROs in these contexts. The included cases where fieldwork was conducted were chosen due to their relevance to the scope of the PhD project; conversely, the scope of the research project was shaped by the knowledge obtained during the various fieldwork [66]. Thus, the engagement in the field initially concerned an improved understanding of PROs, which made me aware that various perceptions of PROs exist, subsequently turning this topic into a specific research area in the PhD project. Theoretically, the case considerations were well-described by Bent Flyvbjerg's thoughts [73], which help explain the type of PRO cases examined in project. Flyvbjerg pinpointed five typical misunderstandings in the work with case studies and concurrently introduced an overview of different types of cases. Accordingly, cases based on quantitative research strive for random case selection, while information-oriented selection is prioritised in qualitative research. The four case design strategies in qualitative research are extreme/deviant cases, which are unusual cases; maximum variation cases, which are similar in various areas and completely different in the area being compared; critical cases, which are representative in the sense that the results potentially apply to other cases and paradigmatic cases, which are rare and impactful cases representing a specific school [73]. The PhD study's interdisciplinary and TAN approach to PRO focusing on the purpose, functionality, constituting elements and association with patient participation stands in contrast to typical validation studies on PROs conducted by HCPs. Therefore, the PhD study in its entirety can be categorised as a paradigmatic case of digital PROs within clinical practice. The scoping review (Paper I) [1] and the document analyses (Papers III–V) [3–5] are classified as critical cases, as the results are considered applicable to similar cases where digital PROs are used as part of chronic care or clinical practice. This is a categorisation based on the extensive scientific studies on which the results and conclusions rest [1,3–5]. The semi-structured interview studies (Papers II and VI) are considered critical cases as well [2,6]. The findings of the expert interviews are based on inputs from key actors working on regional and national levels [2]; therefore, it is likely that their perceptions of PROs are applicable in these two contexts. The sixth study conducted at the CfD can either be classified as an extreme/deviant case, as it is conducted in a municipal setting, which deviates from a typical hospital setting, and because the participating citizens are newly diagnosed with type 2 diabetes, or as a critical case, as the inquiry takes place within diabetes, which is one of the most widespread chronic diseases in a Danish context [6].

3.1.4. SEMI-STRUCTURED INTERVIEWS

A semi-structured interview is an intersubjective and contextual method, meaning that knowledge is constructed socially between the participants within a specific context [74]. Hence, all interviews were conducted with openness towards the third-person viewpoint, ensuring that the empirical data constructed during the interviews were based on the participants' voices, knowledge and experiences. Tanggaard and Brinkmann explained that interviews are particularly useful when examining peoples' experiences and when trying to attain an improved understanding of a specific phenomenon [74]. Therefore, the use of semi-structured interviews in this PhD project was a logical choice as one study concerned Danish experts' perception of PRO [2] and another concerned citizens' experience with PROs [6]. The required number of participants depends on the specific project. However, Tanggaard and Brinkmann argued that less is more, meaning that fewer interviews analysed thoroughly are more valuable than several interviews scrutinised superficially, which might be an alternative if the amount of data becomes insurmountable. Ideally, interviewing stops when a saturation point is reached, indicating that further interviews will provide limited or no new knowledge [74]. These were considerations guiding the recruitment and interview processes in both interview studies. In the case of experts (Paper II), nine were interviewed, and the analysis was based on seven of the interviews [2]. However, experts in a niche area like PRO are naturally limited, and the participating experts were central actors in a Danish context, ensuring that the empirical data were relevant and deemed sufficient considering the purpose of the study [2]. In the study on newly diagnosed citizens' experience with PROs (Paper VI), 10 participants were interviewed [6]; even though there was an option to include more citizens, an initial analysis of the material indicated clear and similar patterns, making the inclusion of further informants less relevant. A solid interview project requires prepared interviewers who possess the knowledge needed to discuss the subject field with the informant, which potentially improves the transcription and analysis of the material as well [74]. Therefore, in the present PhD project, an extensive literature review was conducted on PROs during the period in which the expert interviews were conducted and before the interviews with the citizens. Additionally, the fieldwork on national and regional levels was initiated before the interview studies. Therefore, I possessed a reasonable amount of knowledge on PROs before the interviews with experts and citizens, which likely enhanced the quality of the conversations as it enabled me to comprehend the nuances in the informants' responses and respond with relevant follow-up questions. As recommended by Brinkmann and Tanggaard, an interview guide was created in both cases to structure the interview and ensure that the research questions were answered properly [74]. Moreover, as the quality of the empirical data depends on the interpersonal connection between the researcher and informant [74], general principles in conducting the interviews were followed in both instances. For example, it is focal that participants feel comfortable, safe, respected and genuinely and emphatically listened to, which is reflected by the character of the questions asked by the researcher [67,74]. Hence, a respectful and open approach was applied in all interviews. The interviews with the experts were conducted over a few months, as correspondence with and recruitment of participants required time and resources. The experts were spread all over the country, and all interviews were conducted physically in contexts comfortable to them, which in practice were at their respective workplaces. During the expert interviews, I deliberately undertook the role of an *apprentice* and a more *passive* approach. This strategy ensured that the experts were not restricted in their expression and hopefully felt respected throughout the interview, all of which was done to collect as rich data as possible. Sometimes, I had to step out of the *apprentice* role to follow the expert's lead and ask questions that allowed me to dig a bit deeper. The interview guide ensured that all relevant topics were discussed without restricting the experts too much; hence, the interviews were best described as relaxed conversations. The topic of the interviews did not concern personal or intimate matters; however, as PRO was on the political agenda, it restricted some of the experts to some degree. This problem was sought countered by keeping the experts anonymous. All talks were very comfortable and informative, which might be because the participants were experts in the area of interest and because a personal connection in several cases was established beforehand as the participants were recruited during the fieldwork. Further details on the interviews are accessible in Paper II [2]. The interviews with the citizens took place immediately after the consultations at the CfD, except for one interview that was conducted the next day. Two interviews were held physically at the CfD, while the eight others were conducted online through Microsoft Teams, which was the natural choice because the citizen–HCP consultations were mediated through the Teams under the COVID-19 situation. In these interviews, the participants were not much familiar with PROs, which meant that I had to control the direction of the conversations and continuously introduce relevant subjects. Deeper into the conversations, the citizens understood that the actual topic was their experience and perception of PROs, which made them feel more comfortable, engaged and open. Before the interviews, the citizens had participated in a one-hour consultation regarding their diabetes situation and other intimate matters, which meant that an extra respectful and considerate approach was applied from the beginning of these interviews to ensure that the participants did not feel overburdened or annoyed because of fatigue. Thus, during the interviews, a good connection with the citizens was established through the use of humour and by informing them of the purpose of the study, which was done to make them feel more relaxed and prepared. A participant emphasised how they were surprised by the digital solutions' ability to facilitate an unexpected close human connection, while another explained that participating in the study was their best experience during the last 14 days due to the corona restrictions isolating her at home [6]. To validate the citizens' statements throughout the interviews, questions on some of the same issues were asked in different ways, which is a recognised interview technique [74].

3.1.5. SCOPING REVIEW

As described in Paper I, the scoping review method was chosen because of the complexity of the examined phenomenon and because knowledge of the subject field was scarce. The scoping approach allowed for a nuanced scrutinisation through the inclusion of various studies and a broader overview of the association between PROs and patient participation, which was the intention behind the study. Thus, a systematic review, in which the quality of current knowledge in the field is assessed and ranked, was less relevant. As a guideline, the PRISMA-ScR standards were followed. More knowledge on the method and how the study was executed is available in Paper I [1].

3.1.6. DOCUMENT ANALYSIS

Document analysis was the applied method in Papers III–V. This method was used to obtain a deeper understanding of PROs' functionality, purpose and the constituting elements in clinical practice [3–5]. This is a method recognised in ethnographic and qualitative research, as it offers textual knowledge of social activities, which can impact the social world [66]. When conducting a document analysis, it is important to be transparent about the sampling process and how data are analysed [75]. Thus, the studies were sub-studies based on the relevant materials identified in the scoping review. This is an approach made possible by the extensive scoping review where 256 scientific papers were fully read. This is a substantial number of papers keeping in mind that digital PROs in clinical practice have primarily received scientific attention during the last 20 years and that papers on the topics examined in the PhD project are relatively few. In addition to scientific papers, relevant political reports were also included in the document analyses. Consequently, the document analyses scrutinised PROs' functionality, purpose and constitutive elements through scientific and political perspectives. A thematic analysis was applied in all three studies, which was useful as the aims were to map and identify PROs' functionality, purpose and constitutive elements. Another consideration when conducting a document analysis concerns how to present the results [75], which is a point contemplated in all three studies. In paper III, PROs' functionalities are illustrated in a table (Table 6), which was chosen due to its numerous functionalities. To provide the table with more analytical depth, the functionalities were matched against stakeholders and the mediation of PROs [3]. In paper IV, PROs' purpose is displayed in a figure (Figure 13), which provides a simple overview [4]. In paper V, explaining the type of elements constituting a PRO in clinical practice and the best way to disseminate the results was a focal issue. Thus, a concept map displaying a PRO's constitutive elements was created (Figure 13) [5]. Transparency concerning the type of documents used is also essential when conducting a document analysis; in this context, Lynggaard makes a theoretical distinction among primary, secondary and tertiary documents. A primary document is a document shared among a limited number of actors at a specific point in time close to the event or situation in question [75]. During the fieldwork, I was presented with what would be characterised as primary documents. However, these were not included in the document analysis, as they were considered confidential. A secondary document is also relevant in time but is different from a primary document because it, in principle, is available to anyone. Even though documents, in this case research papers, in principle, are accessible to anyone but actually only to a limited number of people, they are, according to Lynggaard's categorisation, best described as secondary documents. The importance of timely documents is prioritised by the fact that most research papers included in the scoping review were published during 2017–2018 [1]. Hence, the document analyses in the present PhD project are mainly based on secondary documents. The third type, tertiary documents, are, in principle, available to anyone as well but are timewise and not particularly close to the event or phenomenon scrutinised. A strength of document analysis is its ability to elucidate changes and development in an area over a period [75]. This method was used in the present PhD project as it can elucidate PROs' functionality (Paper III), purpose (Paper IV) and constituting elements (Paper V) over a recent period. In this project, the document analyses was valuable, as they produced different and complementary data supplementing the knowledge acquired from the interviews and fieldwork studies. Lynggaard described what he called the *snowball method*, which is a chain-referral approach, meaning that one set of references constantly leads to new references. The process begins with one or a few *mother documents* and ends when an area is extensively covered, which often is the case when new documents contribute only marginally, indicating a saturation point [75]. This method was the very first used in the PhD project, as I started by reading several documents on PROs identified through this approach. This strategy was chosen because I needed more knowledge on PROs before instigating other types of studies. The *mother document* was *Program PRO*, chosen because of its extensive character and because it is focal within a Danish context. The method was merely used as a starting point, meaning that the saturation point was not reached before the literature search linked to the scoping review was initiated. More knowledge on the specific document analyses is described in each of the three papers (Papers III–V) [3–5].

CHAPTER 4. CONTEXT, CONCEPTS AND THEORY

But where danger is, grows – The saving power also.

Friedrich Hölderlin

This chapter concerns the context, key concepts and relevant theories. The aim is to thoroughly explain the main concepts of *patient participation*, *patient empowerment* and *recognition* in the present PhD project. The concepts form the key search words in the scoping review (Paper I) [1], are incorporated in the interview guide with patients (Paper VI) [6] and are focal concepts considering the self-management agenda in Danish healthcare (cf. chapter 1). The intention is not to construct a *true* and universal understanding of these concepts but to clarify the concepts and identify the type of participation, empowerment and recognition linked to PROs. Other concepts, such as self-management, self-efficacy and health literacy, are closely connected to the key concepts in this project. However, to delimit the project and because the study design in combination with practical issues prevent a proper examination of patients' self-management, self-efficacy and health literacy, these concepts are omitted or described to a minor degree. Based on the included literature, there seems to be a clear connection between participation and empowerment. On one hand, 'patient participation can be seen as a strategy to achieve patient-centred care, which in turn can promote patient empowerment' [76, p. 9], and on the other hand, empowerment is described as 'gaining of the capability to participate fully in decision-making processes in an equitable and fair fashion' [77, p. 17]. Hence, there seems to be a reciprocal or dialectic connection between the concepts. Besides these concepts, technology and diabetes are parts of this chapter, where the former enables discussions on PROs as a technology and the latter provides context to the study conducted on newly diagnosed citizens with type 2 diabetes (Paper VI) [6]. First, patient participation is described in terms of its relevance, its substance and degree and what might function as its barriers and enablers. Second, different types of empowerment and patient empowerment are described. Third, different thoughts on technology are introduced by accentuating various concepts, authors and theories. Fourth, recognition primarily based on Axel Honneth's thoughts is explained and connected to PROs and the other key concepts in the PhD project. Finally, facts on diabetes are revealed.

4.1.1. PATIENT PARTICIPATION

In this section, the theoretical approach to patient participation in the PhD project is described. The contributions are included, as they concern substantially different aspects of patient participation. Sherry R. Arnstein's thoughts in *A ladder of citizen participation* [78] are are used to consider the degree of patient participation enabled by PRO use. Interpretations of patient participation are based on Ann Cathrine Eldh's

PhD dissertation, *Patient participation – what it is and what it is not* [77], combined with inputs from Brownlea [78], Snyder and Engstöm [79] and Castro et al. [76]. Some Danish contributions have also been added to situate the concept in a Danish context. These are Lene Pedersen with her book *Patientinddragelse* [80] (Patient participation), Erik Riiskjær's work *Patienten som partner – en nødvendig idé med ringe plads* [81] (The patient as partner – a great idea with a lack of room) and Kim Jørgensen's publication *Patientinddragelse – politik, profession og bruger* [82], (Patient participation – politics, profession and user), as well as ViBIS' publications, *Sunhedsprofessionelles forståelser af patientinddragelse – en kvalitativ undersøgelse* [83] (Healthcare professionals perceptions of patient participation – a qualitative study) and *Manifest for brugerinddragelse* [84] (Manifest concerning user involvement). Moreover, the book *User Involvement in Health Care* [85], authored by Trisha Greenhalgh, Charlotte Humphrey and Fran Woodward, offers an international healthcare perspective on patient participation. Terms such as *patient involvement* and *user involvement* are also used in this section as they have been used by some of the included authors, which is deemed unproblematic as the concepts are closely related to *patient participation* and therefore considered synonyms.

Why patient participation?

Before describing the different aspects of *patient participation*, a question encountered several times during the PhD project needs some attention: *Why is patient participation even important?* This question is likely related to the common perception that patient participation primarily functions as a means to improve healthcare quality and drive cost reductions [85–88]. This question can be answered in several ways. First, patient participation is relevant as it potentially improves the quality of treatment, outcomes and health; patients' QoL, compliance and patient safety; self-esteem and self-management and patient experience. In addition, it decreases mortality and morbidity among chronic patients and empowers patients as it makes them feel more in control and attains an improved overview of their course of treatment. Second, patient participation potentially provides access to the healthcare system; improves ownership of the healthcare system; enhances the quality of healthcare and creates a more efficient healthcare system, as patients are the most qualified to provide HCPs with valuable information on symptoms and describe how healthcare interventions and courses of treatment have affected them [76,80,83,85]. Hence, patient participation provides value to the healthcare system in different ways. When explaining the importance of patient participation in the work with PROs, I have made the following arguments throughout the project:

- A PRO cannot function without patient participation—if patients do not complete questionnaires and/or do not use PRO data during and outside the patient–HCP consultations, then PROs will not function as intended.
- Lack of patient participation, interpreted as low response rates, is another problem as it affects the quality and utility of PRO data and, as a logical consequence, potentially excludes certain patient groups.

- Patient participation is a focal normative ideal in healthcare, linked to the strive for a more patient-centred healthcare system and, in more general terms, to democratic ideals [78,86–88]; hence, patients should participate in the development, delivery and evaluation of the healthcare system [85].
- Patient participation is a focal tool used to counter the increased economic pressure on the healthcare system caused by demographic, technological and cultural changes (cf. chapter 1) [83,84,87].
- In particular, the increasing numbers of citizens suffering from chronic conditions mean that patient participation is not merely something located on a hospital level but a phenomenon unfolding in citizens' homes as they self-manage their disease [79,83,84,86]. Therefore, PROs aim to improve patients' self-management during their everyday life, hence the relevance of patient participation.

Thus, patient participation is pivotal in healthcare and healthcare work based on PROs. It acts as a means to an end and as an end in itself, which is an important point, as the critique I have faced often revolved around patient participation's inferior position as a means to an end. However, even in cases where patient participation acts as a means to an end, it is characteristic of how central and decisive it is in the transformation of the healthcare sector. When patient participation acts as an end in itself, which in a PRO context refers to patients' ability to self-manage their condition outside clinical practice, then it is reasonable to assume that the impact of PROs and patient participation on healthcare is substantial. However, at this point, the connection between PRO and patient participation is unclear, underscoring the relevance of the focus in the present PhD project.

Degree of patient participation

To assess the degree of patient participation instigated by PROs, Arnstein's *Ladder of Citizen Participation* was applied [89]. Originally, the ladder was applied to explain citizens' participation in city planning processes. Arnstein argued that participation only has value when executed properly. In other words, we need to distinguish between the delegation of real power and *the empty ritual of participation*. Thus, Arnstein perceived citizen participation and citizen power as connected entities; consequently, the redistribution and delegation of power determine the degree of citizens' participation. Therefore, if democratic processes do not leave room for genuine power and influence from participants, then these procedures do not benefit the citizens but merely work in the favour of powerholders [89]. Therefore, patient participation initiated by PROs needs to bring value to the patients; a certain degree of patient participation is required to ensure that patient needs are prioritised. Conversely, if PROs do not instigate genuine patient participation, the tool might serve clinicians and those managing the healthcare system instead. As shown in Figure 7, the ladder of participation comprises eight rungs:

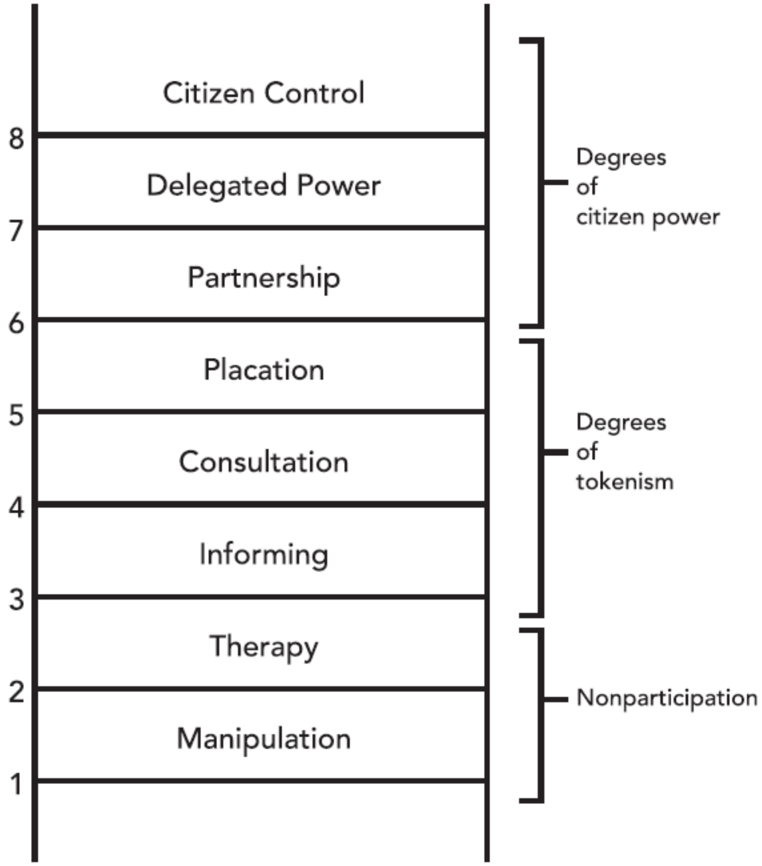

Figure 7. Arnstein's ladder of participation [89,90]

Participation and power increase as one progresses up the ladder. The lowest part of the ladder indicates non-participation, the middle part represents degrees of tokenism and the top section contains examples of participation in which citizens attain real power. The contents of each level/rung are described as follows:

1. *Manipulation*: This category represents situations in which citizens are used as marionettes in public relations by the powerholders. The objective is not citizen participation but to 'educate' citizens.
2. *Therapy*: It refers to cases in which powerlessness is perceived as an individual problem caused by mental issues. Hence, the solution is therapy to 'cure' people, enabling them to grab power and participate. Arnstein underscored that the causality of the problem is reversed and caused by the powerholders; in other words, structural problems are the reason why citizens are powerless and have mental issues.

3. *Information*: This rung represents a basic step to be followed if citizens are to participate. Citizens need to know their rights and options in different scenarios; thus, this category resembles the saying that *knowledge is power*. The reason *information* is this low on the ladder is that Arnstein considered it a one-way interaction; hence, feedback systems enabling participants to affect decisions are not included on this level.
4. *Consultation*: Consultation is when the information flows in the opposite direction, from citizens to powerholders. Arnstein positioned consultation in the tokenism category, as citizens' inputs alone are insufficient in ensuring real power or influence on decisions.
5. *Placation*: At this level, citizens are offered a seat on a public board. This is a step in the right direction, but one cannot be sure that citizens attain real power or influence, which depends on the support they receive to engage in the work and the support from the community.
6. *Partnership*: This level indicates that citizens have gained power, as they are enabled to negotiate with stakeholders as partners and engage in SDM.
7. *Delegated power*: At this rung, citizens have even more power, as they are now delegated the decisive voice in decision-making processes.
8. *Citizen control*: As the label indicates, citizens are now in full control of the process. They manage programs and institutions by themselves [89].

How the rungs are related to PROs is elaborated upon in the Discussion (chapter 6), but simply translated, rungs 1–2 indicate that patients act as means to an end, characterised as non-participation. Rungs 3–5 resemble the traditional approach to patient participation in the healthcare system, indicating the importance of informing and including patients to a limited degree. At these initial rungs, patient participation functions as a stabilising factor and symbolic act through the inclusion of patients in different councils and committees; hence, tokenism ensures that politicians and patients are satisfied. Rungs 6–8 represent an advanced type of patient participation, strived for in political strategies and in the use of PROs, where patients are considered partners and the aim is to improve their control and the ability to self-manage their disease and health.

A problem in this context concerns the professionalisation and institutionalisation of patients, which is required to enable them to understand focal logics and engage in council work. An adjustment process potentially influencing a patient represents attitudes and feelings of affiliation. Another issue concerns representativeness, as recruitment is often based solely on disease categories, which might generate health inequities as this practice excludes less resourceful patients while favouring resourceful patients. Hence, attention to and awareness of the potential health inequities that patient participation might produce as a political tool are important [87].

Arnstein's linking of patient participation and power means that her interpretation of patient participation aligns with the critical approach to empowerment. Hence, it is no surprise that Arnstein’s main purpose is to delegate power and ensure participation from *have-not citizens*, in her own words, to turn *nobodies* into *somebodies* [89]. Thus, it should be considered whether a PRO benefits patients in maximum need of healthcare if it turns them into *somebodies* or *nobodies*. Arnstein emphasised that socioeconomic issues, mobilisation of and support from the community, paternalism, racism and heterogeneous views on the idea of power redistribution act as barriers towards participation [89], which should be considered in a PRO context as well.

Patient participation in healthcare

A recurring theme in the contributions on patient participation is how the phenomenon is not deeply integrated into current health praxes, considering how discourses such as *patienten i centrum* (focus on the patient), demanding a patient-oriented healthcare system and *det nære sundhedsvæsen* (the accessible and closeby healthcare system), which emphasise a close and accessible healthcare system, dominate in a Danish context [80,81,83]. The main challenges are related to structural and cultural barriers; hence, there is a need for a paradigm shift in the approach to patients and relatives [80]. According to Pedersen [80], patients are no longer passive receivers of healthcare; instead, they should be seen as active and well-informed actors who demand influence on their course of treatment. This is a change enabled by the Internet and the increasing digitalisation, which offers patients access to information on diseases, treatment and peer groups comprising people with similar conditions. Despite the current emphasis on patient participation, the healthcare sector has always been interested in how services affect patients, what has changed is the systematic and scientific manner in which patients are involved in healthcare, which likely explains the focus on PROs’ potential to systematise patient participation in healthcare [80].

HCPs’ perceptions of patient participation are examined in the report *Sundhedsprofessionelles forståelser af patientinddragelse* [83]. A relevant contribution in a PRO context is that it can explain HCPs’ attitudes and the perceptions of PROs’ participatory capabilities. Moreover, an interesting subject given the character of patient participation in clinical practice depends on how HCPs and patients perceive patient participation [88]. However, patient participation is a complex matter, which means that various perceptions of the concept exist among HCPs. In general, HCPs think positively of patient participation, find it useful and believe that it regards situations in which the patient

1. Is continuously informed about the disease and its course of treatment.
2. Has co-determination and actively decides the types of treatment.
3. Experiences an emphatic and individualised approach by the HCP.
4. Is treated based on one's needs, preferences and knowledge.
5. Is taught how to self-manage their disease [83].

In other words, patient participation is perceived as taking place during the patient–clinician conversations/consultations [80], and concerns, for example, decision-making and educative interventions but also refers to patients’ self-management activities and participation in research or co-design processes [83,85]. To promote patient participation, HCPs must apply an individual approach based on the patient's life situation, knowledge, preferences and resources and know how to create a relation with patients based on trust, respect and recognition, consequently allowing patients to engage, as they prefer, in conversations and decisions concerning their treatment to enhance their ability to self-manage [80,83].

When directly asked, the meaning of the concepts of participation and involvement can seem quite unclear to patients. However, patients' perception of patient participation concerns being informed; decision-making on treatment; care and health-related issues and their right to be seen, heard and understood [77,91]. Eldh [77] revealed that 'participation occurs when being listened to and being recognised as an individual and a partner' [p. 5], whereas non-participation is experienced when patients are treated as diagnoses/symptoms and not as unique individuals. This is an interpretation of patient participation linked to Honneth's [64] thoughts on recognition, as recognition and respect, according to Eldh, facilitate genuine patient participation [77]. In practice, patient participation in decision-making might be limited to the recognition of patients' situation; hence, even good intentions from HCPs do not always result in patients being heard and treated as individuals [91]. In other words, genuine patient participation can be interpreted as a humanisation of the healthcare system in which patients are no longer seen as a diagnosis but as a human facing unique disease-related issues. This is a holistic approach in which the patient's life situation is central, in contrast to the traditional reductionistic biomedical approach, which focuses on the disease. The demand for holistic care and patient participation especially results from the fact that in chronic care, patients' well-being on physical, mental and social levels is also an important factor [88].

According to Brownlea [78], participation in a healthcare context, '…means getting involved or being allowed to become involved in a decision-making process or the delivery of a service or the evaluation a service, or even simply to become one of a number of people consulted on an issue or a matter' [p. 1]. The World Health Organization (WHO) defines patient participation as 'a process by which people are enabled to become actively and genuinely involved in defining the issues of concern to them, in making decisions about factors that affect their lives, in formulating and implementing policies, in planning, developing and delivering services and in taking action to achieve change' [92, p. 10]. Hence, patient participation concerns decision-making, delivery of healthcare, development of healthcare, evaluation of health services and research activities [76,79]. Decision-making refers to patient–clinician consultations with a focus on SDM, situations in which patients are involved in decisions regarding their health and treatment. In this context, patients' preferences for involvement in decisions and HCPs' ability to facilitate SDM are essential. Patient involvement in healthcare delivery concerns their ability to actively manage their health through self-care, self-management and self-medication, which is enabled through a partnership approach, education, supervision, empowerment and by acknowledging patients' wishes and expectations. This approach indicates that increased responsibility is placed upon the individual patient. Such patient involvement is challenged by the fact that not all patients wish to take responsibility for their health and disease situation. Patient involvement in the development and evaluation of healthcare and research projects concerns how a scientific and systematic integration of patients' perspective can improve the quality of healthcare [76,79,86,88].

Greenhalgh, Humphrey and Woodward elaborated on user involvement and its impact on the healthcare sector on a more general level [85]. In this pursuit, they explained how patient participation can be seen as a transformative mechanism enabling various outcomes in different contexts, hence a situated concept. The authors explained that patient participation can be divided into two branches, a democratic one, where *choice* and *voice* are emphasised and where the aim is to have influence and control over healthcare services, and the consumerist model, in which the strategies of *exit* and *voice* are used to maximise an individual's utility of healthcare services [85].

In summary, different types of patient participation should be considered in connection to the association between PRO and patient participation (Paper I) [1] and PROs' functionalities and purposes (Papers II–IV) [2–4].

Barriers and enablers of patient participation

Numerous enablers and barriers influence patient participation in clinical practice under the precondition that patients are adequately informed. Patients need to initially receive meaningful, understandable and individual information to decide whether they want to participate and to what degree [76–78]. In this context, an HCP's role is to facilitate patients to make treatment choices on an informed basis and to activate their resources; thus, patient participation is a shared responsibility [88]. Sometimes, patients take on a passive or non-participative role, either by preference or because of lack of ability, making active patient participation difficult. In such situations, HCPs should acknowledge the patients' wishes and allow non-participation or a limited form of participation [78,83]. Therefore, it is important to consider how patient participation affects this segment of patients, as patient participation tools, such as PRO, are potentially more favourable to resourceful patients [80]. Thus, HCPs link unsuccessful patient participation to patient disabilities, non-compliance with treatment and a lack of interest in participation [91]. The dilemma in this context concerns the internal discrepancies in the execution of patient participation, as it is difficult for HCPs to respect the wishes and needs of the patients while ensuring that patients participate actively and self-manage their disease. Hence, it is noticeable how decisive a role HCPs have as they are the ones assessing whether a patient can participate actively, which is not necessarily a simple task [83]. Moreover, HCPs influence the degree of patient participation that is allowed, as they decide how much information the patient receives, how much they are willing to listen and whether they include the patient's wishes [80].

In the context of SDM, HCPs' professional treatment suggestions and patient preferences might diverge. A situation occurs when patients are well-informed, knowledgeable and prepared experts in their disease, altering the relation between the

HCP and patient [80,83]. This is a development affecting the dialogue and balance of power between the HCP and patient. Even though the move from the traditional paternalistic system to a gradually more patient-centred system means that physicians have lost some authority and patients have become increasingly active and powerful, it is still so that patients' options, influence and free choice are constrained by the HCP. An asymmetrical balance of power exists between the actors, as the patient is dependent on the actions and choices of the HCP. Situations make the limitation of patient participation clear and explain why it can be frustrating for the involved actors [83]. A slowly changing situation, as patients' altered behaviour, has influenced clinicians, who to a larger degree, acknowledge patients as experts in their disease situation [80,83,85,86]. Nonetheless, HCPs' supportive attitude concerning patient participation and their ability to recognise patients as partners and experts in their disease situation is focal [76]. How PROs might affect this balance of power is interesting to consider and follow in the future.

What might enable and strengthen patient participation is the increasing use of technological and digital solutions, which allows citizens to self-monitor, access health information and engage in peer-to-peer communities, enabling patients to collaborate and actively handle their health problems [86,87]. Likewise, the studies constituting the present PhD project show that digitalisation makes a noticeable difference in PROs' functionality and purpose [2–4].

Visible leadership and a change of culture are essential in the promotion of patient participation in clinical practice [80,83]. Thus, supportive management, the recognition that patient participation might influence clinical workflows and the allocation of sufficient time, space and financial resources influence whether genuine patient participation transpires [76,78,83]. Patient participation should be effective, individualised and based on evidence-based practice. Therefore, problems arise when patients have wishes diverging from the guidelines constituting evidence-based practice as the HCP then needs to choose between following the standardised best practice or being receptive towards the patient's wishes. Nonetheless, a healthcare system based on collaborative and partnership-oriented healthcare practices requires HCPs who know how to facilitate patient participation. A system that systematically mobilises patients' resources makes them apparent, tangible and actionable to HCPs in the treatment [80]. Therefore, the importance of educating HCPs and patients under proper knowledge is what enables patients to participate in practice, take control and self-manage their health [76,77]. Conversely, non-participation occurs when patients are not recognised and respected and are uninformed and lack the required knowledge [77]. Therefore, by strengthening citizens' ability to acquire health information and apply it in decision-making, an improvement of their health literacy can improve patient participation and self-management, subsequently decreasing health inequities [86]. In other words, massive cultural and organisational changes pertaining to patient participation manifest only if they are integrated into the core of healthcare practice and not just exercised as a one-off activity [85].

Logics and structures affecting patient participation

The structure of the healthcare system is an important factor in explaining why patient participation has difficult conditions [86]. According to Riiskjær [81], different types of logics embedded in the Danish healthcare system have affected the pursuit of increased patient participation. In this case, logics are described as systems constituted by different types of knowledge, cultures, praxes, values and technologies. The four intertwining logics are *the public*, embedded in public administration, law, legislation and politics; *the market*, striving for a more transparent healthcare system based on measurable, assessable and comparable indicators; *the medical profession*, where specialisation of HCPs, standardisation of practice and the impact of the evidence paradigm are decisive factors and *the care profession*, derived from the fundamentals of nursing care practice [81].

New Public Management (NPM) affects all four logics and thereby has a focal impact on current healthcare and patient participation [81]. This is a management strategy that has dominated public management for the last 20–30 years [86]. In NPM, public companies are perceived as private companies, where productivity, cost management and efficiency are prioritised, creating a system based on contracts and target management. Hence, quantitative indicators and measures documenting, assessing and comparing healthcare providers' actions and results are the tools used. This is a logic based on *economic man* and rational choice, where the assumption is that humans are fully informed and act rationally, making economic incentive systems central management tools [81,87].

The standardisation of the healthcare system also transpires through law and legislation, where Riiskjær emphasised the Danish Health Care Act [93] (division of tasks and responsibility) and the Authorisation Law [94] (permission to exercise healthcare) [81]. The former enables patient participation, as it states that patients and their self-determination should be respected and that patients have a right to receive information that enables them to make disease-and treatment-related decisions [87,88]. The *public logic* is based on the traditional norms of public administration on rationality and neutrality [81].

Another dominant paradigm, meant to improve healthcare quality, is evidence-based medicine (EBM), defined as '…the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research' [95, p. 2]. Hence, appropriate use of EBM requires that the best external knowledge, the clinician's experience and the individual patient case are considered jointly [95]. The hierarchy of evidence is the model used to prioritise and recommend methods when conducting evidence-based research and EBM, where systematic and meta reviews, together with RCT studies, are highly estimated, while HCP and patient experiences are considered the weakest types of evidence [96]. Table 3 displays some of the systems/structures that standardise healthcare and influence how patient participation is exercised.

Table 3. Systems and structures based on standardised logics in Danish healthcare [81]

Systems/structures	Description
The diagnosis-related group system (DRG system)	A system pricing the value of produced healthcare outputs in relation to each diagnosis, meaning that the providers receive resources according to the amount and type of healthcare interventions produced.
The specialised healthcare system	A healthcare system comprising HCPs who are highly specialised within various disease areas.
Clinical practice guidelines (CPG)	Systematically generated statements applicable by HCPs in decision-making situations promoting standardisation of clinical interventions. In a Danish context, *pakkeforløb* (standardised courses of treatment) is a good example of treatment based on clinical practice guidelines: https://cfkr.dk/
The National Clinical Registries (RKKP)	A performance measurement system and databases primarily based on process indicators. Promoting EBM and transparency concerning the quality of healthcare: https://www.rkkp.dk/
The Danish Healthcare Quality Programme (DDKM)	Model and political strategy meant to improve quality of healthcare and patient pathways and prevent inadvertent mistakes in healthcare: https://www.ikas.dk/den-danske-kvalitetsmodel/
Accreditation standards	Focus is on clinical, organisational and patient-experienced quality, with an aim to improve patient pathways.

Based on standardised thinking, embedded in the different logics, structures and systems, patient participation can be difficult to accomplish due to cases in which

- Standardised treatments are potentially prioritised over individual human needs and values [81].
- The number of administrative systems and tasks increases, with questionable effects on healthcare quality. This time could have been spent on patient care [81].
- Patients have different economic values for providers, promoting a healthcare system based on economic incentives, where chronic and complex patients are either undertreated or avoided by healthcare providers [81].
- Efficiency demands clash with a holistic, patient-centred and partnership-oriented healthcare practice [81]. Thus, how patient participation materialises during the patient–clinician consultation is shaped by productivity and effectiveness demands [88].
- Process measures are prioritised over outcome measures [81], indicating how *objective* measures are prioritised by politicians, public servants and economics [88]. Here, the number of measures is not necessarily the problem but rather the relevance and meaningfulness of the applied measures, which need to have value for clinicians and patients [81].
- A measure becomes an aim in itself instead of a means to an end, potentially resulting in suboptimal solutions [81].

- Measurable indicators are included in the systems; consequently, essential, less visible/invisible aspects of healthcare, not that easily measured, are overlooked when developing and assessing healthcare quality [81].
- Goal realisation has shifted focus away from patients [81].
- Complex and chronic patients are of economic annoyance to providers as they require time and resources, making them expensive; as a result, the easier and cheaper patients' are preferred and prioritised. A utilitarian approach to healthcare emphasises the generation of the most possible healthcare for lowest price [81,88].
- The highly specialised system favours simple and repetitive tasks, creates professional *silos* and only grants access if patients fit into the pre-developed diagnosis system. This system negatively affects the quality of patient pathways by fragmenting them, making coordination across providers difficult and favouring the simple patient cases fitting into a speciality, where patients have the risk of ending up *in the wrong silo* while socioeconomic and individual characteristics are ignored, making a tailored approach challenging [81,88].
- The system results in costly and inefficient patient pathways, which ironically statistically appear as increased productivity [81].
- The disease situations of real-life patient cases are potentially different and more complex compared to the standardised theoretical cases included in clinical practice guidelines (CPGs). CPGs are often based on a *one-disease perspective* incompatible with a healthcare system that experiences an increased number of citizens suffering from several chronic conditions [81].
- *Defensive medicine* is practised in the case where HCPs rigorously follow CPGs, ignoring their clinical expertise as demanded when practising EBM to avoid getting into trouble. Hence, the prioritisation of CPGs over individual patients might threaten the patients' autonomy and limit their options during decision-making [79].
- The guidelines constituting EBM are based on a hierarchy of evidence, promoting specific methods; consequently, healthcare approaches encouraging qualitative methods that enable a deeper and improved understanding of individual patients have a difficult time [81,88,96].

Thus, several mechanisms make patient-centred care challenging. Essentially, there is a clash between a patient-centred healthcare system based on patient participation, designed according to patients' wishes, knowledge and needs, where contextual matters are included, and an NPM-inspired healthcare system based on standardised and evidence-based solutions. Therefore, at present, patient participation is largely based on norms rooted in NPM pertaining to effectiveness, systemisation, standardisation and instrumentalisation [86,88], which is further discussed in chapter 6.

Role of healthcare policies and political norms

Patient participation can also be considered an overall political and management strategy for solving some of the current healthcare problems in the Danish healthcare sector. Hence, current healthcare policies point out the following:

- A cultural change is required to ensure a patient-centred healthcare system.
- Many more patient participation methods need to be applied.
- Patients need to participate in their treatment to a larger extent.
- Patient satisfaction is a focal indicator.
- Patients' own experiences of participation are essential.
- Patient-defined effect measures of treatment should rank alongside clinical quality measures.
- Patient participation should be used as a quality assurance tool.
- Patient participation is an instrument for creating a more effective healthcare system.
- Patient participation should improve decision-making on treatments [86].

These are demands that synergise well with the functionality and purpose of a PRO [2–4]. Patient participation is also relevant in realising *The Triple Aim*, a political healthcare strategy that focuses on improving overall healthcare by ensuring better public health, increasing user-experienced quality and decreasing healthcare expenditure [86].

Frederiksen and Jørgensen explained that the current healthcare system and the emphasis and enactment of patient participation are rooted in a neoliberal paradigm [87,88]. A liberal approach indicates that patients are expected to undertake an increasing responsibility and actively self-manage their health, which rests on individuals' abilities, resources and wishes [88]. This is a paradigm in which *the patient* is perceived as a user or consumer in contrast to a sick and suffering person who needs care, a perception of the patient referring back to the aforementioned market logic [87,88]. This construction of the patient means that healthcare services are allowed to prioritise patients who are capable of participating and self-managing, providing less room for the non-participating, passive patients who might be the ones in maximum need. Hence, the impetus behind the claim that the healthcare system, to some extent, has become an education system teaching patients how to self-care instead of a system in which patients receive the required treatment and care [88]. In this paradigm, a central assumption is that patients who live healthy, responsible lives, accepting the personal responsibility of their well-being, also live longer [87]. Thus, patients are considered autonomous beings who are allowed to make free choices regarding their health [87,88]. The liberal approach also means that an individual is held responsible for increasing healthcare expenditures, which is another reason why citizens are expected to engage in self-management activities. According to Jørgensen, the increased responsibility undertaken by patients concerning their health management is fair to the extent to which it grants them genuine influence on decision-making and treatment, which they believe is not currently the case as patient participation mostly is a symbolic act, meaning that individual patients' wishes remain unmet [88]. The liberal approach is unproblematic as long as patients possess the required capital and capabilities to engage actively in the handling of their disease. However, if patients are suffering, are in pain or lack the necessary abilities to participate, the liberal approach seems problematic [87].

4.1.2. EMPOWERMENT

Different aspects of *empowerment* and *patient empowerment* are described in this section. Based on the various understandings and interpretations of empowerment through a combination of diverse authors, a multidimensional understanding of empowerment is offered. This is a preferred approach due to the complexity of the concept. The intention is not to elicit a true definition but merely to describe different dimensions of *empowerment* and *patient empowerment* to enable a nuanced discussion (chapter 6) on PROs' capabilities in this regard.

Contextual character of empowerment

Empowerment can be described as a situated concept [97,98]. This is indicated by the fact that how, who and for what purpose empowerment unravels depends on the context. Patient empowerment is a fine example of this, as it accentuates how patients primarily are actors who need to be empowered within healthcare [97]. The situatedness of empowerment means that it has various meanings in the healthcare sector. Hence, empowerment might concern individuals' emancipation and gain of power through political mobilisation or informed choice, patient–clinician partnerships, patient participation and involvement and SDM [98].

Levels of empowerment

Empowerment can also unfold on different levels. On a macro-level, empowerment concerns group rights and whether group concerns are considered legitimate political issues; on the meso-level, it regards alteration of organisational structures and the micro-level pertains to individual aspects of empowerment [97]. This is a triadic perspective on empowerment that synergises very well with Honneth's three levels of recognition [64,97].

Critical approach

The critical approach to empowerment concerns how oppressed groups or individuals can arise from a disempowered position to obtain power, knowledge and control over one's life situation. Emancipation is caused by increased education and reflection, resulting in increased awareness, knowledge, power and political influence [97,99,100]. Hence, empowerment is historically linked to concepts such as *social action* and *self-help*, which emphasise that individuals and groups should be enabled to take action through education and information on their rights [101]. Thus, empowerment is considered both a process and an outcome/goal [97,100], making it possible to distinguish between the process of becoming empowered and the state of being empowered [99]. In this interpretation of empowerment, genuine participation and real influence on societal structures are central objectives, resembled by Paulo

Freire's concept of *critical consciousness*. A critical consciousness is developed by educating people [100]. Thus, the emphasis is on institutional modification, democratisation and genuine participation and inclusion, focusing on political institutions and other focal powerful institutions [97]. For Freire, there is no such thing as a neutral education; education either integrates the people into the logic of the current system or enables them to critically deal with societal issues and emancipate themselves [100]. Hence, Freire's quest was to transform citizens from oppressed objects into empowered subjects [101]. Therefore, the emphasis was on disadvantaged actors' situations in the critical approach [97]. This is an interpretation of empowerment that makes one consider whether PRO educates and emancipates the citizens and patients or if it is an instrument used to promote adherence and adjustment. Hence, this is an approach closely linked to Arnstein's description of participation.

Liberal approach

In the liberal approach, an individual's ability to mobilise inherent resources and thereby take control is accentuated. Hence, in this version, empowerment is a subjective matter, as change comes from within, meaning that responsibility and success of progression are placed on an individual's shoulders [97]. Thus, the liberal approach, which is applied in the healthcare sector, is a relatively simplistic perception of empowerment compared to, for example, the critical one. In a healthcare context, empowerment becomes a 'pragmatic, applied technology and within the ideological context of a modified medical model' [98, p. 5]. In other words, in nursing practice, empowerment translates into an enhanced nurse–patient partnership, enabled and facilitated by informative and supportive nurses, subsequently ensuring that patient resources and needs are integrated part of the care. Therefore, the perception and practice of empowerment are limited in this context, as practice occurs within 'a framework of pathology and boundaries outlined by the nurse' [98, p. 5]. This understanding of empowerment is essential to grasp when assessing PROs' empowering potential as the individualised and liberal perception of the concept is dominant within healthcare and, therefore, arguably the most relevant when evaluating PROs' empowering capabilities.

Power of empowerment

Andersen also elaborated on the power aspect of empowerment, discussing whether a relative or absolute understanding of power mirrors the mechanics of empowerment most correctly. Essentially, empowerment is about making someone more powerful; therefore, when empowering a group or an individual, they get relatively stronger compared to other relevant actors, which influences the balance of power. Accordingly, empowerment processes can be perceived as a zero-sum game, and vice versa, as the empowerment of certain population groups potentially benefits society as a whole, acting as a common good, and might also take the shape of a non-zero-sum game [97]. Both these distinctions of empowerment's power potential are relevant in connection to PROs. Hence, how should PROs be categorised and what groups might benefit from their use?

Patient empowerment

In the context of health, empowerment gains influence through the Ottawa Charter for Health, as it underscores the importance of empowerment in health-promotion initiatives and focuses on improving people's social and health conditions preventively, in opposition to the traditional ill-health prevention paradigm [101]. Moreover, the integration of empowerment in healthcare indicates a move away from the paternalistic approach towards enhanced patient–clinician collaboration, a partnership approach linking patient-centeredness and patient empowerment, where patient-defined issues are addressed, patients are part of decision-making on treatments and have rights, increased responsibilities, autonomy and involvement [98,99]. On one hand, empowerment is a helping process, a partnership involving SDM, providing the patient with opportunities and freedom to make choices. On the other hand, patient empowerment requires that patients be actively involved and take on increased responsibility for their health. Therefore, the aim of patient empowerment is to mobilise and strengthen the patient's resources and make them feel in control through education and reflection on their skills and needs. As a result, improved patient experience and satisfaction, positive patient health outcomes and enhanced self-management behaviour can transpire on a patient level and a general level by improving the quality of healthcare systems. Furthermore, empowerment in healthcare describes either a connection between health and power, where the underlying assumption is that empowered patients can live healthier than other patients, or empowerment refers to specific patients who are empowered through education, consultation or communication with HCPs [99]. Another interpretation of patient empowerment pertains to a conceptual dichotomy where empowerment is perceived either as a patient–provider interaction or as a patient-oriented process alone. In both cases, empowerment is considered a process. In a patient–provider interaction context, empowerment concerns communicative and educative aspects, where the actors are striving for a partnership through shared power, knowledge and values. From a patient perspective alone, the aim of the empowerment process is a personal transformation [101]. Hence, empowerment can be perceived as both an interpersonal concept and an intrapersonal concept [102]. The former type of empowerment is a situation in which power is *given* to the patient, whereas power in the ladder scenario is *created* within the person. Similarly, empowerment in healthcare can be considered an ideological approach accentuating responsibility and choice or a skill development process enabling improved disease management; hence, learning is a focal aspect of empowerment [101]. Accordingly, Holmström and Röning [99] applied a quote by Feste and Anderson explaining that empowerment in healthcare 'is based on the assumption that to be healthy, people must be able to bring about changes, not only in their personal behaviour, but also in their social situations and the organisations that influence their lives' [p. 2]. Therefore, in a healthcare context, empowerment translates into increased responsibility on the patient's shoulders, as choices and subsequent consequences affecting health and disease management are seen as an individual responsibility [101].

Castro et al. [76] identified numerous perceptions of patient empowerment. For instance, patient empowerment is considered an *enabling process*, in which an individual is taught techniques and tools that enable self-management of their disease. Patient empowerment is also perceived as an *effect of change*, which refers to a process of personal change and the alteration of social and organisational structures affecting their situation. The most frequent coining of *patient empowerment* revolves around self-determination and autonomy, which is enabled when patients know their rights and can make their own decisions [76].

In clinical practice, empowerment often refers to the interaction between the patient and HCP, where the target group, to a large degree, comprises individual patients or groups of patients suffering from chronic conditions [99]. A particularly important group, since chronic conditions, impacts people's life at a psychosocial level and a behavioural level, potentially making them feel powerless [101]. Hence, the importance of patient empowerment in chronic care is to enhance the health outcomes of patients [102]. In their work with patients, nurses perceive patient empowerment as

- The dissemination of information on treatment options, lifestyle and disease-specific issues enables enhanced decision-making and disease management.
- An interpersonal and holistic approach, embedded in a supportive and trusting nurse–patient relation.
- A role as gatekeepers, where nurses introduce patients and relatives to former patients and support groups.
- Supportive care, where positive thinking enables patients to cope and increases their independence, control and autonomy [98].

Complementarily, patients perceive empowerment as improved knowledge that enables them to better understand and handle their condition. Additionally, empowerment makes patients participate more confidently in physician–patient consultations and allows goal-setting based on their individual needs [101].

Empowering health practice improves patients' self-esteem and confidence and strengthens their ability to exercise decision-making. Thus, patients learn to cope with the individual responsibility their disease situation implies and to withstand external pressure concerning disease management [98]. This process enables patients to identify needs, problems, goals and strategies to better handle their disease situation. In other words, an empowerment process is a patient-centred, open-minded and positive process requiring mutual recognition and connectedness between the patient and HCP [101]. Whether a patient follows the information and advice provided by the nurses is up to individual patients. Hence, even though this might be problematic from a traditional healthcare perspective, ‘it was felt that the nurse should respect and accept patient decisions even though they may feel uncomfortable and find it difficult to help a patient pursue a course of action that they did not condone and that may involve some risk’ [98, p. 3]. This quote emphasises respecting the wishes of individual patients in the decision-making process. Specifically, the acknowledgement of patients’ self-determination is a central aspect of empowerment; therefore, if patients are not interested in making decisive decisions concerning their health and voluntarily delegate responsibility and decisions to the HCP, this should be respected as well [99,101].

Antecedents and enablers of empowerment concern responsibility sharing; a partnership and patient-centred approach based on mutual trust and respect; adequate time; development and enhancement of patients’ psychosocial skills and competencies; motivated and actively engaged patients and providers and good communication and dialogue focusing on who the patients are and not as much on their actions. Moreover, HCPs should attenuate control and paternalistic behaviour and substitute it with a facilitating role instead. Hence, communicative skills and the ability to understand patient needs are key when exercising patient empowering practice [99,101]. Moreover, the empowerment process is improved if patient goals and outcomes are adjusted according to their needs and situation. Essentially, the empowerment process and management of patients’ chronic conditions are shared responsibilities, enabled by improved self-determination and self-management [101].

One of the more prominent barriers/enablers of empowerment is health literacy, as it determines patients’ ability to obtain knowledge and skills. Accordingly, it concerns ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions’ [102, p. 1]. In particular, the intrapersonal features of empowerment are important in this regard; hence, the following terms and questions are relevant:

a) *Meaningfulness*—Do my actions pay off?
b) *Competence*—Am I able to enact specific actions?
c) *Impact*—Do my actions have an impact?
d) *Self-determination*—Am I motivated to bring about specific actions?

A useful model is *the Health Empowerment Model* (Figure 8), which describes the association between patient empowerment and health literacy level.

Patient Types		**Empowerment**	
		Low	High
Health literacy	Low	‘High-needs patient’	‘Dangerous self-manager’
	High	‘Needlessly dependent patient’	‘Effective self-manager’

Figure 8. Health empowerment model [102]

Essentially, sufficient health literacy and empowerment enable patients to manage their diseases, whereas an unbalanced relation between the two creates sub-optimal outcomes; patients being low in both categories require extra attention and care. The empirical studies making the theoretical categorisations tangible demonstrate that *effective self-managers* perceive themselves as having a better health status compared to patients who score lower on either of the two parameters. The aspects of intrapersonal empowerment, *meaningfulness* and *competence*, significantly moderate health literacy and affect patients’ health outcomes [102].
Patients’ empowerment can strengthen their integrated self. Thus, interactions with peers and HCPs enable patients to understand their disease from a different perspective, enhance their inner strength and make better disease-related decisions. In other words, patients gain control over their lives and learn how to self-manage through an increased feeling of power, mastery and control. Hence, self-management is a focal outcome when empowering patients, a concept which can be defined as ‘the individual’s ability to manage symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition and to affect the cognitive, behavioral and emotional responses necessary to maintain a satisfactory quality of life. Thus, a dynamic and continuous process of self-regulation is established’ [103, p. 2].

Hence, there are various understandings of empowerment and patient empowerment. These are relevant inputs that are useful in the discussion of PROs’ empowering capabilities, especially if PROs are to be used as self-management tools.

Empowerment within diabetes

According to Anderson and Funnell [100], patient empowerment in diabetes is a process that aims to instigate changes in patient behaviour through goal-setting. Through meaningful, reflective and realistic goal-setting, patients can solve problems, stay motivated and enhance their self-management. However, empowerment does not occur on its own; thus, the usefulness of the approach depends on the patient’s motivation.

In the diabetes context, empowerment is also viewed as a process and an outcome. In the processual stage, the purpose is to educate, enable and gradually improve citizens' critical thinking and autonomy. Typical outcomes of the process are improved self-efficacy and empowered individuals enabled to make autonomous and informed decisions.

Empowerment is essential in diabetes because

- Patients are responsible for 98% of their care.
- Self-management and appropriate decision-making in patients' daily lives are the primary determinants of their health and well-being.
- Patients are responsible for their health and the consequences of their decisions.
- HCPs cannot undertake patients' self-management tasks; hence, patients need to stay in control, which requires that the HCPs ensure that patients are informed and educated in ways that enable them to make appropriate self-management decisions [100].

Anderson and Funnell indicated that for HCPs, an empowerment practice involves a paradigm shift in diabetes care and education, clashing with former approaches. Hence, instead of implementing a genuine empowerment practice, HCPs can adjust empowerment to fit their beliefs and practices. Consequently, numerous misconceptions about empowerment currently flourish. Therefore, even though HCPs can support empowerment normatively and intellectually, they do not necessarily practice empowering healthcare due to these misconceptions. First, some HCPs believe that patients do not wish to be empowered and are not doing as told. However, it is an individual patient's responsibility and choice whether and to what degree they wish to engage. The second misconception is that empowerment concerns patient compliance and adherence [100], a claim opposed by researchers in the field [101]. This is an interpretation of empowerment that stands in opposition to the real purpose of empowerment, which regards the freedom and emancipation of patients based on adequate education and information. Third, HCPs claim that socio-economic factors make it impossible to empower some patients. However, even though self-management is a challenge to some patients, HCPs should try to enable patients to make autonomous and informed decisions. Fourth, HCPs are uncertain when to apply an empowering approach (e.g. whether it can fit the newly diagnosed patients). However, empowerment is an overall approach to diabetes education, not just a strategy; therefore, initial encounters with patients should concern the patient's role in their diabetes self-management. Fifth, according to a radical liberal interpretation of empowerment, some HCPs believe that the patient alone is responsible for their health situation. This is a misconception, as several factors determine patients' health situation, such as the quality of healthcare services, adequacy of self-management initiatives and predetermined genetic factors. Sixth, some HCPs believe that empowerment and self-management transpire automatically when patients are appropriately informed, which is not always the case. For this reason, patients should receive tailored help and information to facilitate the acquisition of the skills and knowledge required to improve self-management. These are the six examples of how misconceptions of empowerment threaten the adoption and exercise of empowerment in diabetes care [100].

Anderson and Funnell listed some questions that should be answered with a *yes* to achieve an empowering healthcare practice [100]. In transforming the questions to the scope of the present PhD project, it enables an assessment of PROs' empowering potential; thus,

a) Does a PRO help patients identify and address their primary diabetes concerns?
b) Does a PRO encourage them to talk about the emotional aspects of having diabetes?
c) Does a PRO help them identify and choose goals that are relevant and important to them?
d) Does a PRO respect their right to make decisions clashing with HCPs' recommendations?

These questions are pertinent considering the findings on the PRO experience of newly diagnosed citizens with type 2 diabetes [6]. The importance of empowerment and self-management in diabetes also makes a discussion on PROs' capabilities in this area relevant, especially when patients are responsible for 98% of their care [100].

4.1.3. TECHNOLOGY

This section presents different interpretations of technology, describing the relations between technology and humans, subsequently allowing considerations of a PRO as a technology in chapter 6. Due to the complexity of the included inputs, the theorists and their respective thoughts are presented one-by-one. First, the ideas in Martin Heidegger's *The Question Concerning Technology* [104] are explained. Second, Don Ihde's description of the field is outlined based on the books *Philosophy of Technology [60]* and *Postphenomenology and Technoscience—The Peking University Lectures* [61]. Third, Peter-Paul Verbeek's Mediation Theory, described in *Beyond Interaction: A short introduction to Mediation Theory* [105], is included as it builds on Ihde's thoughts on human–technology relations. Finally, Susan Leigh Star's concept *boundary object* is elaborated upon through her works *This is Not a Boundary Object: Reflections on the origin of a concept* [105] and *Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39* [106]. Boundary objects are not necessarily technologies, but Star's concept is placed here as a PRO's capability as a boundary object is especially linked to the digitalisation of the tool.

Question concerning technology

In the short presentation of key points in *The Question Concerning Technology* (1954), some explanations and concepts are omitted to keep it as simple as possible. In this essay, Heidegger discusses how technology constitutes the world and the relation between humans and technology. It is an interpretation of technology with a capital 'T', which indicates that Heidegger perceives technology as an ontology; it is technology that constitutes everything else: science, human life, etc. [104]. Consequently, technology is rejected as a neutral instrument or as a mere means to an end; technology actively influences human lives and is not just an object or tool of man [61,104]. Technology is formed by the concrete use context, and the knowledge is embedded in practice use. Hence, 'the "praxical" "knowledge" that Heidegger attributes to the manipulation of tools, equipment, is not "cognitive" but tacit' [61, p. 33]. In contrast, humans can be the tools of technology if we do not acknowledge technology's immense impact on our world. The author distinguished between traditional and modern technology and between technology and the essence of technology. Hence, '…the essence of technology is by no means anything technological' [104, p. 4], and the essence of modern technology differs from traditional technology in terms of impact and character. The essence of modern technology is labelled *Gestell*, translated into *enframing*, indicating that how we as humans perceive the world depends on the construction of the *enframing*. In Heidegger's own words, 'Enframing means that way of revealing which holds sway in the essence of modern technology and which is itself nothing technological' [104, p. 20]. Due to technology's decisive influence on human life, what matters is that we as humans master the technology and manipulate it based on human needs and values, instead of letting the essence of technology determine the shape of the world and human thinking. Heidegger's mission in revealing the essence of modern technologies is to let us know how technology has already shaped our world and what needs to change. The ambiguity in the human–technology relation is that on one hand, the technology constitutes our world, which can have immense negative consequences for humans, but on the other hand, it is the key to understanding the truth of the world, which Heidegger referred to as *revealing*. Hence, the true essence of the world is potentially revealed through technology. However, depending on the constitution of the *enframing*, technology can also influence the representation of the thing in a way that keeps the true essence hidden and instead provides an understanding based on the characteristics of modern technology, which concerns instrumentality, ordering, calculation, effectiveness, production and systemisation. An important aspect in this regard is that modern technology reveals nature and humans as a *standing reserve*, which means that they are considered a resource used by technology. This is why Heidegger believed that danger and freedom are found at the same place, as the technology that might reveal the world and set humans free also has the capacity to endanger human existence or the human aspect of human existence by shaping our lives according to the current *enframing*. Thus, for man to truly be free, he needs to ensure that the *enframing* is constituted in a way that enables humans to reveal the world in a more authentic manner emerging from human nature and not the essence of technology. As expressed by Heidegger, '…the challenging Enframing not only conceals a former way of revealing, bringing-forth, but it conceals revealing itself and with it That wherein unconcealment, i.e., truth comes to pass' [104, p. 27]. In other words, the ambiguity in Heidegger's work indicates that human–technology relations can not only improve human life but also destroy it, where we as humans have the opportunity and responsibility to actively consider the type of technology we develop and apply. Inspired by Heidegger's thoughts, we might ask what the essence of PROs is, what enframes PROs? How can the PRO technology affect human lives, in this case primarily patients and HCPs? These are the questions implicitly considered in the papers on PRO's purpose and functionality [2–4].

Philosophy of technology

According to Ihde [60], the philosophy of technology originates from pragmatism, positivism and phenomenology; however, Heidegger is especially credited as the grounder. As a result, the philosophy of technology is problem-oriented and focuses on concrete real-life problems. Another focal aspect of this branch of philosophy is its concern with inquiries of technologies in practice and the knowledge that aspires from actions in practice. Ihde referred to science, based on this philosophy, as technoscience, a concept coined by Latour, which means that science is embodied in technology, or put differently, science today is embedded in technology and dependent on technology. Due to the complexity of the technology concept, Don Ihde stuck to a descriptive definition, which entails that technology. Technology is connected with humans through various relations.

a) Consists of a concrete component.
b) Must be used in some sort of human praxis.
c) Is connected with humans through various relations.

Regarding human–technology relations, Ihde explained two things: (1) human–technology relations are *universal* and go way back in time, and (2) the shapes of the specific human–technology relations are culturally embedded, resulting in diverse praxes. These points concern technology that requires awareness when engaging in solving problems related to modern technology. Furthermore, technology is non-neutral and transformative of humans and the world, which is even more important to be attentive to in times of modern technology, where the magnitude and amplification of changes are even greater. In other words, progression and technology are closely connected, which can entail a utilitarian interpretation of technology, where the aim is *the greatest good for the greatest number*. Moreover, Ihde explained the distinction between technological determinism and social determinism. The former asserts that technology determines and constructs society, whereas the latter perceives technology as a controlling and oppressive power instrument applied by the elite (the groups in power). A decisive difference between the two approaches concerns the neutrality of technology; hence, social determinists see technology as a manipulatable tool controlled by the elite, whereas technology determinists perceive technology as non-neutral, influencing the shape of human lives. When explaining the philosophy of technology, Ihde accentuated three philosophers: Langdon Winner, Albert Borgmann and himself. Winner described how the use of technology creates new forms of human activity, new worlds. He explained that for technologies to work properly, humans need to adapt to them. In addition, he perceived artefacts and technologies as political instruments. Moreover, he stated that '…technologies goes where it has never been' [60, p. 105], which underscores how the boundaries of technology are constantly expanding, exploiting the Earth's resources in new places. Hence, Winner's primary concern was the limits of technology: At what point does the technological expansion stop? Albert Borgmann believed that 'technologies are like forms of life-they belong to complicated and non-neutral human praxes' [60, p. 106]. He described how there has been a liberal approach to technology, where technologies' progressive features and benefits to humans and the world have been emphasised. An optimistic understanding of technology praises humans' control over nature. The problem is, however, that even though, aligned with the liberal approach, technology might free humans to some extent, it cannot solve all human problems as promised. What the liberal approach to technology accomplishes, though, is to promote the importance of material goods and values aligned with quantitative thinking. Borgmann argued that technology is a sort of device paradigm in which various devices are applied as means to an end. Conclusively, Ihde remarked that 'Winner and Borgmann hold that (a) technologies are clearly not neutral; (b) they generate patterns of human praxis or worlds; and (c) that modern technologies have, in effect, taken over larger and larger territories of that human praxis' [60, p. 108]. Finally, Ihde emphasised his own work on technology, which concerns an interrelation ontology of human–technology relations. Ihde highlighted four types of relations:

- *Embodiment*: humans and technologies experience the world in unity, also characterised as a perceptual-bodily, symbiotic experience of the world (human – technology) → technology.
- *Hermeneutic*: the world is experienced and interpreted through technology and instruments, reading of signs created by technology.
  human → (technology – world).
- *Alterity*: concerns human–robot interactions,
  human → technology (world).
- *Background*: Situations in which technology acts as part of the context/background, human (technology/world) [60,61].

In all relations, technology acts non-neutrally and shapes how humans experience the world. Hence, technologies are, according to Ihde, analogous to forms of life or worlds. The human–technology relations are affected by the praxes, history and culture it is embedded in. Making it even more complex is the fact that human–technology relations are cross-cultural [60,61]. Therefore, Ihde indicated that 'only sometimes are technologies actually used (only) for the purposes and the specified ways for which they were designed' [60, p. 116]. This is an interesting statement in a

PRO context, where the purposes and functionalities of PROs have expanded due to their digitalisation and integration in clinical practice [2–4].

Mediation theory

Verbeek [107] was interested in the interactions between humans and things, as these are pivotal when designing technology. Hence, the focus is not on the things in themselves but on the interactions that are created between technology and humans. This is where mediation theory becomes useful, as it can be used to describe the relation between human practices and technology. Verbeek recognised that technology always affects human behaviour to some degree; therefore, we need to ensure that technology is created responsibly and desirably and beneficial to humans. Meanwhile, humans also shape technologies. Technology is not just something humans use; technologies are in many cases better understood as immersions or fusions, meaning that human behaviour is deeply integrated with technologies. Hence, technologies are not objects or instruments used by humans but acting entities, mediating, shaping and determining the human behaviour. Verbeek emphasised three relations among humans and technology:

- Extension: technologies act as tools for humans—a neutral role of technology.
- Dialectics: technology and humans have a dialectic relation—technology is alienating humans as it, to some degree, substitutes humans taking over physical (machines) and cognitive (automatisation) tasks.
- Hybridity: technology and humans shape each other—technologies are an integrated part of humans as reality is mediated through technologies.

As Verbeek indicated, technologies '…help shape how human beings can be present in the world and how the world can be present for human beings' [107, p. 4]. Verbeek suggested the following types of relations between humans and technology, which are additions to the four relation types described by Don Ihde:

- *Cyborg/fusion*: humans and technologies are a unit
  (human/technology → world).
- *Immersion*: interactive environments in which technology acts intelligently, monitoring and influencing human behaviour
  (human ←→ technology/world).
- *Augmentation*: When hermeneutic and embodied relations are combined:
  (human – technology) → world + human → (technology – world) [107].

According to Verbeek, the degree to which technologies affect humans depends on the type of influence they exert, as displayed in Figure 9.

	Strong	**Weak**
Apparent	Coercive	Persuasive
Hidden	Decisive/Implicative	Seductive

Figure 9. Technologies' degree of influence on humans [107]

As examples of coercive technologies, Verbeek emphasised safety belts and turnstiles that require tickets; persuasive technologies can be equipment providing one with feedback; location of technologies inside buildings affecting human interaction counts as a seductive technology and decisive/implicative can be structural entities having a greater impact on human behaviour (e.g. elevators or bridges). The consequence of the inter-relations between humans and technology is that technological mediation shapes the human condition. An ontological approach yields the conclusion that the design of technologies becomes pivotal in shaping the world and human conditions; hence, 'designing technology is designing humanity, in a sense' [107, p. 5]. The point is that we cannot avoid the impact of technology; what we can do is utilise technologies desirably by designing technologies that improve human freedom [107]. What is interesting in a PRO context on human–technology relations is the inter-relation between PROs and healthcare praxis, HCPs and patients.

Boundary objects

The concept of a boundary object is included as it seems reasonable to consider PROs and *PRO Elements* (Paper V) as boundary objects. The contextual and complex character of a boundary object makes its description difficult. This is the impetus behind Star's article titled *This is Not a Boundary Object: Reflections on the Origin of a Concept* [105]. According to Star, a boundary object is '…an analytic concept of those scientific objects which both inhabit several intersecting social worlds (…) and satisfy the informational requirements of each of them' [106, p. 8]. In this article, Star highlighted three components qualifying an object as a boundary object: internal flexibility, the objects' material/organisational structure and its scalability/granularity. Internal flexibility indicates that a boundary object is constituted by and represents different interpretations. This is a noticeable aspect of a boundary object that allows communication, coordination and collaboration across communities and disciplines, despite the existence of divergent perceptions. The boundary objects' material/organisational structure refers to how they influence informatics and work processes. A practice-oriented aspect emphasises how boundary objects might function across different organisational levels and in connection to various work processes in practice. The third component is related to the scalability/granularity of an object, underscoring the dynamic and adaptive nature and the ill-structured and structured use of a boundary object [105]. Hence, on one hand, boundary objects are flexible and contextually adaptable constructions formed by the needs and constraints instigated by users and stakeholders locally. On the other hand, boundary objects are robust constructs that promote a common identity, making them useable and relatable across sites. This implies that boundary objects are conceptually stretchable, meaning that they can be weakly structured and used on a general level, as well as strongly structured and applied for particular purposes in a specific context; hence, 'they have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation' [106, p. 8]. In other words, 'boundary objects are a sort of arrangement that allow different groups to work together without consensus' [105, p. 2]. Boundary objects can be both abstract and concrete entities but their '…materiality derives from action, not from a sense of prefabricated stuff or "thing"-ness. So a theory may be a powerful object' [105, p. 3]. Hence, these features comprising boundary objects make it relevant to consider and discuss *PRO Elements* and PROs' potential as boundary objects in a healthcare context. However, whether PROs and *PRO Elements* actually act as boundary objects in clinical practice requires contextual studies to capture the actions that constitute them as boundary objects. Star pointed out that boundary objects crop up and disappear in a continuous circular process within specific contexts, taking the form of either a *residual category*, *boundary object* or *standardised* object. Hence, the processual categorisation concerns how well structured an object is. *Standardised* refers to a situation in which a boundary object takes a specific form across contexts based on a broad consensus. However, standardised systems produce *residual categories*, which Star explained as contextual emerging categories that are not categorised or specified elsewhere. As the *residual categories* are spread to different contexts, new *boundary objects* emerge, which, in time, may turn into standardised objects [105]. This is a processual framing of the development of boundary objects, relevant to be considered when elaborating on PROs' and *PRO Elements'* potential as boundary objects.

4.1.4. PATIENT RECOGNITION

Patient recognition and *recognition* are key concepts in the PhD project, especially as part of the scoping review [1] and as themes included in the interviews conducted with citizens [6]. Definitions of patient recognition are difficult to find, but looking at the literature as outlined above, recognition of patients aligns with Eldh's interpretation of patient participation, which concerns listening to them and their needs, to see them as they are [77]. In the present project, it is also linked to Honneth's recognition theory [64] and the concept of patient empowerment. In this section, recognition is elaborated upon mostly based on Alex Honneth's recognition theory [64], which is based on the concepts included in Figures 10 and 11. Even though it might be bold, two additional layers are added to Honneth's theory of recognition, one on technology and another on empowerment, which is done to show how recognition plays a role in these areas. This is a modification entailing a mix of post-phenomenological ontology and the critical theory of recognition and a manoeuvre that enables us to apply the concept of recognition not only to human relations but also to human–technology relations, subsequently facilitating elaboration upon technological recognition issues linked to PROs.

Spheres of recognition	**Forms of recognition**	**Recognised by**	**Relation to self**
Love	Intimacy and love from close ones	Family and friends	Self-confidence
Rights	Legal rights	Civil society	Self-respect
Solidarity	Respect and solidarity	Community, society, work	Self-esteem

Figure 10. Recognition and the self [64]

Forms of disrespect	**Effects**
Physical abuse	Physical and psychological harm
Violation of legal rights	The person becomes an object
Social exclusion	Loss of dignity and honour, disempowerment

Figure 11. Lack of recognition and disrespect [64]

I have considered three options in the inclusion of technology and empowerment in Honneth’s recognition theory. First, technology and PRO can function as additional spheres of recognition. Second, technology and empowerment can function as overall contexts in which all other types of recognition and PRO are embedded, which is a type of general framework. Third is the impact of technology and empowerment on the different recognition spheres. The first and third options are chosen as these are deemed analytically most fruitful.

According to Taylor, humans have a basic need for recognition, as this influences our identity. In this context, Taylor distinguishes between the politics of universalism and difference. The former means that citizens have equal rights and value, while the latter emphasises the distinctive character and identity of individuals and groups, granting them specific rights [108]. This is a relevant distinction to consider in the discussion of PROs’ purposes and functionalities in healthcare [2–4].

Recognition is based on reciprocity. It requires autonomous individuals and groups who have the ability to recognise each other, thereby strengthening an individual's self and autonomy. In other words, recognition is based on independent individuals who are able to recognise others who are again dependent on others to recognise them. Hence, recognition is based on the idea that all have equal status as individuals with a right to be recognised, which, however, is not the same as being equal. Thus, recognition is an inter-relational and dialectic phenomenon, a behaviour that requires individuals to be emphatic and able to understand other people, their position and conditions. Recognition in practice is a moral action conducted in accordance with the value another person should have. Therefore, one cannot act solely according to one's own egoistic interests but needs to account for the recognition of the other person. Moreover, recognition is contextually embedded, as it varies what type of behaviours and actions deserve recognition in a society [64,108,109].

As Figure 10 illustrates, there are different spheres and forms of recognition. The three spheres stem from the original framework on recognition. Figure 12 presents the categories *human values* and *empowerment*, which are additions placing PROs inside Honneth's recognition theory. A theoretical suggestion to instigate relevant discussions on PROs, technology and recognition is made in chapter 6. This is a reasonable addition to Honneth's framework of recognition, as recognition is not necessarily limited to questions on moral and social matters [108].

Honneth's approach to recognition is normative and based on a morally motivated fight for recognition instigated by individuals and groups who lacks recognition. Hence, individuals and groups wish to fight the disrespectful treatment they experience by rectifying the lack of recognition they rightfully deserve. According to Honneth, the fight is social because the demand for recognition is a universal matter. Hence, the ideal and aim for Honneth is a society based on reciprocity and recognition, subsequently ensuring a healthy self [64,108].

Humans need to be recognised in three different spheres. The *love* sphere concerns an individual's experience of intimacy and love with family and other close relations. Based on Winnicott's theory, Honneth emphasised the symbiotic relation between a child and mother as decisive. Here, the child learns how close relations and love are based on reciprocity [64,108]. Recognition becomes an important aspect as the parent needs to balance the child's need for a symbiotic relation and gradual autonomy. This process should teach the child to be able to be alone based on an experienced trust, where the parent is ready to help if needed. These child experiences and primary relations influence the character of an individual's self-confidence. Hence, the logic is that sufficient love and trust and strong relations result in a self-contained person with healthy self-confidence. In contrast, failed relations as a child and disrespect through physical abuse (i.e. torture, rape and violence) negatively impact a person's self-confidence, as indicated by the physical and psychological damage the individual experiences [64,108].

The second sphere, *rights*, indicates that an individual should also be recognised by being granted their legal rights—a right that has been historically linked to an individual's social status. However, in today's society, such rights are somewhat universal, also linking this sphere to the democratisation of society. Importantly, the rights of a person are linked to normative obligations. An individual is considered a free person who is expected to act rationally, respect social norms, obey the law and treat others as free persons. Hence, in this sphere, recognition of others transpires through the acceptance of law. A system is based on the assumption that individuals are able and willing to follow the law. A person's self-respect is positively affected by the recognition of an individual as a legal person and negatively affected by the removal of rights, degradation and insults [64,108].

In the *solidarity* sphere, recognition concerns individual qualities. Thus, this sphere describes how we as humans need to be recognised as individuals and at the same time wish to be recognised as part of a group, community or society [64,108]. Whether others are solidary with an individual depends on that person's abilities, contributions and achievements. Thus, the recognition process entails both an individualisation process and a social inclusion process [108]. In this sphere, thinking is based on the principle of equality; hence, everyone should be able to become part of society and that of political, cultural and economic communities. However, to be accepted as a unique person, one must develop their self-esteem [108]. If an individual's identity, on the other hand, is disrespected and cannot be recognised, it impacts the person's self-esteem negatively [64,108].

Spheres of recognition	**Human values**	**Empowerment**
Forms of recognition	Freedom and control	Participation, access and use
Recognised by	Technology	PRO
Relation to self	Self-determination	Self-management
Forms of disrespect	A world based on the essence of technology	Disempowerment
Effects	Loss of control and obedience to technology	Lack of access to healthcare

Figure 12. Recognition, the self and disrespect – Human values and empowerment

The fourth sphere, *human values*, indicates that technological recognition is essential in the current digitalised society. Technological recognition is possible when technological development and functionality are based on human control, promoting freedom and human values. Subsequently, this will strengthen individuals' and groups' self-determination. If technology is based on the essence of technology, as explained by Heidegger, individuals and groups might lose control and become resources/means used by technology. This indicates the importance of incorporating human values into technology to recognise individuals and groups and avoid technologies that treat humans in a disrespectful manner.

The fifth sphere, *empowerment*, emphasises PROs' recognition of patients if PROs are to empower patients. PROs' recognition of patients entails that they are allowed to genuinely participate in PRO development, granted access to PRO data and allowed to use them, which subsequently enables the use of PROs as an empowerment and self-management tool. However, such recognition also implies that patients are enabled to use PRO data and that clinicians also use PRO data in clinical practice. In cases where PROs are developed and applied in a manner that does not recognise the patient, disempowerment and a lack of access to healthcare are the potential negative outcomes.

Honneth's original three spheres imply that recognition takes place on various levels: an interpersonal level, a group level and a societal level. Time is another issue, as recognition is a process that might change throughout an individual's life [108]. Hence, Honneth's theory does not concern the recognition between technology and individuals/groups, which is why Figure 12 incorporates human values and empowerment pertaining to technology and PROs, respectively.

4.1.5. DIABETES

The sixth study of the present PhD project covers the experience of newly diagnosed citizens with type 2 diabetes in PRO use [6] and the research stay at AAUH as part of the VBS PRO-DIA group also concerned diabetes. Therefore, this section describes different aspects of diabetes.

According to WHO, diabetes is '…a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves' [110, Diabetes section].

In general, there are two primary variants of diabetes, type 1 and type 2, in addition to type 1.5, and numerous rarer versions of diabetes. Type 1 is a chronic autoimmune disease most often discovered in children or younger people, whereas type 2 diabetes is a lifestyle and often age-dependent disease.

In 2018, approximately 280,000 citizens suffered from diabetes, which is approximately 4.9% of the total Danish population; 28,000 (10%) had type 1 diabetes, while citizens with type 1.5 diabetes[3] or type 2 diabetes amounted to 252,000 (90%). Hence, type 2 diabetes is the most frequent type. It is estimated that, by 2030, the total

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[3] The type 1.5 diabetes group comprises 10% of the total population but is part of the type 2 diabetes number as this is typical practice.

number of citizens suffering from diabetes will be approximately 430,000. The number of citizens with diabetes has doubled since 1996, and based on the calculations from 2011, diabetes costs 31.8 billion DKK every year.

What causes type 1 diabetes remains uncertain, even though heredity, environment, psychological factors, caesarean section and intestinal flora are generative mechanisms; however, preventive interventions and cures do not exist currently. The autoimmune aspect means that the body attacks and destroys healthy cells in the pancreas, destroying the body's ability to produce insulin. Consequently, citizens suffering from type 1 diabetes are required to inject insulin into their bodies to manage their blood sugar. Insulin is a hormone that helps transform carbohydrates from the food we eat into blood sugar and energy. This is the reason why insulin injection is linked to meal intake, where the types of food and physical activity affect the blood sugar level. Therefore, the right relations among food, exercise and insulin are pivotal in diabetes management, where the aim is to stabilise the blood sugar level. To facilitate this, blood glucose test strips are useful for monitoring the blood sugar levels. In clinical practice, these continuous and instant measures of blood glucose levels are complemented by the measures of patients' long-term blood glucose level, which shows the patient's average blood glucose level of the last two months. Thus, diabetes is diagnosed based on blood tests, where a blood sugar level of 7.0 mmol/l or above indicates that the citizen suffers from diabetes.

Similar to type 1 diabetes, there is no cure against type 2 diabetes; however, due to the lifestyle-related aspect of type 2 diabetes, healthy living enables disposed citizens to either extend or prevent the disease. However, when you are diagnosed with type 2 diabetes, it is a chronic condition lasting for the rest of your life. When suffering from this disease, you have low insulin sensitivity, which means that your body has problems utilising insulin and might not produce sufficient amounts. Consequently, instead of obtaining sufficient amounts of blood sugar and transforming it into energy, the blood glucose levels increase and make citizens with type 2 diabetes feel uncomfortable. Heredity, environment, lack of physical activity and overweight are the risk factors influencing a citizen's risk of getting type 2 diabetes [111].

In diabetes, comorbidity is a normal phenomenon, which is often linked to an unregulated long-term blood glucose level, blood pressure and cholesterol level. Other risk factors are smoking and heredity. Typical comorbidities are hypertension (high blood pressure), dyslipidaemia (abnormal cholesterol and triglyceride levels), cardio- and cerebrovascular diseases, retinopathy (eye disease), nephropathy (kidney disease) and neurotrophic diabetic ulcers (foot condition) [111,112].

Comorbidity means that citizens with diabetes often die earlier compared to the average population; however, today, prevention and management of comorbidity have significantly decreased the number of citizens with diabetes who die early or suffer from comorbidity. Nonetheless, excess mortality is 4–5 times higher among citizens with type 2 diabetes compared to the average population, especially due to cardio- and cerebrovascular diseases [112]. Stress and mental issues, such as anxiety and depression, are other common issues related to diabetes, which are important to be aware of since self-management of diabetes requires structure and surplus energy. In particular, considering that citizens, according to the Danish Diabetes Association, self-manage their diabetes 99% of the time, feeling physically and mentally fit is important. The burden associated with the self-management of diabetes is massive and emphasised as a focal stress factor; therefore, citizens are advised to seek help if the burden becomes an unbearable task that decreases their quality of life, generates self-blame and restrains people from going to work and spending time with friends and family. Thus, self-management is key when citizens have to handle their diabetes as part of their everyday life. In this regard, physical activity and exercise are accentuated as the main activities enhancing citizens' physical and mental well-being. However, often physical activity is not sufficient; hence, medication, adjusted eating habits, smoking cessation and regular visits to the doctor are required. Overall, the aim is to reach a satisfying long-term blood glucose level.

As a newly diagnosed citizen with diabetes, the Danish Diabetes Association and the municipalities are valuable institutions. The Danish Diabetes Association offers valuable information. Municipalities also offer professional help and financial support concerning additional expenditures incurred by citizens due to their diabetes treatment. Treatment of citizens with diabetes is coordinated and organised across sectors, due to the need for various treatments across medical specialities, rehabilitation and professional counselling. This cross-sectional organisation of the diabetes area is one of the main reasons why a functional IT infrastructure is required. Citizens with type 1 diabetes are typically treated at a hospital or an outpatient clinic, where citizens with type 2 diabetes regularly consult their GP [111]. The occurrence of type 2 diabetes is often linked to socioeconomic aspects and age. This means that citizens suffering from type 2 diabetes might have fewer resources, low functionality, lower adherence, lower quality of life and a high average age, making self-management and proper use of the healthcare system challenging [111,113].

CHAPTER 5. FINDINGS

I have no idea, you might as well have asked me about a location on the dark side of the moon.

Informant D

In this chapter, the findings of the project are described. First, the findings obtained from fieldwork and participant observations in different contexts are outlined. These findings are not published anywhere else, as the scope of the fieldwork was to enhance my pre-understanding of the field and PROs. Additionally, the fieldwork strengthened my network, eventually allowing me to conduct qualitative studies on PROs. In the second part, results on the research questions comprising the PhD project are presented. The results stem from the project's six studies described in the research papers referred to throughout the thesis (Papers I–VI). Even though the studies are different in scope, they share a common subject field, which is PROs as part of clinical practice, post their digitalisation considered from a patient participatory perspective. This chapter primarily focuses on the results of the studies, and the background justifying the studies is explained in the six research papers constituting the PhD project and in chapter 1 in the present dissertation. The studies are presented in chronological order, meaning that the initiation of a study in the research process determines when the study appears in the following presentation. The adopted methods and included materials/ participants are described briefly, whereas the findings are unfolded in more detail. The first study, *The association between Patient-Reported Outcomes (PROs) and patient participation in chronic care – A scoping review* [1], concerns the research question 'How are PROs and patient participation associated?'. In the second study, *Experts Perception of Patient-Reported Outcomes (PROs) in a Danish Context* [2], the research question 'How do experts perceive PROs in a Danish context?' is answered. The third study, *The Digital Transformation of Patient-Reported Outcomes' (PROs') Functionality within Healthcare* [3], regards the research question 'What are the functionalities of PROs?'. Fourth, a document analysis examines the research question 'What are the purposes of PROs?', which besides an outlining of purposes, results in a reconceptualisation of PROs, described in the paper *The purpose of Patient-Reported Outcome (PRO) post its digitalization and integration into clinical practice: A redefinition resembling PROs theoretical and practical evolvement* [4]. In the fifth study, *Exploring, describing, and mapping the constitutive elements of Patient-Reported Outcomes (PROs) used in clinical practice* [5], an interdisciplinary concept map is developed to answer the research question 'What elements constitute a PRO in clinical practice?'. In the sixth study, *The Experience of Citizens with Newly Diagnosed Type 2 Diabetes with the use of Patient-Reported Outcomes (PROs) in a Municipal setting* [6], the following research question is investigated: 'How do newly diagnosed citizens with type 2 diabetes experience and perceive PROs when applied in practice in a municipal setting?'

FIELD STUDIES

As described in chapter 3, fieldwork and participant observation took place in four different contexts, at the

a) PRO development workshops hosted by the PRO secretariat.
b) Quarterly meetings on a regional level with the PRO project group.
c) Weekly meetings with the VBS PRO-DIA group at AAUH.
d) CfD, where the use of PROs was observed in practice.

In this section, observations and experiences from the fieldwork are described; however, findings from the study at the CfD are outlined further down. The experiences and knowledge attained from the three former fieldworks are not considered primary data but have been used throughout the project as it

- Provided access to different settings and stakeholders.
- Enabled the conduction of studies.
- Inspired studies of PROs' purpose and functionality.
- Granted me with knowledge and an improved understanding of how a PRO works in practice at various levels.
- Facilitated comparisons between literature findings and how a PRO functions in practice.
- Allowed the identification and recruitment of the experts participating in the second study (Paper II).

During the fieldwork activities, intentionality has deliberately directed actors' perceptions of PRO and the types of issues and challenges faced in the different contexts in their work with PRO.

5.1.1. PRO DEVELOPMENT WORKSHOPS ON A NATIONAL LEVEL

Various topics were brought up during the eight workshops hosted by the PRO secretariat. In general, the stakeholders were highly engaged during the workshops. Due to the character of the fieldwork and to ensure that the participants stay anonymous, empirical findings are purposely not traceable to a specific workshop or person but are presented in a general manner. This section gives an impression of the types of themes discussed during the PRO development and discloses issues considered by central stakeholders.

Development of PRO questionnaires

The PRO questionnaire needs to be not too long, simple, meaningful and comprehensive to not burden the patients too much. However, a participant explained that in his experience, clinicians worry more than necessary, as patients often are happy to participate when it concerns their health, even if the questionnaires are considerably long. In contrast, it is underscored that the questionnaire contains several themes and that patients have different resources. In the case that a comprehensive questionnaire is preferred over a simple one, it should be ensured that the PRO scores are used for something in clinical practice. How to ensure that all relevant elements were part of the questionnaire was a topic as there was a trade-off between content validity and the questionnaire's length. One idea was to let the PRO questionnaire evolve along with the patient, meaning that patients should receive a questionnaire resembling their current disease situation. Others suggested the creation of a conditional branching questionnaire, allowing it to be tailored to patient needs. How often the PRO questionnaire had to be answered was another topic; it had to not be too frequent and either be adjusted to what made sense in clinical practice or adapted to patient needs. Similarly, it was discussed how long before the consultation patients were to receive the PRO questionnaire, where 14 days was suggested based on experiences from other disease areas. Another matter concerned whether everyone should complete the questionnaire, including the newly diagnosed citizens—a subject participants seemed to disagree on. In this regard, it was emphasised that it only made sense to distribute the questionnaire to those who could properly answer it. Regarding the content, some participants argued that positive and empowering questions had to be incorporated to prevent the questionnaire from focusing only on problems, as it potentially has a negative effect on patients. In addition, the questions needed to have an individual character instigating a productive dialogue on the patients' disease situation. The balance in content was a central theme as well: how to reach an appropriate balance between questions on medical, physical, diet and psycho-social issues. Whether to include questions regarding existential issues was also debated. Several participants made it clear that citizens' health and existentialistic problems had to be separated; hence, questions with an existentialistic character ought to be excluded. The inclusion of questions concerning self-management was debated as well, which were linked to patients' health literacy; hence, it was discussed how to include and unfold issues on such matters. Health literacy levels need to mirror the capabilities of patients and be constructed in a proper language, a language that is understandable to both patients and HCPs. The importance of determining the purpose of the questionnaire in the development context was also emphasised, as a PRO used as a visitation tool probably has to be more specific than a questionnaire solely used as a dialogue tool. There was consensus on the fact that the PRO had to comprise both generic and disease-specific questions. The balance between closed and open questions was discussed as well; hence, too many open questions were problematised, as it is uncertain how HCPs are supposed to handle this information. It is important that a PRO is easy to interpret and apply in clinical practice; therefore, closed questions were suggested, which should be able to instigate a dialogue. Furthermore, there was a fear that HCPs might not use PROs if too many open-ended questions were included. In contrast, it makes no sense to develop very specific PRO questions if the aim is to obtain the patients' perception of their disease situation. Hence, the construction of the questions was a focal theme. The discussion was closed by a participant who pointed out that the pilot tests would provide empirical evidence regarding patients' experience with the questionnaire that would likely shed more light on content-related issues. The pilot tests were also supposed to clarify whether users would need to be educated on the use of PROs and whether the application of PROs in consultations requires additional time and resources. The development of a questionnaire from a *one-disease perspective* was another concern, especially in cases where patients suffer from multiple chronic diseases. Are these patients supposed to complete several different PROs? In this context, it was emphasised how PROs were potentially a huge benefit to chronic care with the increasing numbers of patients suffering from chronic conditions, and at the same time, it was underscored that PROs might lead to health inequities. A participant explained that it had to be transparent whether a condition was caused by diabetes or something else, and that the causality between cause and effect was clear. In other words, if problems were caused by other diseases, it should be clear in the questionnaire.

Use in clinical practice

Participants expressed that clinicians must recognise the efforts and patient burden the use of PROs entails, which is done by using the available PRO data in consultation with the patients. Therefore, the importance of providing feedback to the patients based on the PRO data was accentuated several times by the participants. There was no consensus regarding whether patients in PRO use should be explained what a PRO is, as some considered it an insurmountable task. Therefore, it was suggested that videos should be produced to guide patients and explain the purpose of a PRO. The relevance of purpose and meaningfulness from a patient's perspective was deemed important, as it was deduced that such things can affect the response rates. A practical point concerned the positioning of the computer screen displaying the PRO data during consultations, which should be positioned in a way that allows patients and HCPs to see the PRO scores jointly. When using the PRO data during the consultation, attention is paid to patients' health problems (red/yellow issues); however, positive results and progression should also be included in the dialogue with the patient to facilitate a more supportive approach (green issues). The scarce time available during consultations should prioritise the interpersonal patient–HCP dialogue and not simply unfold as a scrutiny of PRO data on screen. Hence, the PRO questionnaire should frame the patient–HCP conversation while allowing a holistic approach with a focus on the patient. Matching expectations was a focal topic; specifically, patients cannot expect clinicians to automatically go over all topics contained in the PRO questionnaire. Conversely, they have a right to expect that the focus areas included in the PRO questionnaire will be discussable during the consultation. A minor problem, according to a participant, as patients have a good understanding of how time is a limited resource in clinical practice and that the number of issues requiring attention based on PRO data is typically limited. In practice, a PRO provides an easy overview of a patient's disease situation, and the interpretation of PRO scores is quite intuitive and unproblematic. Nonetheless, the interpretation of the different colour categories and the types of clinical actions required was a concern to some participants (e.g. that the algorithms analyse and sort the PRO data). To ease the use and interpretation of PRO data, scores should be presented simply and should not contain several long textual explanations. Another participant argued that clinicians are obliged to take action on the topics included in the PRO questionnaire independent of the number of issues and the clinicians' expertise, emphasising that the PRO-based treatments should be tailored to patient expectations and not clinicians' needs. This is an expectation which demands a functional referral system to assist clinicians in cases where PRO data disclose issues positioned outside clinicians' area of expertise. Subsequently, there needs to be a clear link between the content of the questionnaire and the referral options to ensure that patients' alarming issues are actionable in clinical practice. In other words, PROs need to have clinical value. This also means that for PROs to function as part of clinical practice, they must be supported organisationally through the construction of functional technological infrastructure. Thus, a link between PROs and other data and the instruments used in clinical practice would be beneficial as well; for example, one should be able to compare PRO data with KRAM factors and other types of clinical data. If PRO use is not supported through adequate referral systems and sufficient time, it might result in HCPs not using PROs. A participant pointed out that the causality might be reversed, meaning that a PRO is a tool that paves way for organisational changes. Awareness on how PROs might influence clinical workflows was another central subject; some believed that PROs would have quite an impact on clinical workflows, while others presumed that it more or less involved the same work tasks, why changes would only be minor. However, those who had clinical experience in PRO use explained that the impact on workflows was substantial, especially for the nurses who mainly handled the PRO answers. Data security was another concern, as the security of data and how it was shared had to be handled properly. Table 4 illustrates the themes discussed in the workshops concerning PRO use in clinical practice, indicating what might require attention in PRO use in clinical practice.

Table 4. Themes concerning PRO use in clinical practice

The useability and value of PROs in clinical practice
Guidelines on how to use PROs in clinical practice
PROs should be patient-oriented: adjusted to the needs of patients
When and how often should PROs be completed?
The patient perspective is important but the HCPs' professional knowledge should also be acknowledged in the use of PROs
What does PRO offer to clinical practice that we do not already have?
What is the purpose of PROs in clinical practice? How are we supposed to use it? Is it for screening tool or to diagnose patients?
How many resources should be used for the implementation and use of PROs?
How do we know this technology is not a failure, like previous systems?
On one hand, patients should not have to complete PROs right away; on the other hand, PROs would provide value to the initial meetings with patients?
Do PROs contain a learning element for clinicians?
PRO is different from traditional clinical data, which is why PRO provides value.
PRO offers a holistic impression of the patient's health status.
Do the issues elicited by PRO data align with the knowledge and qualifications that doctors possess and the type of work they are supposed to handle?
How is data security ensured? Who has access to the data?
PROs might elicit issues on patients conditions, which HCPs priorly have had a difficult time getting access to.

Substance, purpose and functionality of a PRO

The participants also debated the substance, purpose and functionality of PROs. Note that PROs do not elicit the full patient story but reveal particular aspects of an individual's disease situation. A participant pointed out that a PRO is a tool complementing traditional approaches or data, not a substituting tool. However, the purpose of the measures are different. Traditional measures have been used to predict death, whereas PROs can be used to predict changes in a patient's disease situation. Some believe that PROs can enhance patient compliance, whereas others underscore that the purpose is not to make patients compliant but to improve the treatment they receive. Therefore, one said that the *controlling* approach should be abandoned and substituted with a *goal-setting* approach; hence, the hope is that PROs can be used as a goal-setting tool. Moreover, it was considered whether the increased responsibility placed on patients is beneficial or problematic if patients can handle the responsibility constructively, and to what extent PROs might lead to inequity in healthcare. PROs were also seen as a visitation tool used to identify patients' health status and ensure they receive the best possible treatment. Thus, PROs can elicit patient needs, and the HCP's job is then to offer the patients the most adequate treatment. The participants disagreed on whether algorithmically based visitation systems are applicable as part of diabetes care. Furthermore, a PRO was considered a symbol of cultural change in healthcare, as the QoL content provided by a PRO entailed a paradigmatic shift. The traditional focus in clinical practice has been on treatment; however, the integration of PRO, clinicians and patients can enhance patients' QoL. The traditional perception of clinical practice was also represented in the workshops, represented by the following comment: *What are PROs actually supposed to measure? The tool is not made for the sake of the HCP!* When used in clinical practice, a PRO is meant to enable structured, effective and focused patient–clinician dialogues, based on the patient perspective. This is a feature considered in favour of the less resourceful patients, as it might help them verbalise important issues in conversations with HCPs. Furthermore, a PRO allows patients to detect problems and assist in the handling of their disease; hence, PRO was also considered a self-management tool. This is a functionality linked to patients' access to their PRO data at Sundhed.dk, which can allow them to follow their disease progression, formulate individual goals in relation to their health and learn how to handle their disease more beneficially. The primary use of PROs concerns its use for clinical practice patients; research purposes are considered secondary. Whether the primary user was a clinician or patient seemed more difficult to determine. A PRO's capabilities as a management tool were emphasised, and one of the participants warned the others with a belief that all future healthcare work will be measured and assessed in detail because of instruments like PROs. Irrespective of the use of PROs, their usability depends on individual patients, and all patients are very different. Various participants asked the question *Is this PRO?*, disclosing that they were insecure about what a PRO is, which, among other things, inspired studies on a PRO's purpose and functionality contained in the present PhD project (Papers II–IV). The themes discussed are displayed in Table 5.

Table 5. Perceptions of PROs as part of clinical practice. PROs concern

Patient information
QoL
Physical functionality
Improved treatment of patients
Clarification of patient needs
Individualised treatment
Patient pathways
Goal-setting
Psychological and cognitive functionality
Social functionality
Pain and other side-effects
Education of patients
Self-management issues
Improved dialogue with patients
Socioeconomic issues
A holistic perspective on a patient's disease situation
Visitation of patients
Coordination and sharing of patient data, potentially improving collaboration across providers and sectors
Promotion of patient participation
Science and research
Assessment and benchmarking of healthcare providers
VBHC
Improved quality in healthcare
Management of healthcare on a national, regional and local level

Implementation

The implementation of PROs was also discussed, where generic implementation across sites was favoured and the information and education of HCPs and other key actors were recommended to facilitate the implementation process. Hence, guidelines and professional knowledge and assistance on how to use and interpret PROs were considered important to ensure the use of PROs in clinical practice. The workshop participants considered themselves to be focal ambassadors and frontrunners, responsible for spreading PRO knowledge to make the implementation process smoother. In the PRO implementation, clinicians should be made aware regarding the effect on clinical workflows, as PROs might result in additional work for clinicians.

Patient perspective

During the patient workshops, the participants had a positive attitude; they were highly engaged and, in general, seemed to appreciate the PRO questionnaires. The questionnaires were not considered an annoyance; the patients underscored that the information provided by a PRO was useful, that PRO use was meaningful to them and that the questionnaires were relatively easy to understand and complete. They believed that a PRO, as a dialogue tool, was useful and made sense. The patients preferred if issues concerning loneliness and psychological problems were included as well, even if the physician had no idea how to treat it, as they imagined that the physician would be able to refer them to another health professional, who then would be able to help. It was important to the patients that the questionnaires were specific. Another topic was data security; hence, patients wanted to be sure that their data were handled securely. The patients realised how a PRO can place more responsibility on their shoulders, which is why one patient underscored that the HCPs were the ones who are responsible for the treatment—it is their job—and that treatment responsibility should not be placed on the patients. Some of the patients got the impression that they were the ones who had to decide the type of treatment they needed, which was problematised. *Are we really able to do this?* Themes on the handling of their disease, such as the right type of diet, how to manage one's blood sugar and the importance of an active lifestyle, were central topics. They opinionated that knowledge and advice need to be as concrete as possible to make them useful in self-management activities. Even though only a minor segment of the patients used Sundhed.dk, they would like the PRO data to be accessible at Sundhed.dk to visually follow their disease progression. For the same reasons, the patients would prefer PRO data to be accessible to their GP. Hence, one patient believed that the ability to track changes can have an empowering effect. Even though PRO data at Sundhed.dk might be useful, a patient underscored that they would still like to be able to contact an HCP to discuss future test results.

5.1.2. MEETINGS ON A REGIONAL LEVEL

Participation in the regional PRO project group in the Region of Northern Jutland provided me with new and useful knowledge and a useful network in the field. The meetings were held quarterly; hence, I participated in approximately 20 meetings, which granted me access to PRO arrangements in the region. Hence, I had the opportunity to experience the presentation of a newly developed PRO instrument in psychiatry and to participate in a PRO workshop where professionals from various disease areas in the region shared their knowledge and experience regarding PRO use. By attending the meetings, I gained an understanding of the difficulties faced when implementing and spreading PROs in a regional context. It was clear that attitudes towards PROs varied with disease areas, hospitals and clinicians. Moreover, the increasing number of disease areas that PROs were spreading to and how PRO demand seemed to constantly increase were striking observations. PROs' functionality as a visitation tool potentially enabling an economically efficient healthcare system was a highly valued functionality at this level. This priority was likely caused by the fact that the group had to report to decision-makers; hence, it became clear that, for a PRO to be supported by those managing the healthcare system, it had to generate not just qualitative but also economic gains. This is a logical prioritisation considering that the regions in a Danish healthcare context function as economically responsible operating units. As the project group consisted of HCPs, PROs' qualitative functionalities in healthcare were appreciated internally; hence, when introducing PROs to HCPs in various disease areas, these aspects of PRO were highlighted. Importantly, the group meetings confirmed that my work on PROs' purpose and functionality was a useful scientific contribution as this knowledge provided value at this level. This is especially true as the group had to communicate about PRO to decision-makers and internally to HCPs. Therefore, it was interesting to be part of a group in which the many functionalities of PROs was constantly a topic being discussed, because PROs' functionality often had to be clarified within the specific disease areas.

5.1.3. PARTICIPATION IN THE VBS PRO-DIA GROUP

The meetings in the VBS PRO-DIA group concerned the clinicians' continuous experience with PRO use, the PRO research project the group was working on, the pilot testing of the national PRO questionnaire within diabetes and the planning and discussion on the studies I was to conduct as part of my PhD project. Overall, the numbers of group meetings, the researchers running the group and other activities with the group members resulted in approximately 40 meetings and activities. The participation revealed the complexity in implementing a PRO system in clinical practice, which, for example, required proper integration into IT systems and considerations on how PRO would affect clinical workflows. The project nurses in the group were highly engaged in the project, and my impression was that they were quite satisfied with a tool like PRO as part of clinical practice. Hence, PRO had, according to the nurses, some positive effects on consultations with patients. Being part of another research environment and culture helped me understand how PRO was handled and perceived in this environment and on a broader scale and how the assessment and perception of PRO from a positivistic approach deviates from the techno-anthropological approach. The fieldwork also disclosed differences in scientific practices; thus, the group leaders required that my studies be ethically approved and that I prepare a clear and thorough study protocol. Common requirements in medical science, which had little relevance in my studies, but due to the context of the studies and because these were the requirements to gain access to the field, I engaged in these tasks. The national PRO questionnaire, being pilot-tested by the group, consisted of several instruments developed by the group. To me, this is an interesting ethical and scientific issue. Thus, it is problematic when those developing the questionnaire, those who gain from its success, are the same as those who evaluate the value and functionality of the tool—incentives that potentially affect the validity of the research findings. This situation can explain why my access to conducting critical studies was unexpectedly difficult. As explained in the Method chapter, the stay taught me that polite and respectful participation is not always enough when trying to gain access to conduct your studies. Sometimes, diverging interests might function as a barrier in a research context.

ASSOCIATION BETWEEN PRO AND PATIENT PARTICIPATION

In the first paper, *The association between Patient-Reported Outcomes (PROs) and patient participation in chronic care – A scoping review* [1], the aim was to examine the association between PROs and patient participation in chronic care. The applied method was a systematic scoping review based on PRISMA-ScR guidelines. The study findings were based on the inclusion of 84 scientific articles on PROs. The research question answered in this paper is 'How are PRO and patient participation associated?'

5.1.4. RESULTS—PAPER I

The inquiry was exploratory and inductive, as the aim was to identify as many connections as possible between PROs and patient participation, which was best done through an open approach. The included studies disclosed that the connection between PROs and patient participation concerned the following themes:

a) PRO development
b) Response rates and patient burden
c) Patient empowerment and self-management
d) Display and quality of data
e) Patient–clinician communication
f) Shared decision-making
g) Organisational and attitudinal aspects

PRO development

In PRO development, patient participation is acknowledged to be important methodologically and normatively and to validate the tools. Four of the studies included in the scoping review found that patient participation is adequate, in respectively,

1) 9 out of 26 examined development processes
2) 6.7% of the examined development processes
3) 6 out of 26 examined development processes
4) 3 out of 14 examined development processes

As these studies illustrated, satisfactory patient participation is relatively low in the development processes of PROs. Hence, the quantity of patient participation is an issue, and at the same time, qualitative issues are challenging. Accordingly, two additional studies revealed that citizens with low literacy skills tend to be excluded from PRO development processes. This exclusion is typically caused by the eligibility process, where this type of patient is removed due to the shaping of the recruitment materials and/or because the administrative methods are not tailored in accordance with the demanded reading levels and the cognitive abilities of the citizens. Therefore, equal access and a lack of validity of PRO tools are some of the problems faced in several of the current development processes of PROs. By increasing patient participation in the development processes, the PRO instruments' reliability, sensitivity, interpretability, validity, meaningfulness, relevance, holistic capabilities and ability to reflect the patient perspective can be improved. Additionally, appropriate PRO instruments assume that they positively affect the response rates and ensure more efficient use of resources, as valid instruments require fewer corrections and are more likely to be used in clinical practice.

Response rates and patient burden

The next theme concerns response rates and patient burden. Four of the included studies indicate that completion rates of PROs vary based on the following response rates:

- 54%–70%
- 55%
- 81%–98%
- 85%–95%

The response rates are identified to be affected by several factors pertaining to respondents and setup, such as

- Age.
- Severity of disease.
- Ethnicity and language fluency.
- Socioeconomic status.
- Gender.
- Procedure type.
- Health literacy and reading level.
- Cognitive and physical capabilities.

Five of the included studies found that the reading levels of PROs are too high. Recommendations suggest that reading levels resemble fifth- to sixth-grade levels, whereas the scrutinised PRO questionnaires required seventh- to ninth-grade reading levels. One study found a link between socioeconomic status and patients' electronic accessibility, subsequently affecting this patient group's degree of participation in their health management. Patient preference varies in terms of the location of completion of PRO questionnaires. On one hand, patients prefer completion in a homely environment, as the subsequent appointment is then less time-consuming, and it offers a more flexible process as completion is not carried out at a specific time or within a delimited timeframe. On the other hand, when completing the questionnaire at the site, professional assistance is at hand and the tasks related to the patient–clinician consultation are gathered at one point in time. Patients with low health literacy form an interesting case as their situation indicates that privacy during completion is highly valued, suggesting completion in homely settings, whereas assistance from an HCP in a healthcare setting is beneficial in cases of uncertainty and practical questions. This is a task that familiar relations might undertake, enabling the completion of PRO questionnaires at home if preferred. Essentially, the location of completion should be individually adjusted to facilitate higher response rates and lower patient burden.

Display and quality of data

To promote PRO-based patient participation, the display and quality of data must be in accordance with patient and clinician preferences. In general, clinicians tend to demand more extensive disease information, directionality in data and a more detailed statistical analysis of results and indicators on the clinical significance of PRO data. Both patients and HCPs appreciate simple linear graphs, an option to follow disease progression over time and informative support facilitating a correct interpretation of scores. Henceforth, appropriate information related to the severity of symptoms and disease-related issues to be aware of are prioritised by PRO users. For patients, textboxes allowing qualitative inputs is a preference, and the importance of contextual information is emphasised as well.

Patient empowerment and self-management

Based on the insights obtained from 10 different studies, PROs

- Enable an increased focus on disease-related issues that matter the most to patients.
- Ensure a more holistic approach to patients.
- Enhance patients' understanding of their health, disease and treatment.
- Promote disease-related reflections, leading to increased attention on psychosocial issues and symptoms.
- Help patients distinguish between disease-specific and general symptoms.
- Equip patients with an improved disease-related vocabulary, which enables them to discuss troublesome issues that were previously overlooked (i.e. sexual functionality, psychosocial issues, sadness and anxiety).
- Might have an empowering effect on patients, indicated by an increased sense of control, ownership, motivation and a feeling of autonomy.
- Give a sense of improved well-being and self-perceived health.
- Improve goal-setting, disease activity and self-management.
- Can be used in patient–clinician consultations, have a positive effect if patients receive feedback on PRO answers, can structure conversations and patient thinking and provide a useful overview of the patients' disease situation.
- Improve patients' decision-making ability.
- Enhance adherence to drug regimes.

Antecedents to PROs' empowerment and participation capabilities pertain to:

- Patient education in general.

- Information on how to instigate behavioural changes.
- Educational programmes on physical and mental well-being.
- Individual HCP characteristics enabling confidence, motivation, involvement and good communication and collaboration between the actors.

Patient–clinician communication

How PROs affect communication during patient–clinician consultations has been extensively examined, and the overall conclusion is that PROs both enhance and increase communication. In more detail, PROs

- Promote patient-centred communication.
- Enable patient-driven consultations, where the patients' perspectives and disease experience are in focus.
- Provide the actors with a shared understanding of the patients' health status.
- Allow the identification of patients' unmet needs and formerly neglected or unrecognised concerns and issues.
- Offer disease-specific information and encourage conversations on symptoms, HRQoL, treatment and functioning about social, sexual, emotional and psychosocial issues.
- Lead to patient–clinician consultations, which are both more effective, as central issues are discussed right away, and productive, as talks are more holistic.
- Facilitate interprofessional communication.

Several factors facilitate improved patient–clinician communication and patient participation (e.g. how PRO data are engaged in the consultation to influence its utility in the communication). Thus, jointly reviewing the PRO data on the clinician's computer screen or their printed summaries are possible solutions to ensure improved patient–clinician communication. Hence, the positioning of the clinician's computer screen and how the actors are physically positioned in the room require consideration. Another relevant point is the clinicians' approach to the PRO-based dialogue. Hence, a positive and encouraging approach acknowledging patients as partners in the dialogue is necessary to allow the productive use of PROs in patient–clinician consultations.

SDM

Knowledge on PROs' effect on SDM is scarce, whereas the reverse causality (i.e. SDM's effect on PRO) has been examined. Thus, the character of SDM affects patients' PRO scores. In other words, a poor SDM leads to worse PRO scores, whereas sufficient SDM has a positive effect on the scores. Other studies have focused on patients' attitudes and preferences related to decision-making. Essentially, the extent to which patients wish to participate in decision-making varies and is an individual matter. Hence, studies demonstrate that what matters is that there is a clear link between a patient's preference for the degree of participation in decision-making and the extent to which they are allowed to partake in the decision-making process. Acknowledging patients' needs in this context can improve their subjective outcomes in the form of PROs. The tendency, however, is that most patients wish to actively participate by sharing treatment responsibilities with the clinicians. As in the case of communication, the success of SDM and patient participation in decision-making during patient–clinician consultations also depends on clinicians' actions. Thus, encouraging, motivating and engaging clinicians, providing the necessary feedback on PRO answers, increase the chances of patient involvement in SDM.

Organisational and attitudinal aspects

The issues that pertain to either an organisational level or that might be changed as an effect of organisational alterations, in other words, issues on an organisational level that function as enablers or barriers concerning the connection between PROs and patient participation are described as follows:

- *Education of clinicians and patients*: Clinicians and patients need systematic education on the purpose, functionality and hands-on training in PRO use.
- *Use of PROs*: One study has shown that clinicians find QoL data useful in 42% of patient–clinician consultations; this number underscores the varying use of PROs. In some cases, HCPs neglect, normalise or downplay the information provided by PROs. This is an issue, as patients' expect that the use of PRO instruments in patient–clinician consultations matches the work they have invested into the completion of the questionnaire.
- *Attitudinal and cultural barriers*: Clinicians' perceptions are heterogeneous. Some reckon that PROs can enhance patient-centredness and patient–clinician consultations, whereas others believe that PROs have negative effects on practice, quality of care and the patient–clinician relation. Patient attitudes are another barrier to consider; hence, patients must understand that PROs are more than a data-collection or time-saving instrument, and that PROs have potential value for them and others in a similar situation.
- *Structural barriers*: Accessible and useful support systems and appropriate mediation of PROs are focal to ensure that clinicians use PRO systems correctly.
- *Organisational barriers*: PROs influence workflows, and vice versa; hence, the utility of PROs in clinical practice is a contextual matter. Workflows determine how PROs are used and administered, and PROs might alter workflows, often through additional and changed working tasks. Thus, it is important to consider how PROs and workflows affect each other, to ensure that there is synergy between the two, ensuring that PROs facilitate enhanced workflows and workflows do not function as barriers to PRO systems. Time and resources are some of the most frequently mentioned barriers. Time is of relevance when interpreting PRO data while integrating them into the patient–clinician consultations. A PRO offers a holistic perspective on a patient's disease situation, which means that interpretations can be complex

and that more disease-related issues are elicited in the patient–clinician consultation. At the same time, PRO consultations are often expected to have the same duration as prior consultations. Hence, there is a noticeable clash that might affect PRO-based patient participation. On one hand, PROs are expected to ensure more efficient use of resources and time, resulting in shorter or at least similar consultation times, and on the other hand, PROs are expected to integrate the patient perspective, have a holistic approach to the patient and ensure qualitative better consultations [1].

FUNCTIONALITY AND PURPOSE OF PROS

The following research questions are examined in the present section: 'How do experts perceive PROs in a Danish context?', 'What are the purposes of PROs?' and 'What are the functionalities of PROs?'. These questions were examined in three different studies using the methods of document analysis and semi-structured interviews. The results are disseminated in three different papers (Papers II–IV). In the second study of the PhD project, *Experts Perception of Patient-Reported Outcomes (PROs) in a Danish Context* [2], the objective was to attain an improved understanding of how experts in a Danish context perceived PROs. This was done to achieve an improved understanding of PROs, to identify the differences between perceptions on a regional and a national level and used as an indication of the direction in which PRO is heading in Denmark. Next is the paper *The Digital Transformation of Patient-Reported Outcomes' (PROs') Functionality within Healthcare* [3], which concerns the functionalities of PROs. This article aims to identify PRO functionalities, to scrutinise how PRO functionality has changed after its digitalisation and integration into clinical practice and to consider how stakeholders are related to the identified functionalities. In the fourth paper, *The purpose of Patient-Reported Outcome (PRO) post its digitalization and integration into clinical practice: A redefinition resembling PRO's theoretical and practical evolvement* [4], the objective is to identify purposes of PROs after their digitalisation and integration into clinical practice. The paper elucidates how the purpose of PROs is perceived in different ways and, based on these observations, suggests a descriptive redefinition of PROs. The two document analyses are sub-studies of the scoping review (Paper I) and are therefore based on systematically selected segments of the 256 articles included in the initial part of the scoping review. In both cases, supplementary literature has been added when it provides new and valuable insights concerning the subject field [3,4].

5.1.5. RESULTS—PAPER II

The interviews with the seven Danish experts disclosed nine different perceptions of PROs. There was consensus regarding the first three understandings of PROs (1–3), discrepancies related to other points (4–5) and four additional perspectives on PROs (6–9):

1. *Population PRO* and *individual PRO* (consensus).
2. *Passive PRO* and *active PRO* (consensus).

3. Quality improvements within healthcare (consensus).
4. An economic efficiency tool (discrepancy).
5. Data usable for VBHC (discrepancy).
6. Patient-centred healthcare (additional perspective).
7. Part of clinical practice (additional perspective).
8. A digitally mediated tool (additional perspective).
9. A disease-and context-dependent tool (additional perspective).

Population PRO and individual PRO

All informants perceived PROs according to the common dichotomy between individual and population PROs, referring to the fact that PROs are patient-and clinician-oriented tools used as part of patient–clinician consultations with a specific patient (individual level), and at the same time, PROs are applied to accumulate population data, for example, applicable in research and as a quality improvement and development tool (population PROs). One informant highlighted that, on an individual PRO level, how important it is that clinicians apply PRO data in patient–clinician consultations, as experiences indicate that some clinicians neglect the use of PROs.

Active PRO and passive PRO

Active PRO and *passive PRO* is another dichotomy referred to by the informants—a conceptualisation of PROs, coined in a Danish context, more specifically in the report *Program PRO*. The terms refer to the same levels of use as individual PRO and population PRO; the difference is mostly tied to that in the connotation. Hence, *active PRO* indicates that the application of PROs in clinical practice is the data actively used in healthcare practice to activate and engage patients, whereas *passive PRO* is the data stored in quality databases for later use in, for example, research and quality improvements. One informant explained that the latter use of PROs has been part of Danish healthcare for many years; it is the *active* functionality of PROs that is the new dimension added to their use. The change in functionality means that PROs have moved from primarily being a measuring tool to now being a communication tool used to improve patient–clinician consultations. Hence, the informant elaborates on the potential clash between PROs' clinical value and the rigorous methodological requirements historically attached to PRO tools, indicating that the customisation of a PRO should reflect the purpose of the tool.

Quality improvement

The informants agreed that PROs are intended quality improvement and assurance work within healthcare. This is a common perception aligned with the portrayal of PROs in *Program PRO*. The thought is that the inclusion of patient data complements traditional quality data in the quality databases. Thus, PROs are considered a benchmarking and knowledge-sharing tool, an instrument used to improve healthcare interventions and actions on a departmental level and to allow an improved quality of healthcare on a national level.

Economic efficiency

The informants also mentioned that PROs are considered tools intended to bring about a more economic healthcare system. However, one informant pointed out that PROs' economic potential, as perceived on a management level, is incompatible with reality considering the resources needed to establish and run PRO systems. Other informants did not believe that PROs are an economic tool or that this is their purpose. More specifically, PROs are not a money-saving tool but do enable resource allocation, allowing a more judicious use of resources.

VBHC

PROs are also associated with VBHC. Essentially, a PRO complements the traditional reimbursement system where measures focus on productivity, activity and effectiveness. An informant explained that the traditional system has an excessive one-sided focus on quantitative parameters, which does not necessarily lead to a more effective healthcare system. In other words, in the long term, many low-quality operations will not necessarily be economically efficient compared to few high-quality operations. Therefore, measurements of quality are needed to complement existing measurement tools, which is a functionality enabled through the use of PROs, as they allow the collection of information on the quality of healthcare interventions from a patient's perspective. In other words, PROs are connected to VBHC, as they offer transparency concerning the value a healthcare intervention has for a patient. Another informant acknowledged that some stakeholders consider PROs as a VBHC tool but emphasised that this is a subordinate functionality of PROs. This informant warned that PROs, as an integrated part of the reimbursement system, are not yet applicable in a Danish context.

Patient-centred care

Another interpretation of PRO concerns its ability to drive patient-centred care; hence, PROs are seen as a tool that can empower patients and improve their participation and self-management. The informants linked patient participation to PROs' ability to systematically integrate the patient perspective into the patient–clinician consultation. Increased patient participation is also associated with PROs' informative potential; the idea is that patients' use of PRO questionnaires can educate and thereby empower them, subsequently allowing them to become more active in conversations with clinicians. Thus, PROs provide patients with knowledge on their disease, and clinicians attain an improved understanding of patients' subjective disease situation; hence, there is an increased focus on patient perspective and patient participation in patient–clinician consultations. The educative and empowering potential of PROs can also enable patients to enhance the self-management of their condition.

Clinical practice

A PRO is perceived as a tool used within clinical practice, where informants emphasise functionalities pertaining to decision-making, treatment and dialogue. The improved communication is expected to occur as patients' subjective understanding of their disease situation is integrated into the patient–clinician dialogue. When using a PRO in clinical practice, it might create awareness of issues that formerly have been skipped in patient–clinician consultations and enable a more systematic approach when obtaining anamnesis. Moreover, the additional information offered to clinicians by PROs facilitates enhanced decision-making and treatment.

Digitally mediated tools

Another description of a PRO is as a technology. Specifically, informants explained that PROs can be used for monitoring patients' health status, to allow coordination across sectors and as part of an algorithmic visitation system, which are features promoted by the digitalisation of PROs. The visitation system triages patients, based on their health status, into three groups, green, yellow and red, where the greens are allowed to skip consultation, yellows are further assessed and reds are invited in for a consultation at an outpatient clinic. According to one informant, a system, needed as a response to the increasing number of outpatient consultations, and a PRO application that can ensure more efficient use of resources and higher productivity are focal priorities on a management level. In this case, increased productivity occurs as a segment of patients is handled merely through PRO questionnaires, enabling allocation of time and resources to those patients who need a physical consultation. Additionally, this use of a PRO is beneficial to patients who are in control of their health condition and are allowed to skip consultation, as healthcare is adjusted to their individual needs. As mentioned, PROs can also be used as a monitoring tool, where patients' health status is followed over time; this indicates the value of a PRO in chronic care. This use of PROs offers timely data on patients' disease situations, enables preventive health interventions and, in cases where data are accessible to patients, self-monitoring might facilitate improved self-management. The third emphasised functionality enabled by PRO digitalisation is the coordination feature, which implies that PROs allow data-sharing across sectors and organisational levels. The objective is to improve patient pathways through the sharing and accessibility of data across providers. In this context, the relevant antecedents are adequate technological infrastructures and cultural homogeneity.

Disease and context-dependent tools

Another important point is that PROs are contextually dependent; therefore, the shaping and utility of a PRO varies with the disease area of usage. Hence, the informant explains that in epilepsy, a PRO functions as primary data, whereas in diabetes care, it acts as more than a supplementary data source. Therefore, the utility and importance of PRO data vary between disease areas. Another example is the case of cancer. Here, the informant explains that a PRO can improve treatment, but PRO as part of an algorithmic triage system is not an option in this context, as all patients need to show up for consultation and treatment [2].

5.1.6. RESULTS—PAPER III

Paper III concerns PRO functionality after its digitalisation and integration into clinical practice. The objective of the study is not to assess PROs' capability concerning each functionality but merely to provide an overview of functionalities after the instrument's digital transformation. This analytical approach means that the concept of electronic PROs (ePROs) is emphasised in this study. Its functionalities (Table 6) are interpreted in connection with four relevant stakeholders: Patients (P), Clinicians (C), Managers/politicians (M) and Industry (I) [3]. The study is a sub-study, as results are based on a document analysis of the materials identified through the conducted scoping review (Paper I) [1]. Some themes are merged into one row, but overall, 33 different functionalities of PROs are identified. Table 6 illustrates that the pre-digitalisation functionalities of PRO pertained to drug testing, research and limited use in clinical practice. The main users at this point were clinicians and industry. Post the digitalisation of PROs, the traditional applications persist, but PRO functionalities have expanded, where the accentuated ePRO functionalities in the paper regard clinicians', patients' and managements'/politicians' use of ePROs. Regarding stakeholders, the overall functionalities of PROs have become increasingly patient-and management-oriented.

Table 6. PROs' functionality pre and post their digitalisation linked to relevant stakeholders [3]

Stakeholders	Functionality	Pre digitalisation (PRO)	Post digitalisation (ePRO)
C	Decision-making and treatment	x	x
C	Diagnosing	x	x
CP	Patient perspective	x	x
CP	SDM	x	x
CI	Drug testing	x	x
CI	Research	x	x
CPM	Patient-centred healthcare	x	x
CP	Communication/dialogue	x	x
C	Screening	x	x
CPM	Patient satisfaction	x	x
P	Patient participation		x
P	Self-management		x
M	Health policy development		x
CPM	Quality of care		x
CM	Best practice		x
CP	Adherence		x
M	Reduced health care costs/efficient use of resources		x
CM	Triage system based on algorithms		x
P	Patients goals		x
M	Monitor population health/preventive tool		x
C	Monitoring and patient management		x
M	VBHC/Benchmarking/Reimbursement/Accountability		x
CM	Coordination tool/ Interdisciplinary/multidisciplinary communication		x
P	Patient empowerment		x
P	Self-monitoring		x

Clinicians' use of ePRO

ePROs enable clinicians to access timely data on patients' health conditions. The digitalisation of a PRO also allows clinicians to access continuous monitoring of patients' disease situations. These features support clinicians' decision-making and patient management, improving the diagnosis and treatment of patients.

Patients' use of ePRO

The digitalisation of PROs has made the tools more patient-oriented. The use of ePROs means that patients can

- Access PRO data in a homely environment.

- Continuously track their subjective health conditions.
- Attain an improved understanding of their condition based on the informative and educative potential inherent in ePROs.
- Feel more empowered.
- Self-manage their condition more extensively.
- Self-monitor and formulate disease-related goals, where PRO scores function as baseline data.
- Participate more actively in patient–clinician consultations, SDM and handling of their disease in general.

Management and politicians' use of ePRO

On a management level, the focal functionality of ePROs is the coordination potential of the tools. ePROs allow sharing of information across sectors and organisational levels, potentially improving collaboration between HCPs. Furthermore, this application of ePROs means that patients avoid answering the same disease-related questions over and over again and that all HCPs are given access to timely data. Another anticipated feature of ePROs from a management perspective is the establishment of VBHC. VBHC uses ePROs to gain access to patients' subjective assessment of the quality of healthcare interventions they have experienced and to establish a healthcare and reimbursement system based on patient preferences. The intention is to improve quality in healthcare through benchmarking, enhance provider accountability and create an economically efficient system by lowering costs and ensuring better use of resources. A PRO, as part of a triage system, is an example of a more recent application, where ePROs are part of an algorithm-based visitation system (cf. Figure 6); hence, ePRO scores categorise patients and identify those who are invited to a patient–clinician consultation. Once again, potential gains pertain to a more efficient use of resources and more patient-tailored solutions [3].

5.1.7. RESULTS—PAPER IV

Paper IV is also a document analysis based on the research articles identified through the scoping review (Paper I) [1,4]. The objective of this study was to identify and describe the purposes of a PRO after its digitalisation and integration into clinical practice. Based on a PRO's modified purpose and in comparison to former definitions, its alternative redefinition is suggested. Overall, the purposes of PRO concern

- Research and drug testing.
- Quality and economy.
- Patient-centred care.
- Politicisation and democratisation.
- Organisation and culture.

Research and drug testing

PROs are traditionally used for research and drug testing—a PRO utility that aligns with the evidence-based medicine approach, as PROs offer systematic and standardised measuring of healthcare interventions. PROs are used on a group and an individual level in clinical trials, where the tools have traditionally functioned as secondary endpoints. This enables testing of healthcare interventions and new drugs in connection with the potential side-effects, adverse effects, comorbidity, etc.; hence, this is an approach to disclose patients' subjective experiences and perceptions of healthcare services and drugs. This approach ensures a more comprehensive assessment of healthcare interventions and drugs and a way to choose between drugs when the clinical efficacy is identical.

Quality and economy tool

PROs are also used in quality improvement and assurance work and as an economic instrument in the healthcare sector. Quality and economy are closely associated in healthcare, resembled by *The Triple Aim*, where enhanced quality, economic efficiency and improved population health are the three focal pillars in the quest to ensure a sustainable healthcare sector. Another example of the close relation between quality and economy is the VBHC approach. The idea is that healthcare quality is assessed based on patients' subjective outcomes, specifically on PRO scores, compared to the costs of healthcare interventions. This is a patient-centred approach to quality improvement, as the quality of care is based on the patient's perspective. Hence, a systematic approach to the measurement of patient value is based on aggregated PRO data, which allows benchmarking of providers who are allocated resources according to their performance scores—an approach meant to facilitate knowledge-sharing and provider accountability. VBHC is not meant to substitute former volume-based reimbursement systems but to complement the traditional quantitative focus with measures on quality and measures that are closely related to issues that matter to patients. The visitation system based on algorithms, as explained in other studies, is another use of PROs potentially having a quality and economic impact. Economically, resource allocation ensures a more efficient use of resources and positively affects productivity, whereas the qualitative aspect is connected to cases in which patients who are not in need are allowed to not show up for consultations.

Patient-centred care

Patient-centred care concerns patient needs, preferences and values, which are characteristics that PROs are able to elicit. Hence, PROs' capability to provide a holistic perspective on patients' disease situations aligns well with a patient-centred approach to healthcare. Moreover, PROs potentially promote patient participation by enabling a partnership and recognising approach, and through systematic integration of the patient perspective, patient-relevant issues and SDM in patient–clinician consultations. The activation of patients can also have an empowering effect, potentially leading to improved self-management.

Politicisation and democratisation

PROs are also portrayed as political and democratic instruments. The point is that PROs implicitly provide patients with a *voice* in healthcare matters, potentially influencing the political agenda and decision-making. A noticeable feature offered through the use of PROs as increasing health expenditures challenges the sustainability of healthcare systems and because citizens demand greater democratic influence due to increasing knowledge and awareness on healthcare issues. Hence, current healthcare policies emphasise patient participation, a standpoint normatively aligned with democratic values and an endorsement of patients' expertise on their respective disease situations.

Organisation and culture

When a PRO is introduced as part of clinical practice, it impacts healthcare institutions on an organisational and a cultural level. Organisationally, PROs can affect

- Clinical workflows.
- Work practice.
- The technological infrastructure.
- Formal organisational structures.
- Communication in multidisciplinary teams.
- Coordination and communication across departments, organisations and sectors.
- Patient pathways.

Culturally, PROs potentially

- Affect HCPs' attitudes.
- Affect HCP values.
- Include patient attitudes.
- Include patient values.

PROs are expected to promote patient-centred healthcare through an organisational and cultural alteration of the system. This is a PRO-based transition that requires support from a political and management level through explicit use and emphasis of the type of outcome produced by PROs. Barriers to a PRO's ability to commence an organisational and cultural transformation concerns

- Adequate time and resources.
- Correct interpretation and use of data in clinical practice.
- Guidelines and education of clinicians.
- The instruments' contextual adaptation to clinical workflow and practice.
- An increased work burden on HCPs.
- Accessibility to timely PRO data in clinical practice.

Hence, numerous barriers regarding the use of PRO in clinical practice are decisive to consider if PROs are to facilitate increased patient participation and partnership-oriented patient–clinician consultations.

Definitions of PRO

In Paper IV, definitions created by FDA, ViBIS and The International Society for Quality of Life Research (ISOQOL) are included to accentuate different interpretations of PROs. The definitions have specific focus areas, which stand in contrast to a descriptive, interdisciplinary and more holistic redefinition of a PRO presented at the end of the paper. This is a definition underscoring the complexity of a PRO [4]. Hence,

'...a PRO is defined as a: validated questionnaire; developed in collaboration between patients, clinicians, and other pertinent stakeholders; systematically applied; mediated digitally or paper-based; completed directly by the patient, with assistance or by a qualified proxy; composed of generic, disease-specific, condition-specific or preference-based measures; consisting of content pertaining to the patient's physical and mental health condition, functioning, symptoms, well-being or health-related Quality of life (HRQoL); providing objective and/or subjective outcomes, and individual and/or population data' [4, p. 10].

PRO ELEMENTS—THE ELEMENTS CONSTITUTING A PRO

In Paper V, *Exploring, describing, and mapping the constitutive elements of Patient-Reported Outcomes (PROs) used in clinical practice* [5], the objective was to identify the elements constituting a PRO in clinical practice and to organise these elements into a concept map (*PRO Elements*). This is formulated as the following research question: 'What elements constitute a PRO in clinical practice?'. Hence, *PRO Elements* illustrate how different elements constitute a PRO, allowing different types of PROs to emerge in clinical practice [5]. The study is considered a sub-study based on the extant literature identified through the scoping review (Paper I) [1].

5.1.8. RESULTS—PAPER V

This study identifies eight main elements and several sub-elements, which constitutes *PRO Elements*, displayed in Figure 13.

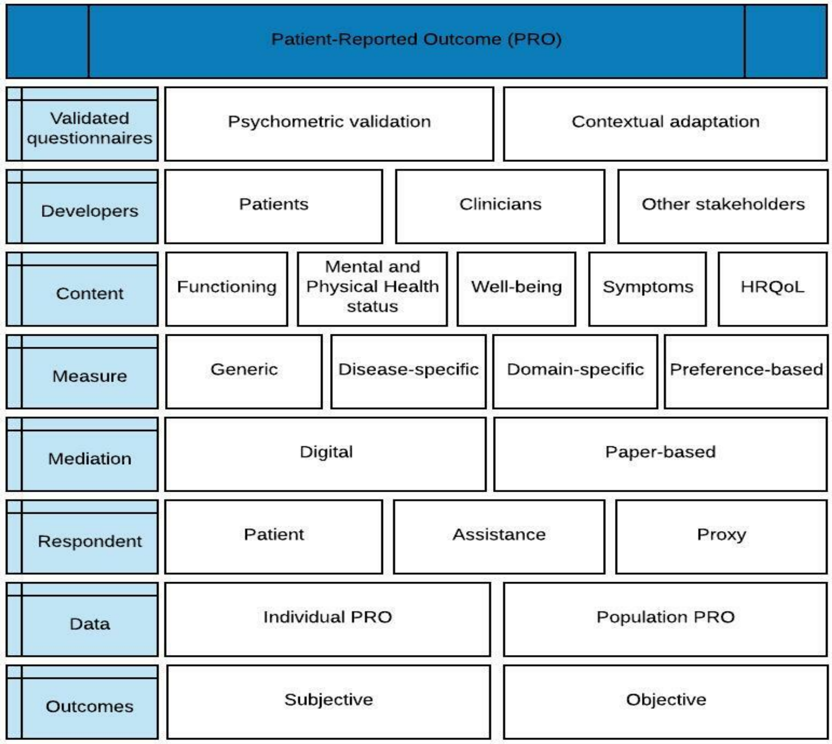


Figure 13. PRO Elements - the basic elements constituting a PRO in clinical practice [5]

The eight main elements are presented in the light blue column, while the sub-elements are presented in the white boxes. The dark blue pillar at the top, *Patient-Reported Outcome (PRO)*, symbolises the top of a box to indicate that the elements underneath are those potentially contained in a PRO. Theoretically, more columns and sub-elements can be added in each row, and the elements are not disjunctive. Thus, Figure 13 is suggestive and tentative and not necessarily a comprehensive illustration of the elements constituting a PRO in clinical practice. *PRO Elements* are meant to

- Provide an overview of the elements constituting a PRO in clinical practice.
- Illustrate the interdisciplinarity of PROs in clinical practice.
- Improve newcomers and experienced users’ understanding of PROs.
- Promote PRO-based dialogue, collaboration and coordination across stakeholders and users.
- Enhance development, application, implementation and evaluation of PROs.

Moreover, *PRO Elements* might facilitate a more judicious use of PROs in clinical practice, subsequently allowing PROs to function as tools that promote patient participation.

Validated questionnaires

The first row, *validated questionnaires*, contains the sub-elements *psychometric validation* and *contextual adaptation*. This row emphasises PRO questionnaires being methodologically valid since this is decisive if PROs are to be used as part of clinical practice similar to traditional clinical measures. *Psychometric validation* concerns how PROs should be validated, statistically robust and standardised measures to enable the systematic collection of useful PRO data. *Contextually adapted* regards the importance of assessing PROs' impact on healthcare (e.g. PROs' influence on the clinical workflow). Conversely, PROs are also shaped by the context of use; hence, how the context alters the use and functionality of a PRO should also be considered.

Developers

A PRO is a construction created by a specific segment of developers, and who these are determines the type of PRO that is produced, which is why this is the theme in the second row. The sub-elements are *patients*, *clinicians* and *other stakeholders*. *Clinicians* are emphasised, as these are and traditionally have been essential to the development of PROs due to their professional knowledge. Moreover, clinicians have a central role as they are the ones to use PRO data as part of clinical practice. *Patients* form another highly relevant group as they are the ones ensuring the PRO measures' content validity. Patients are the ones who have a subjective understanding and experience with a specific disease, and are the ones who are to complete the PRO questionnaires and use the data. This indicates the importance of creating meaningful and useful PRO tools in collaboration with the main users. *Other stakeholders* are the large group of others, such as quality improvement workers, statisticians, software developers and representatives from various organisations, which are needed to ensure the creation of the best possible PRO instrument.

Content

The sub-elements in this row describe the content of a PRO, which typically concerns patients' *functioning*, *mental and physical health status*, *well-being*, *symptoms* and/or *HRQoL*. Hence, the content of a PRO provides a holistic perspective on the patient's health status in connection to psychological, social and physical factors. The inclusion of a patient's subjective understanding of their disease situation and the increased focus on HRQoL is a noticeable shift in healthcare practice in comparison to the former approach based on traditional clinical data. Moreover, the increased use of HRQoL indicates an increased focus on chronic care, where such measures are of particular importance. The actual content of a PRO varies depending on the purpose of the PRO.

Measures

PROs comprise different measures, indicated by the sub-elements *generic*, *disease-specific*, *domain-specific* or *preference-based*. Generic measures are applicable across disease areas and patient groups, allowing comparisons on a population level. Disease- and condition-specific measures offer clinicians and patients information on the patients' subjective health situation, and therefore, these PRO instruments are applied in clinical practice. Disease-specific measures regard several aspects of a patient's disease, whereas domain-specific measures refer to a specific issue (e.g. pain and anxiety). Preference-based PROs have a different purpose, as they are economic instruments meant to elicit the value of healthcare interventions in comparison to patient preference and experiences. As each type of PRO has a different purpose and relevance, it is not unusual that PRO questionnaires contain a combination of different measures.

Mediation

This row indicates that PROs are mediated in different ways, *Digital* or *Paper-based*. Traditionally, PROs were paper-based but are increasingly mediated digitally, as this extends the functionality and utility of the instruments. The digital completion process enables individualised technologies, such as computerised adaptive testing, which is a branching system in which respondents' PRO answers continuously determine the questions they receive. Digital mediation is also what enables algorithm-based visitation systems.

Respondents

The sixth row contains the categories *patient*, *assistance* and *proxy*, representing potential respondents of a PRO. In common definitions of a PRO, it is accentuated that patients are the ones answering the PRO questionnaires, which is the intention and, therefore, correct in most cases. However, when a PRO is used routinely as part of clinical practice where all types of patients are included, the completion of questionnaires is not always done solely by a patient. Sometimes, patients need assistance for different reasons (e.g. cognitive issues, low health literacy and disease severity), which can be provided by an HCP, friends or family members. On other occasions, patients cannot participate at all in the completion; hence, there is a need for a proxy to complete the PRO questionnaire. Consequently, respondents are not always just the patient or the patient at all. This means that from a data quality perspective, it might be useful to include checkboxes in questionnaires indicating who the actual respondent is.

Data

In this row, data are presented as a dichotomy between *individual PRO* and *population PRO*. *Individual PRO* is data applied in clinical practice concerning an individual's health status. In this context, PRO data are, among other things, used to monitor the patient's disease progression, to improve patient–clinician communication and to promote SDM. *Population PRO* refers to situations in which aggregated PRO data are used as part of quality improvement work, preventive healthcare, benchmarking systems and research. Such PRO data are also applicable in clinical practice, where they function as baseline data when an individual's disease situation is appraised in comparison to a specific patient population.

Outcomes

In the last row, the outcomes are divided into *subjective* and *objective*. Originally, PROs were introduced to elicit *subjective outcomes*, using patients' perceptions of their diseases to complement traditional clinical data. This is a pivotal functionality of PROs that is still widely used. As the use of PROs has expanded in clinical practice, objective outcomes have been integrated into the instruments; hence, some PROs contain questions on, for example, blood pressure or blood sugar levels, answered by measuring the respective values. Therefore, *outcomes* are displayed this way in *PRO Elements*, because even though the idea with PROs is to disclose subjective outcomes, some of the instruments might produce various outcomes in practice [5].

CITIZENS' EXPERIENCES WITH PRO

In Paper VI, the research question scrutinised is 'How do newly diagnosed citizens with type 2 diabetes experience and perceive PRO when applied in clinical practice in a municipal setting?'. Hence, the paper has the following title: *The Experience of Citizens with Newly Diagnosed Type 2 Diabetes with the use of PRO in a Municipal setting* [6].

5.1.9. RESULTS—PAPER VI

The study was conducted at the CfD, located in *The City of Copenhagen* (the municipality of Copenhagen). The study is based on semi-structured interviews conducted with 10 citizens newly diagnosed with type 2 diabetes and participant observation of the citizens' consultations with an HCP. Two interviews and observations were conducted physically, while eight were conducted online. The study results are described in more general terms in this section, whereas more detailed descriptions can be found in Paper VI [6].

The analysis in the paper is divided into three sections describing the citizens' impression of the PRO questionnaire, the use of PRO data in practice and other issues.

Citizens' assessment of the PRO questionnaire

The citizens' experience of the PRO questionnaire was ambivalent as they believed it was meaningful and relevant in general but lacked meaningfulness and relevance at times as newly diagnosed citizens with type 2 diabetes. The citizens believed that the questionnaire concerned their disease situation, and its purpose was to improve the citizen–HCP consultation.

To some of the citizens, it was slightly annoying that the questionnaire was too long, while others felt that, even though the questionnaire was too long, it was okay because it concerned their health and had the length required to provide a holistic description of their disease situation. Four informants stated that the length was fitting. All citizens could understand all questions, but some of the questions required knowledge that they as newly diagnosed did not possess yet, which made it difficult to answer these questions properly. Consequently, the citizens felt that they provided the wrong answers or were unsure how to answer some of the questions. The citizens were not conscious of the questionnaire's educative potential as they believed it provided them with no new knowledge. Nonetheless, during the interviews, they gave different examples of how the questionnaire offered them new knowledge of diabetes. Specifically, the citizens acquired an improved understanding of how diabetes is linked to eye, feet and sleeping issues; heart symptoms and sexual problems. In contrast, the questionnaires' difficulty to the newly diagnosed citizens also made them aware of all the disease-related knowledge they lacked. This is a lack of knowledge that, on one hand, frustrated citizens and made them anxious, and on the other hand, made them aware that others are worse off, motivating them to expand their knowledge on diabetes and engage more actively in self-management activities. Hence, the questionnaire had both an empowering and a disempowering effect, which varied among citizens.

The location and mediation of the questionnaire were generally satisfactory to the citizens. Digital completion from home, which was the applied distribution method, was preferred by all citizens. In contrast, paper-based solutions and completion at the site were not preferred by any citizen; however, some of the citizens would accept and participate if these were the conditions. The digital solution was appreciated as it offered citizens' privacy and the comfort of a homely environment. It was deemed ergonomically better when completing the questionnaire, flexibility concerning when and where to complete the questionnaire and more effective use of their time, as the time needed for the visits at the CfD was reduced.

Utility of PRO data during consultation according to citizens

All citizens felt that the time allocated for the conversation at the CfD was adequate and got around all topics they wanted to discuss. Whether the citizens believed that they or the HCP controlled the conversation varied. However, what was noticeable was that they were all in control to their preferred degree and were given the necessary *voice* to bring forth their inputs. Most citizens perceived the HCP to be in control, which they thought was fine as they were the professional experts and could structure the conversation, ensuring that all relevant topics were discussed. The citizens also felt included in the decision-making process. The HCPs did not dictate what the citizens had to do but functioned more than facilitators and advisors, informing citizens of possible options and courses. Then, they were allowed to choose what path to take.

The citizens had varying experiences with the presentation of the PRO data during the consultation. The two citizens who experienced the physical consultations found the use of PRO data confusing, as data were divided into nine different categories and as the data were presented at a screen positioned to the site between the HCP and the citizen. This meant that the citizens throughout the conversation were unsure where to look, at the HCP or the screen; as a result, they lost track of the topic being discussed, having difficulties identifying the topic on the screen while feeling that the intimacy of the conversation was affected. The experiences of the citizens participating in the digital meetings were mostly positive. The shared screen option, which allowed citizens and HCPs to view data, discuss topics and see each other simultaneously, was appreciated by the citizens. All citizens found the red, yellow and green division and display of data easily and intuitively understandable. The red and yellow answers were interpreted as alarming issues and made citizens aware of the things they, if able, had to do something about. The green answers were useful as well, as they confirmed to the citizens that they did well in specific areas, some of which was a joyful experience. Data were displayed as nine different categories. Citizens pointed out that the conversations could be improved if topics were shown one at a time on the screen, if the HCPs actively used the mouse cursor to guide citizens during the conversation and if the HCPs got to know the individuals before diving into the data.

When asked directly, the effect of PRO data during the consultation was, according to the citizens, doubtful. Some said it had no effect and was unnecessary, as the subjects being discussed would have been part of the conversation even without the use of PRO data. Nonetheless, during some interviews, citizens explained how the PRO data elicit mental, physical and sexual issues. A citizen also said that she now feels less lonely in handling her disease. Especially, the PRO data's ability to structure conversation was emphasised by the citizens, which prepared the citizens and HCPs, provided a common starting point and enabled a more effective and relevant conversation, as the topics that mattered the most to the citizens were discussed without having to spend a long time getting there.

Other issues, improvements and routine use of the PRO questionnaire

The citizens were generally satisfied with the questionnaire and approved its application in clinical practice. Nonetheless, they got the impression that the questionnaire was not tailored to the needs of newly diagnosed citizens with type 2 diabetes. This impression was based on the fact that they were asked to answer questions on diabetes not matching their current knowledge of the disease and their disease situation as such. Furthermore, the citizens criticized the narrow scope of the PRO questionnaire, as they pointed out that the questionnaire excluded patients' disease history and other conditions. This meant that some of the conditions patients lived with were linked to diabetes in the PRO questionnaire, even though, according to the citizens, it had nothing to do with diabetes. Hence, the lack of historical background knowledge regarding their disease situation meant that some of their answers were misleading. One informant was puzzled by the fact that no questions concerned his current job situation, as he perceived this topic as focal in relation to his overall well-being.

The following were the suggested improvements:

- Inclusion of textboxes, allowing explanations on whether a condition was linked to diabetes and whether the citizen suffered from other disabilities.
- Adaptive questionnaires, meaning that the questionnaire adapts to an individual's responses during the process of completion, ensuring that newly diagnosed citizens are faced with suitable situation questions.
- Short-form questionnaires based on a few mandatory questions complemented by additional answer options, allowing citizens to provide more comprehensive answers.
- A two-questionnaire approach, meaning that the questionnaire received by newly diagnosed citizens should be different and simpler than that received by more experienced citizens with diabetes.
- The integration of *not relevant* or *not currently relevant* answer options to more accurately resemble the newly diagnosed disease situation.

On one hand, the citizens supported the idea of using a PRO as part of routine care, and on the other hand, continuous completion of questionnaires seemed less attractive for some citizens. According to the citizens, the benefits of routine use of PRO data include an improved understanding of one's disease situation; better first-time consultations between citizens and HCPs; the potential to track citizens' disease progression and the option to use the data comparatively to identify changes in the disease situation. The barriers mainly concern the increased patient burden of continuous completion of questionnaires cause. Additionally, one citizen pointed out that the completion of PROs requires that the data are used and provide value to clinical practice, whereas another citizen underscored that the data need to be used across healthcare providers as the completion of similar questionnaires at different healthcare providers would be a waste of the citizens' time.

Opinions on digital access to PRO data when used routinely varied. Some had no interest or need to access and use the PRO data; some were already able to handle their disease; one pointed out that their body informed them of their current health status; one simply did not feel sick and therefore had no need for the data and one explained that digital solutions were irrelevant to them. Others were keener on using PRO data; one was keen because they often used technical gadgets and were excited by the opportunity to follow their disease progression graphically and statistically, while others explained that it was an interesting opportunity and that they would give it a try [6].

CHAPTER 6. DISCUSSION

For every complex problem there is a simple solution that is wrong.

George Bernhard Shaw

In this chapter, the research project's findings are discussed against the context, concepts and theories described above.

PATIENT PARTICIPATION, EMPOWERMENT AND RECOGNITION

Based on the findings of Paper I, it is relevant to discuss the implications linked to the association between patient participation and PROs. As demonstrated, the association between PROs and patient participation concerns the PRO development process, patients' completion of PRO questionnaires, patient empowerment and self-management, application of PRO data and communication and SDM during patient–HCP consultations. Moreover, organisational and attitudinal issues represent focal barriers and enablers (Paper I). Therefore, the connection between PROs and patient participation can be divided into three phases, with patient–HCP consultations as a reference point (Figure 14) [1].

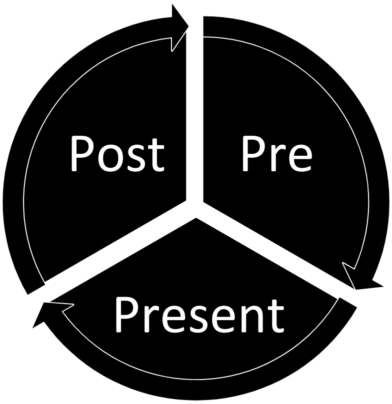


Figure 14. Phases of association between PROs and patient participation in chronic care with patient–clinician consultations as the reference point [1]

Figure 14 illustrates that the use of PROs in chronic care, where PROs are typically used, is an iterative process indicated by the arrows at the edge of the circle. Hence, PROs and patient participation are associated during the consultation (*Present*), which concerns the use and display of PRO data, communication and SDM; before the consultation (*Pre*), referring to the development processes and situations in which patients complete PROs and the period between the consultation and completion of a PRO questionnaire (*Post*), which occurs outside the hospital and concerns a patient's ability to self-manage their chronic condition [1]. Even though the latter phase timewise constitutes 98%–99% of the patients' disease management [100,111], PROs are almost exclusively examined during the *Pre* and *Present* phases [1]. This is probably because the self-management functionality of PROs is relatively new and patients' access to useful data illustrating progression remains relatively limited. Hence, more knowledge on the use of PRO data in the *Post* phase is needed; for example, it would be relevant to scrutinise how, whether and why/why not patients use PRO data as a self-management tool.

6.1.1. *PRE* PHASE

Development of PRO

Theoretically, the interpretation of patient participation as something that unfolds during the development processes aligns with the definitions of patient participation included in the dissertation, which emphasise how patient participation is systematically used to improve healthcare quality [76,79,86,88]. Patient participation in the *Pre* phase is still limited, which concerns PRO development where the exclusion of patients having cognitive issues, learning disabilities or weak health is an issue [1,5]. Hansen et al. [114], in their study on the quality of PROMs, found that most of the 61 assessed PROMs had validity issues pertaining to the content and/or construction. Hence, PROMs' methodological weaknesses disclosed in this rather comprehensive study are, according to the authors, caused by a lack of patient participation and inputs obtained from statisticians during the development process [114]. Wiering et al. [115] examined the relevance and use of PROMs developed without patient involvement—a study indicating that patients in most cases confirm that PROs developed without patient participation still have relevance. However, this study also showed that patient preferences and the type of PROMs they find important vary. Therefore, Wiering et al. emphasised an individual approach to the use of PROs in clinical practice [115]. Additionally, Wiering et al. [116] conducted a scoping review to examine the extent and character of patients' participation in PRO development processes over time. Based on 193 PROM development processes, the study revealed that only in 6.7% of the included cases, the patients were involved in the entire development process; in 25.9% of the studies, they were not involved at all. Hence, 'although patient involvement in PROM development is essential to develop valid patient-centred PROMs, patients are not always involved. When patients are involved, their level of involvement varies considerably' [116, p. 1]. A potential problem, given the low or non-participation by patients, might result in PROs not reflecting the patient perspective, which potentially affects the quality and use of PRO data in clinical practice in a negative manner [116,117]. Consequently, it is relevant to consider the number and profile of patient participants in the development process to ensure the creation of valid PROMs. This is a particularly relevant point if patients are supposed to use PROs routinely in the self-management of their condition(s), assuming that PROs' ability to mirror the patients' disease situation affects their usefulness to patients. Showell and Turner [118] addressed a design problem on biased design solutions, wherein they explained that personal eHealth systems need to not only be useful to resourceful *people like us* (*PLUs*) but also be accessible and useable by the most vulnerable patient groups, referred to as the *disempowered, disengaged and disconnected (DDDs)*. They argued that eHealth systems should primarily be designed to fit the needs of *DDDs,* as they are the ones who are most in need of medical attention [118]. In this light, awareness of patient participation in PRO development processes seems decisive, making the study of Haywood et al. [117] relevant, who explained that 'the extent to which participants are representative of the target population and condition—considering variations in gender, age, disease severity and presentation—is essential to concept elicitation and item generation, ensuring content relevance and validity' [p. 108]. Considerations were integrated into Haywood et al.'s model, as displayed in Figure 15, which functions as a guideline on how to involve patients in PROM development processes to ensure high face and content validity [117].

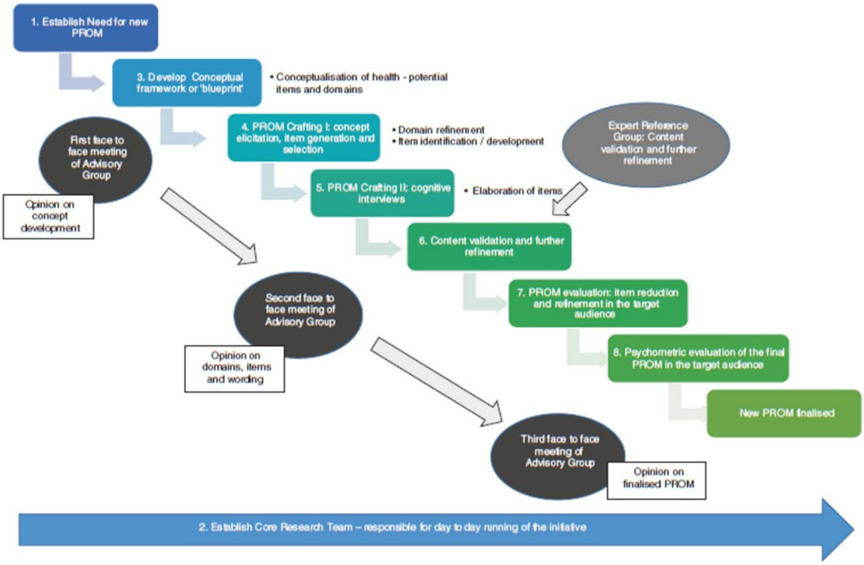


Figure 15. Development of PROMs based on patient participation [117]

According to Haywood et al., patient participation is relevant throughout the development process. Therefore, patient representatives are members of the advisory group that continuously provides inputs during the development process and are part of the expert reference group that comments on the PROM at the key stages (Figure 15). Moreover, these authors argued that patient research partners should be included in the core research team and engage in daily research activities [117]. In this context, Patrick et al. [119,120] explained how to methodologically approach and ensure the content validity of PROMs by applying various qualitative interviews to capture the patient perspective.

Considering the degree of patient participation in the development process, the categories of *manipulation*, *placation* and *partnership* in Arnstein's ladder of participation are useful [89]. *Manipulation* applies to scenarios in which participants are used as marionettes. Developing processes in which patients are included as a signalling effect to satisfy external partners, while genuine patient participation is no real objective. Therefore, this situation resembles the non-participation level on Arnstein's ladder [89]. In a PRO development context, *placation* concerns a situation in which patients are part of the development process, informed of the purpose and functionality of the PRO and listened to. Nonetheless, clinicians and project leaders are still the ones who make decisive decisions and determine how a PRO is constructed. In this case, patient participation takes the form of tokenism as patients are granted no real power. Hence, even though patients' inputs are listened to, it does not necessarily mean that their opinions and ideas are recognised or accepted and, therefore, have no impact. Finally, *partnership* involves developing processes in which patients are considered partners and have real influence and decision-making power. In this case, the patient inputs influence the construction and final shape of the PRO questionnaire. This is a development process in which the patients have real power, which can be characterised as a *partnership* and genuine patient participation. The development processes I experienced on a national and a hospital level land somewhere in between the *placation* and the *partnership* approach. At both levels, the patients are listened to; however, whether the patient inputs have any influence varies. Thus, patient preferences and wishes are, among other things, weighted against clinician inputs, scientific matters and technical and practical circumstances. These are the factors limiting the influence patients actually have during the development of new PRO tools. This is a relevant area to follow in the future considering the former lack of patient participation in PRO development and how patient participation is theoretically emphasised in the development, delivery and evaluation of PROs and healthcare systems [85,117].

In this *Pre* phase, Heidegger's thoughts on technology are relevant [104], especially when combined with Honneth's recognition theory [64], as illustrated in Figure 12. Hence, in the development process of new technology, participants need to be recognised by the technology, which implies that it is developed based on human values to promote human self-determination. When developing new PROs, patients need to be recognised by PROs, which implies that PROs are developed based on patient preferences and what matters most to patients. Consequently, such PROs facilitate participation, access and use of PROs. The idea is that patient recognition enables the empowerment of patients, which subsequently supports their self-management efforts. Conversely, if PRO development processes are conducted without patient participation, patients do not have access to PRO data and PROs are not used by patients or HCPs, then the opposite result might be obtained: disempowered patients who experience a lack of access to healthcare and possess inferior self-management skills. Hence, aligned with Heidegger's fear of an enframing based on the essence of modern technology—instrumentality, ordering, calculation, effectiveness, production and systemisation—making humans blind to the true essence of the world [104], the constructions of PROs ignoring the importance of patients' participation, access and use of PROs might provide a false picture of the patients' disease situation, preventing clinicians from obtaining a valid impression of the patient outcomes. In other words, the true revelation of patients' disease situation requires that PROs are constructed based on genuine patient participation, a patient recognition that subsequently enables PROs to empower patients. This is a technological recognition transpiring when technological development and functionality are based on human control, promoting freedom and human values. Subsequently, this will strengthen individuals' and groups' self-determination (Figure 12). Conversely, if technology is based on the essence of technology, as explained by Heidegger, individuals and groups might lose control and become resources/means used by technology [104]. This indicates the importance of incorporating human values into technology to recognise individuals and groups and avoid technologies treating humans in a disrespectful manner, which is why patient participation in the development process is pivotal [1], particularly when PROs are to be used routinely in clinical practice. Another issue concerns how the lack of patient participation in the development process might affect response rates negatively, because of tools not reflecting the patient perspective adequately (i.e. PROs that do not recognise the patients' actual needs and preferences) (Figure 12). Moreover, low response rates might affect the quality and utility of PRO data, emphasising sufficient patient participation. Therefore, sufficient information, reminders and motivating encouragements are important, as they can increase the response rates. Studies concerning the response rates and patient burden in the longer term in clinical practice are limited; therefore, assuming that PROs are used routinely as part of clinical practice, such studies need to be carried out in the future [1]. The importance of empowerment in this phase links to the sixth study concerning the PRO experience of citizens newly diagnosed with type 2 diabetes. Even though, when directly asked, the citizens are unaware of PROs' empowering effects, the concrete examples provided by the citizens disclose the educative features of the questionnaires. Thus, the PRO questionnaire examined in this study has the potential to enlighten citizens newly diagnosed with type 2 diabetes, which is a central aspect of the empowerment process [6]. Nonetheless, constant awareness of the type and degree of patient participation in this context is essential henceforth. Guidelines and valuable contributions already exist within the field, not necessarily solving all challenges of representativeness and exclusion of particular patient groups but enabling developers to create PRO tools based on patient participation.

6.1.2. *PRESENT* PHASE

In the *Present* phase, where PROs are used during the consultation, patient participation particularly concerns communication and SDM.

PRO, communication and SDM

Based on scientific evidence, PROs' effects on patient–clinician communication are quite significant. Thus, conversations in clinical practice between HCPs and patients become more holistic, substantive, effective, relevant and patient-engaging through the use of PROs [1]. The results aligned with the citizens' experiences in a municipal setting, who explained that the PRO diabetes questionnaire enabled a structured, effective and relevant conversation, allowed the participants to show up prepared and ensured a common starting point [6]. Both in the scoping review and through the semi-structured interviews, it was underscored that one strength of PROs is their ability to elicit patients' unmet needs, symptoms and other relevant disease-related issues while providing a holistic understanding of the patients [1,6]. As a PRO is acknowledged as a decision-making tool, potentially improving patient treatment, the limited number of studies concerning PROs' influence on SDM is remarkable. However, patient preferences concerning the degree of participation in decision-making vary [1]. Whether and in what ways PROs enable SDM are relevant to be examined further in the future. The applications of PROs in clinical practice are related to nurses' perceptions of patient empowerment and patient participation in clinical practice, which combined concerns

- The dissemination of information on treatment options, lifestyle and disease-specific issues.
- Co-determination and active decision-making on treatments.
- An interpersonal, holistic and emphatic approach embedded in a supportive and trusting nurse–patient relation.
- Individualised treatment, based on the patients' needs, preferences and knowledge.
- Role as gatekeepers, where nurses introduce patients and relatives to former patients and support groups.
- Supportive care, where positive thinking enables patients to cope, increase their independence, control, autonomy and enable increased self-management [83,98].

The first four perceptions of empowerment and patient participation are relevant in the *Present* phase, whereas the last point concerns the *Post* phase; the fifth perception is relevant in both phases. Considering the empirical evidence on PROs in the literature and the findings of this PhD project in comparison to the above interpretation of patient empowerment and patient participation, PROs, in general, have a positive effect on patient empowerment and patient participation. This conclusion is based on knowledge, indicating that PROs inform patients about their disease situation, improve patient–HCP conversations and enable an individualistic and holistic approach during consultations [1,3,4,6].

Eldh's conceptualisation of patient participation concerns the *Present* phase, as the emphasis on sufficient information and patients' influence on decision-making in treatment, care and health-related issues is linked to the patient–HCP consultation. Additionally, Eldh explained that patients' right to be seen, heard and understood is decisive in instigating patient participation. Accordingly, in this interpretation of patient participation, the patient needs to be recognised as a unique individual [77]. For this reason, in the study on the PRO experiences of citizens newly diagnosed with type 2 diabetes, the participants were asked about these particular aspects in the conversation. All citizens felt seen and heard and believed that the conversation concerned them and their specific disease situation. When asked who controlled the conversation and whether this was aligned with the citizens' preferences, they provided various answers to the former question but confirmed in all cases that they controlled the conversation to the preferred degree. These experiences indicate that the citizens felt recognised by HCPs. Most citizens preferred that the HCPs control the conversation during the consultation due to their position as professional experts [6]. Therefore, based on the citizens' experiences (Paper VI), PROs do not act as a barrier between patients and HCPs, as the citizens were recognised by the HCP in PRO-based consultations. In contrast, the PROs might have had a positive influence on the matter, as they provided a holistic impression of the patient and accentuated alarming issues [6]. Hence, according to Arnstein's categories, these conversations resemble the rung called *delegated power*, which are scenarios in which patients have real decision-making power [89]. The HCPs informed the citizens and enabled them to make qualified decisions, and then the citizens chose the desired programs and advice to follow. Hence, how to proceed after the conversation ended was entirely up to the individual citizen [6]. It is in this context that Anderson and Funnell's questions on patient empowerment are relevant [100], here translated into a PRO context; hence,

a) Do PROs help patients identify and address their primary diabetes concerns?
b) Do PROs encourage them to talk about the emotional aspects of having diabetes?
c) Do PROs help them identify and choose goals that are relevant and important to them?
d) Do PROs respect their right to make decisions clashing with HCPs' recommendations?

Based on the experiences of the citizens newly diagnosed with type 2 diabetes in the sixth study, affirmative answers can be applied to all these questions. This is another way to verify that at least the examined PRO has a patient empowering potential [6].

Barriers and enablers

Based on the findings of the scoping review and document analyses included in the PhD project [1,3–5] and the conducted fieldwork, a summation of relevant barriers/enablers concerning PRO use in clinical practice is identified and listed below. Barriers/enablers are emphasised, as they influence whether PROs can promote patient participation and function systematically as part of healthcare. Barriers/enablers are not written separately, which is deliberate, indicating that barriers and enablers are two sides of the same coin; hence, whether an issue functions as a barrier or enabler varies. The brackets containing *patients* and *HCPs* indicate who a specific matter primarily concerns. Other stakeholders, such as the management, software developers, statisticians and representatives from central organizations in the healthcare sector, could also have been added, but to keep it simple, only HCPs and patients are included here. The barriers/enablers identified throughout the PhD project are as follows:

- **Technological infrastructure**
    - Accessibility (patients/HCPs)
    - Data security (patients/HCPs)
- **Organisational level**
    - Workflow (HCPs)
    - Increased work burden (HCPs)
    - Culture (patients/HCPs)
    - Resources (HCPs)
    - Time and space (HCPs)
    - Administration of PROs (HCPs)
    - Work organisation (HCPs)
    - Guidelines on how to use PROs (patients/HCPs)
    - Education (patients/HCPs)
- **Individual level**
    - Health literacy/eHealth literacy (patients)
    - Cognitive and physical limitations (patients)
    - Health status (patients)
    - Disempowered (patients)
    - Attitudes (patients/HCPs)
    - Forgetfulness/busyness (patients)
    - Understanding how PROs are different from former measures (patients/HCPs)
    - Strong and trusting relation between HCP and patient (patients/HCPs)
    - Culture and language (patients)
    - Network and family who can assist (patients)
    - Understanding the purpose of PROs (patients/HCPs)
    - Knowledge of how to use PROs (patients/HCPs)
    - Lack of use and feedback on PRO scores (patients/HCPs)

- **Quality of PRO measures, data and questionnaires**
    - Usability of data/ease of use (patients/HCPs)
    - Synergy with other clinical data (HCPs)
    - Relevance/meaningfulness (patients/HCPs)
    - Clinical value of data/actionability (HCPs)
    - Patient burden/respondent fatigue (patients)
    - Validity of data (HCPs)
    - Reliability (HCPs)
    - Sensitivity (HCPs)
    - Interpretability (patients/HCPs)
    - Timely data (HCPs)
    - Tracking of progression/ Responsiveness (patients/HCPs)
    - Display of data (patients/HCPs)
    - Notifications/personal reminders (patients)
    - Computer adaptive testing (CAT)/tailored questionnaires (patients)
    - Short-form PROs, easy to complete (patients)

[1,3–5]

The overall barriers/enablers concern *the technological infrastructure, the organisational level, individual aspects* and *the quality of PRO measures, data and questionnaires*. Possibly due to PROs' origination, *the quality of PRO measures, data and questionnaires* has received extensive scientific attention, as indicated by the number of validation studies conducted in the field. The quality of PROs, primarily referring to their psychometric properties, continues to be an important issue and needs to be handled continuously to ensure that HCPs support the use of PROs as part of clinical practice [1]—hence the emphasis on psychometric validation in *PRO Elements* [5]. The last points under the category of *the quality of PRO measures, data and questionnaires*—CAT and short-form PROs—align with some of the citizens' suggestions in Paper VI on how to make the diabetes PRO questionnaire better match their needs [6]. On the use of PRO data, HCPs and patients agree that they need to be useful, easy to use, relevant, meaningful, allow the tracking of disease progression, interpretable, indicate alarming issues and presented by simple and understandably preferable line graphs. Distinguishing the two is the HCPs' need for more detailed information [1]. According to the citizens in a municipal setting, the digital presentation of the results and the simple intuitive categorisation of data into red/yellow/green were satisfying, while the use of data in physical consultations tended to be confusing. Moreover, the citizens emphasised HCPs' guidance while showing the PRO data [6]; hence, good PRO measures are not sufficient. How the PRO data are actually used in clinical practice is essential and related to the next category *individual aspects*. *The individual aspect* is a good example of how new barriers/enablers emerge when PROs move from being a drug testing and research tool to being used in clinical practice. The focal point in this context is that HCPs and patients comprehend PROs' purpose and functionality, as these features influence the

HCPs' and patients' ability to not just use PROs but to use the tools correctly. In particular, the significance of HCPs' and patients' attitudes has been emphasised in the literature. These are attitudes influenced by several of the barriers/enablers listed above. Specifically in the patient case, these attitudes might be influenced by a lack of interest in PROs, (un)acceptance of PROs, individual stress levels, attitudes towards technology and computers, former negative experiences with questionnaires, altruistic incentives based on the ability to help others through PRO completion and lack of feedback and use of PRO scores during the patient–HCP consultation. *The individual level* is influenced by *the organisational level* and *the technological infrastructure*, which needs to facilitate and support PRO use to function as a tool that systematically promotes patient participation in clinical practice [1,3,4]. However, the categories can also be differentiated, as *the technological infrastructure* functions as a type of precondition for a digitalised PRO system, whereas the points included at *the organisational level* are areas in which the management can facilitate HCPs' and patients' use of PROs in clinical practice. Hence, other barriers/enablers become relevant after the digitalisation and integration of PROs into clinical practice. In more detail, the best foundation for PROs in clinical practice is a patient-oriented culture and practice based on multidisciplinary teams, adapted to clinical workflows and work tasks, where HCPs and patients are educated in the use of PROs and practice supported by adequate resources [1,4]. Overall, several barriers/enablers illustrate the complexity concerning the use of PROs in clinical practice, which is important to be aware of if PROs are to promote patient participation in healthcare.

6.1.3. *POST* PHASE

The *Post phase* is where PROs' participatory, empowering and self-management functionalities become particularly relevant considering the increasing number of citizens suffering from one or multiple chronic conditions [8]. The *Post* phase also indicates that patient participation is not merely something located at a hospital but a phenomenon that to a larger degree unfolds in citizens' homes, where the self-management efforts are situated [79,83,86]. Thus, PROs' functionality in this phase concerns the patients' abilities to actively participate and self-manage their disease as part of their everyday life. Studies in this area are few; little is known of PROs' self-management potential in this phase [1]; nonetheless, it is a focal theme in the future considering that patients are responsible for 98%–99% of their care [100,111]. In this phase, *The Health Empowerment Model* (Figure 8) is useful to elaborate on PROs' self-management potential. Hence, according to the terminology in *The Health Empowerment Model*, the aim in this phase is to increase the number of e*ffective self-managers* (high empowerment/high health literacy) [102], which can be achieved because of the informative and educative potential inherent in PROs [1,2,6]. This indicates the relevance of the results in Paper VI, in which the citizens newly diagnosed with type 2 diabetes seem to be enlightened through the completion of the questionnaires and the use of PRO data in practice [6]. According to Arnstein's terminology, the *Post* phase concerns how PROs turn *nobodies* into *somebodies* by empowering them [89], which according to *The Health Empowerment Model*, need to be combined with adequate health literacy to avoid patients becoming *dangerous self-*

managers [102]. Patients need to be sufficiently informed, enabled to use this knowledge and acquire the needed power to become e*ffective self-managers* [102], which in practice can be challenging due to socioeconomic, structural and cultural factors [89]. Therefore, even if PROs can improve empowerment and self-management, awareness of the multitude of barriers is warranted [1,3–5]. In this context, the type of empowerment (e.g. the macro-, meso- and individual levels) and the liberal/critical empowerment dichotomy become relevant [97].

PRO and health inequities

In contrast to current healthcare policies (cf. chapter 1), Signild Vallgårda warned about a one-sided emphasis on patients' ability to self-manage their disease. Hence, PROs' potential mobilisation of individual patients and groups is acceptable but only to the extent that it does not lead to inequities in healthcare, which refer to differences in patients' health status along with their use and access to health services. Even though geographical locations, level of education and parents' level of education lead to inequities in healthcare, the generating mechanisms that create these differences between patients and groups are focal. However, the societal focus is on individual characteristics, which means that individuals and groups are stigmatised and blamed for their health status; hence, factors such as heredity and genes are ignored. Instead of changing the generation mechanisms causing peoples' bad health, patients are individually taught how to manage their lifestyle and handle their health. However, even responsible citizens might get sick, meaning that changing individuals' health behaviour is an insufficient approach to counter the current inequities in healthcare [65]. This is an important point considering PROs' purpose and functionality regarding patient participation, empowerment and self-management [1–3]; according to this reasoning, PROs might not change health inequities or have a negative impact. Nonetheless, in the current dominating healthcare paradigm, the central assumption is that autonomous patients who live healthy, responsible lives, accepting the personal responsibility of their well-being, also live longer [87,88]. Valgårda's critique of current healthcare was supported by Frederiksen and Jørgensen, who focused on the critical aspects of the neoliberal approach in healthcare [87,88]. Accordingly, patients are perceived as users/consumers instead of sick persons, who are suffering and in need of care, and as self-managers, who need to be educated and taught how to self-care [87,88]. Consequently, aligned with Riiskjær's points [81], the *best* patients, those who are able to participate and self-manage, are prioritised as they are easier to handle and, therefore, economically attractive. In contrast, passive patients and less capable patients, *DDDs*, do not receive the required care [88,118]. Consequently, the neoliberal approach is, according to Frederiksen, unproblematic, as long as patients possess the required capital and capabilities to engage actively in their disease handling [87] and as long as they are e*ffective self-managers* [102]. However, the patients who are suffering and/or lack the necessary abilities to participate and actively self-manage their health do not benefit from this system [87]; hence, a healthcare system does not match the needs of *DDDs*, *nobodies* and *high-needs patients* [89,102,118]. Following the same reasoning, it must be assumed that the type of *patient empowerment*, stressing SDM, self-reflection, patient rights, increased responsibility, autonomy and involvement [98,99], can support some of the *DDDs* but primarily benefit the *PLUs* [118]. This is the reason why the degree of patient participation should be matched to an individual patient's needs and preferences [1,83]. However, to empower the *DDDs*, a complete change in the healthcare system, similar to Vallgårda's suggestions, is required [65]—a change that probably requires a version of *patient empowerment* linked to the critical approach of empowerment, focusing on changes on a macro-level. Accordingly, PROs' ability to instigate such changes depends on how they influence the cultures and structures comprising the healthcare system. If PROs enable systematic patient participation in clinical practice, not merely by activating the patients but also by altering HCPs' behaviour in a patient-oriented direction, PROs would have an empowering impact aligned with the *critical approach*. This is a transformation and mobilisation which, however, requires that HCPs as well as patients are educated in PROs' purpose, functionality and use in clinical practice [1]. Hence, PROs can facilitate empowerment at the individual level, which is aligned with liberal empowerment and the current approach in healthcare. As shown in the study on the PRO experience of citizens newly diagnosed with type 2 diabetes, the questionnaire and data have an educative potential [6]. These findings are supported by studies included in the scoping review in paper I [1]. Therefore, through continuous completion of PRO questionnaires and if PRO data are accessible, presented in a useful and interactable manner to patients, the resourceful patients, the *PLUs* [118], will likely be able to integrate PRO data into their self-management activities. Additionally, the *DDDs' critical consciousness* might be positively affected by PROs, as increased knowledge of their disease situation might mobilise resources, increase their participation and improve the handling of their health. However, this potential is largely determined by the *DDD's* opportunity and ability to use the information contained in the PRO questionnaires and in the PRO data, as indicated by *The Health Empowerment Model* [102]. Therefore, the opposite scenario is an option as well, where the *DDDs* are further disempowered, as the inability to use PROs instead becomes yet another barrier in their access to the healthcare system. Valgårda, Arnstein, Jørgensen, Frederiksen and Riiskjær emphasised that patient empowerment and patient participation are possible, but only to the extent that the societal structures and the organisation of the healthcare system facilitate these developments [65,81,87–89]. Vallgårda suggested that individuals and groups are treated according to their disease severity and equally independent of the social status or individual capabilities. Additionally, she encouraged an increased focus on diseases flourishing mostly among citizens with lower education level [65]. Considering these points, PROs can reduce inequities in health, as their primary use is within chronic care [27], to increase patient participation and facilitate holistic care [88], which is relevant as a chronic disease is linked to socioeconomic circumstances [65]. Thus, PROs can improve chronic care and enable a more tailored approach in healthcare, whereby healthcare interventions match patients' disease severity to a larger degree [1,3,4].

In this context, the content of PROs is another factor to consider [5]. The application of HRQoL measures in healthcare practice through PROs means that, for example, social conditions are systematically integrated into healthcare practice. This paradigm shift indicates a closer link between the social area and healthcare in a Danish context. Whether cultural factors which, according to Vallgårda, also generate inequities in healthcare [65] are systematically applied in future healthcare will be interesting to follow. This would entail that QoL factors, on context and culture and not merely HRQoL issues pertaining to physical, psychological and social functioning, are systematically considered in clinical practice [5]. Regardless, the paradigm shift symbolised by PROs entails increased interdisciplinary collaboration between disciplines; this raises the need for conceptual models, such as *PRO Elements*, to facilitate collaboration, communication and discussions among various groups and disciplines [5]. Another relevant functionality and purpose is PROs' ability to enhance the patients' *voice*, which might influence health inequities. Hence, PROs' potential to politicise and democratise healthcare [4]—concerning PROs' empowerment potential on a macro-level [97], or rather the distinction between the two—is relevant when considering PROs' impact on health inequities. Thus, the application of PROs can lead to increased transparency through systematic benchmarking and the implementation of VBHC, subsequently improving the accountability of providers [3,4]. These are potential changes aligned with the incorporated aims in *market logic* and NPM [81]. This application of PROs would primarily benefit decision makers, politicians and managers of the healthcare system. A strengthening of the power holders, which stands in opposition to the traditional critical empowerment approach, stresses the need to mobilise and educate the less resourceful groups and individuals [98–101]. However, considering PROs' association with patient participation [1], citizens also hold political and democratic power through PROs [4], which can be exercised through the strategies of *voice, choice* and/or *exit* [85]. In a healthcare context, *voice* can refer to the citizens' opportunity to raise their voice in discussions on healthcare, *choice,* to citizens' possibility to freely choose between providers and *exit* and to citizens' option to boycott a specific provider. Hence, increased transparency through PRO data can benefit citizens as well, as it potentially enables them to engage in democratic discussions and choose and boycott providers on a more informed basis [4]. Based on this discussion and the analysis of the type of stakeholders primarily benefiting from various functionalities of PROs in paper III [3], it is interesting to consider whether a PRO is a zero- or a non-zero-sum game [97]. Therefore, based on the knowledge that several stakeholders seem to benefit from PRO use, the empowerment instigated by PROs seems to take the form of a non-zero-sum game. Nonetheless, it is reasonable to assume that how much the individual patients and groups benefit and are empowered by PROs varies.

PURPOSE, FUNCTIONALITY AND SUBSTANCE

In this section, the findings on PRO functionality, purpose and substance are discussed, where relevant considerations concern how PROs affect patients, HCPs and healthcare praxis.

System and patient level

As shown, the purposes of PRO concern

- Research and drug testing
- Quality and economy

- Patient-centred care
- Politicisation and democratisation
- Organisation and culture [4]

This finding implies that PROs are expected to be used and have various impacts in different areas and on different levels. These purposes are scrutinised in more detail in this section. The individual/system dichotomy is relevant in all studies conducted on PROs' purposes and functionalities as well as in the conducted fieldwork [2–4]. A dichotomy is embedded in the division between *population PRO* and *individual PRO* and in the *passive PRO* and *active PRO* categorisation [2,4,5]. In Paper III, PRO functionalities are sorted according to relevant stakeholders and PROs' digital/paper-based mediation and use [3]. To complement this, a categorisation of the functionalities on the individual, intersectional and system levels is introduced below. In practice, the system and individual levels are connected and affect each other, sometimes making a clear division difficult, also indicated by the analytical need for an intersectional level.

The system level concerns improvements in the healthcare system in general, the individual level refers to functionalities benefitting patients and HCPs and the functionalities on the intersectional level are relevant on both levels. Hence, based on the findings in the present PhD project, the following functionalities concern the use of PRO on a system level:

- Research
- Drug testing
- Health-quality development
- Reduced healthcare costs
- Monitoring of population health
- VBHC
- Reimbursement systems
- Benchmarking
- Accountability
- Management of healthcare
- Politisation
- Democratisation

On the intersectional level, the following PRO functionalities are identified:

- Integration of the patient perspective into healthcare
- Screening
- Patient participation
- Self-management
- Patient satisfaction
- Best practice

- Efficient use of resources
- Visitation system
- Preventive healthcare
- Coordination tool
- Collaboration across sectors and providers
- Effective healthcare
- Patient pathways
- Patient data
- Patient information

On the individual level, the following functionalities are identified:

- Diagnosing
- Treatment
- Decision-making
- Communication
- SDM
- Dialogue
- Patient empowerment
- Adherence
- Goal-setting tool
- Monitoring
- Self-monitoring
- Patient management
- Interdisciplinary communication
- Multidisciplinary communication
- Holistic understanding of patient disease situation
- Patient education
- Tailored approach [2–4]

This is a division of a multitude of PRO functionalities complementing the findings presented in Papers II–IV [2–4]. The number of functionalities comprising the intersectional level is noteworthy, as it indicates how several PRO functionalities are valuable on the system and individual levels. Hence, the relatively large number of functionalities comprising the intersectional level can explain why PROs are considered a coordination tool with the potential to establish a more coherent healthcare system. Moreover, the intersectional level analytically supports PROs' potential as boundary objects in healthcare, which is further discussed below. As pointed out in the expert interviews, how each functionality unfolds in practice is contextual and depends on the disease area [2].

Substantial reflections

After unfolding matters concerning PROs' functionality and purpose, the next part outlines reflections on PROs' substantial character linked to the findings in Papers IV and V [4,5].

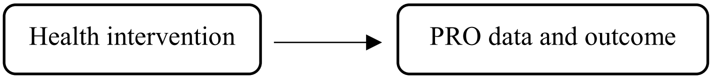
First, do PRO data actually originate from the patients, as claimed in the most common definitions, and is it the patient's perspective that is used in the consultation? A relevant consideration after PROs' digitalisation and integration into clinical practice and the perspective *directly from the patient* indicates that the data are untouched and represent an authentic patient perspective. In short, as explained in Paper IV, PRO answers are not always obtained directly from the patient or necessarily represent a timely patient perspective [4], as

- In-between the completion of the PRO questionnaire and the application of PRO data during the consultation, the patients' disease situation and/or their perspective on the matter might have changed.
- The construction and content of the questionnaire restrict the type of patient perspective entering the patient–clinician consultation.
- The mediation of PRO questionnaires influences patients' accessibility and ability to complete PRO questionnaires. In other words, infrastructure and sociotechnical setups affect whether patients' perspectives enter consultations.
- Presentations and algorithmic interpretations of data need to be valid, intelligible and useful to mediate the patient perspective as authentically as possible.
- The utility of PRO data and the patient perspective potential in clinical practice are formed by the HCPs' interpretations and the functionalities and purposes linked to each PRO. Hence, some HCPs are unsure how to interpret PRO data, as they potentially abstain them from using PRO data or use them incorrectly. As a result, the PRO-based patient perspective is either denied or part of the consultation in an invalid representation.
- Patients sometimes need assistance when completing a PRO questionnaire or an actual proxy to provide PRO answers for them. Consequently, the validity of the response is questionable and the perspective *directly from the patient* is not obtained in this case [4].

These are examples of how the ideal concerning untouched and patient-generated PRO data, to some extent and in some cases, are dubious when PROs are used in clinical practice. Therefore, I suggest that an indication of who completed the PRO questionnaire might be useful to improve the quality of the PRO data and make PRO scores more transparent.

Another point concerns the validity of the PRO questionnaires unfolded in the paper containing *PRO Elements*. Traditionally, PROs only had to be psychometrically validated to ensure that the measures were valid. However, the digitalisation and integration of PROs into clinical practice mean that technological and contextual validations and evaluations are needed as well [5]. This is theoretically aligned with Ihde's and Verbeek's descriptions of the reciprocal character of human–technology relations [60,61,107] and methodologically linked to the emphasis on the contextual approach applied when examining human–technology relations in techno-anthropological studies [62,63]. From these perspectives, the inter-relation between technology and human praxis means that PRO and patients and HCPs and clinical practice mutually shape each other. Hence, the interpretation of PROs as technological and digital tools demands additional types of evaluations. Complementary studies are also required because of the expansion of PROs' purpose [4]; hence, to assess the quality of a PRO in clinical practice, the traditional psychometric validations are too limited in scope; as the *PRO Elements* illustrate, PROs are no longer merely measures [5]. A change can also be elucidated by considering a PRO as a dependent/independent variable. Hence, traditionally, PROs have been used PRO as secondary endpoint data when assessing patient outcomes after healthcare interventions and as part of drug testing studies [4], a correlation where PRO functions as a dependent variable, which can be described as follows:

However, PROs can also function as an independent variable, which has been instigated by the increased focus on the use of PRO data as a patient-oriented tool to promote patient participation, SDM and self-management [1,4]. This correlation can be described as follows:



However, PRO digitalisation and integration into clinical practice enable PROs to be used as independent variables promoting patient participation, patient empowerment and self-management [1]. This is an important change when considering the transformative impact PROs have had on clinical practice and healthcare. Furthermore, this is a development indicating that various methods and interdisciplinary collaborations would probably be beneficial in the validation, evaluation and assessment of PROs henceforth, which links to the scientific issues of PROs in clinical practice, as raised by Ishaque et al. [48]. These authors emphasised that the included studies in their systematic review were based on methods focusing on statistically significant results, not necessarily ensuring that a PRO instrument is clinically meaningful. 'While P values can provide important evidence of a difference in average outcome scores, they indicate only the probability that study findings such as those reported (or more extreme) could have occurred due to chance alone if there really was no difference in the two groups in the underlying population. As such, they lack the ability to inform clinicians whether (in general) the difference really matters to their patients, i.e. if it was clinically meaningful' [p. 22]. This is a relevant point as it justifies the qualitative and ethnographic research design applied in the present PhD project, but more importantly, the statement describes how current scientific approaches to the assessment of PROs' purposes and functionalities, embedded in EBM, are problematic when examining the value of PROs in clinical practice. Thus, when assessing the impact of PROs on clinical practice exclusively on methods such as systematic reviews and RCT studies, PROs' potential and effects, especially the qualitative gains, remain hidden. In several of the included papers, the researchers required stronger evidence on PROs' capabilities in clinical practice, referring to the lack of RCT studies and systematic reviews on the subject [1]. The problem is, however, that such studies are not necessarily able to provide a comprehensive picture of PROs' value and qualitative gains in clinical practice. Hence, it is strongly encouraged that the assessment of PROs' value and capabilities in clinical practice be determined by relevant research questions, not by predetermined methods that constitute the research questions—an approach that requires qualitative evidence in this context to be considered equal to quantitative evidence. The studies constituting the present PhD project reveal that the purposes and functionalities of PRO are multifaceted [3,4]; hence, a reductionistic methodological approach to the examination and evaluation of PROs in clinical practice will neither do justice to PROs' complexity nor enable an accurate, adequate or comprehensive understanding of their potential and value. The demand for the relatively one-sided methodological approach integrated into EBM is also slightly ironic in this context, as the integration of PROs in healthcare underscores the importance of subjective experiences and perceptions. In other words, if one accepts the value of PROs in clinical practice and research, it seems strange that qualitative studies, based on similar logic, are not accepted as proper evidence. Therefore, even though PROs are traditionally considered measures applied in research, drug testing and now clinical practice, their interdisciplinary character requires an open-minded approach to fully comprehend the impact and value of PROs in clinical practice.

TECHNOLOGY AND DIGITALISATION

Relation between PROs and patients

Throughout the project, PROs have been perceived as a technology, which is possible when placing PROs within Ihde's descriptive definition of technology [60]. Therefore, PROs as a technology implies that PROs

- Consist of a concrete component.
- Are used in human praxis.
- Have an inter-relation with humans [60].

In other words, PROs are non-neutral and transformative tools having an inter-relation with patients, HCPs and healthcare practice. Considering Ihde's and Verbeeks's human–technology relation categories, the hermeneutic relation, where humans experience the world through interpretations of text, numbers and symbols mediated by technology [60,61,107], best describes how PROs inter-relate with patients and

HCPs and affect healthcare practice. The fusion between a PRO and the world, represented by the *hermeneutic relation*, corresponds to how PROs represent patients' disease situations as text and numbers. An interpretation of the PRO–user relation is even more relevant and useful when PRO data are mediated digitally, and by using algorithms, displayed on computers through numbers, colours, text and graphs. Another PRO–patient relation that might become relevant in the future is the *immersion relation*, which refers to a situation in which technology acts as an interactive environment that monitors and affects human behaviour [107]. Hence, if PRO data are further integrated into patients' self-management praxis, an immersion relation between PRO and patients might arise, for example, if PROs' monitoring of patients is combined with frequent notifications and suggestions on how to alter the health behaviour and improve self-management of one's condition. This situation resembles an immersion relation, as it can be interpreted as an interactive environment where PROs actively monitor and influence patient behaviour. Accordingly, an immersion relation is rooted in PROs' monitoring capabilities and a more flexible interpretation of what constitutes an interactive environment.

Considering technologies' degree of influence on humans, according to Verbeek's categorisation [107], the influence of PROs in healthcare can be characterised as *persuasive* (apparent/weak), as PRO data are visible and affect patients, HCPs and clinical practice by providing feedback on patients' disease situations [1,3,4]. However, if at any point, it becomes mandatory to complete PRO questionnaires to gain access to healthcare, PROs will additionally function as a *coercive* (*apparent/strong*) technology. PROs' influence is *apparent*, because the completion of PRO questionnaires is a conscious action and *strong* as they determine whether a citizen is invited to see an HCP. Another example, closely related to the potential mandatory PRO completion, concerns PROs' influence on healthcare practice when part of a visitation system. In these cases, algorithms interpret PRO answers and determine who is invited for consultation with an HCP. This is a seemingly *coercive* use of PROs; however, currently, the system is not fully automated, as *yellow answers* are often additionally assessed by HCPs to ensure the patients' safety and patients who are not automatically invited to a consultation still have the option to ask for a consultation with an HCP [3–5]. However, should this change, meaning that the process becomes fully automated and that only the algorithm's assessment of patients' health status determines their access to healthcare, then PROs would act as a *coercive* technology. Another relevant scenario is when PROs are integrated into the reimbursement system [3,4], which might make PROs act as *coercive* technology. This can happen if PRO scores influence how resources are allocated as providers, which would then have an *apparent* economic incentive to, first, apply PROs and, second, to increase awareness of PRO scores in clinical practice. These are merely examples of current relations and realistic future scenarios on PROs' inter-relation with patients, HCPs and healthcare as such; however, as functionalities are numerous [3], several other relations are possible.

PRO Elements and PROs as boundary objects

This section focuses on the potential of PROs and *PRO Elements* as boundary objects. Therefore, it is relevant to consider all three aspects constituting a boundary object: the internal flexibility, the objects' material/organisational structure and its scalability/granularity [105]. Hence, PROs' ability to mediate patients' disease situations and health status among patients, HCPs and other stakeholders across disciplines, sectors and departments is relevant. This is true not just in practice but also in this context, as it means that PROs fulfil all three criteria as a boundary object.

- Internal flexibility refers to the point that PROs can be used and interpreted by various stakeholders.
- The material/ organisational structure indicates how PROs are integrated into clinical workflows.
- Scalability/granularity is what enables the use of PROs on an individual level in clinical practice and on an aggregated level to improve healthcare quality [105].

Thus, PROs can be used on an individual level or a population level by patients or HCPs in clinical practice or potentially as a self-management tool for research, preventive healthcare or as part of a reimbursement system [2–4,6]. Hence, PRO data can be used on different scales depending on the objective of use. As a result, PROs on theoretical and general levels are artefacts that distribute information across intersecting social worlds, which allow stakeholders to collaborate without consensus, aligned with the requirements pertaining to boundary objects [105]. However, whether a specific PRO is a boundary object depends on its construction and contextual use, which are linked to the functionality and purpose of a PRO [2–5]; hence, Star's emphasises on boundary objects as something that emerges through contextual actions [105]. Consequently, PROs' potential as boundary objects is best disclosed through studies on their actual use in clinical practice. In the case of *PRO Elements*, the eight rows comprising the concept map illustrate how PROs are constituted by various elements linked to various scientific disciplines (Figure 13). This is an interdisciplinary interpretation of PROs, providing the map with internal flexibility. The concept map's intended use is as part of development, implementation, application and evaluation processes [5], resembling the material/organisational structure requirement linked to the boundary object [105]. *PRO Elements'* scalability/granularity potential is also determined in these processes; however, when considering this aspect, the concept map's useability on managerial and political levels needs to be scrutinised as well. Therefore, similar to PROs, *PRO Elements* also have the potential to become boundary objects, which should be examined in future tests of the map when put into action in various settings. Star pointed out that the emergence and status of a boundary object is a continuous process, unfolding in specific contexts. Hence, depending on the step in the process, a PRO can either take the form of a *residual category*, *boundary object* or *standardised* object [2010]. The flexible use of PROs [3–5] probably means that different PROs can be placed in all three phases. The new uses of PROs, often patient-oriented and enabled by the digitalisation of PROs (e.g. PRO as a self-management tool) [3,4], and the reconceptualisation of PROs, exemplified by *PRO Elements* [5] and the descriptive redefinition of PRO [4], contained in the current PhD project, are good examples of *residual categories*. New uses and the interdisciplinary interpretations are considered *residual categories,* as they do not yet or to a limited degree impact clinical practice and/or research studies. Nonetheless, this categorisation implies that these conceptual contributions and PROs as patient tools can become *boundary objects* over time. These *residual categories* arise from, and at the same time, complement the traditional and *standardised* perceptions of a PRO. Examples of a *standardised* practice and perception concern PROs' use in RCT studies and drug testing [4], where there is a relatively clear understanding of how to use PROs, as mirrored by the guidelines published by the FDA [17].

Holism-effectiveness dilemma

An interesting theme is what I would term *the holism-effectiveness dilemma*, which is presented in the technology and digitalisation section, even though it concerns other aspects of the study findings as well, because it primarily links to a PRO's role as a technology. On one hand, a PRO is supposed to improve the healthcare quality by integrating the patient perspective into the clinician–patient consultation and to enable a holistic understanding of the patients' disease situation. On the other hand, a PRO is meant to create more effective and standardised consultations [2–4]. These two objectives are potentially achievable simultaneously but might also clash. The holistic perspective on the patients' disease situation logically entails a deeper, broader and potentially more time-demanding understanding, whereas an increasingly effective consultation suggests a better use of the limited time in this context or refers to a PRO as a time-saving tool; hence, it is a consultation in which only a few selected issues are discussed. Therefore, it is relevant to consider whether a PRO is a tool that breaks with former thinking and measures resulting in standardised healthcare, which, according to Riiskjær, is an undesirable direction due to the consequences such a system entails [81]. In other words, PROs are actually a standardisation of patient participation based on the logic embedded in the market, the public and the medical profession [81], a scenario in which the power required to instigate patients is not delegated to patients and where patient participation is not necessarily based on their terms; this is a type of patient participation taking the form of tokenism [89]. Alternatively, does the PRO-mediated patient perspective enable genuine patient participation, providing patients with increased power and influence [89]? As Riiskjær explained, the problem with current standardised measures in healthcare is the undesirable economic incentives they create, their lack of relevance in clinical practice and how they potentially become aims in themselves in opposition to a means to an end. Consequently, the application of standardised measures might result in prioritisation of measures over patient needs and values, increased administrative tasks and scenarios in which the patients experiencing complex conditions are undertreated [81]. This is a critique of healthcare measures aligned with Heidegger's description of how the *enframing*, if not actively and consciously influenced by humans, might promote instrumentality, ordering, calculation, effectiveness, production and systemisation, a technological world in which humans are means and not goals in themselves [104]. This is a scenario in which the limits of patient participation are determined by PROs' construction and capabilities. Therefore, from a critical perspective, it will be interesting to follow whether PROs are just another instrument embedded in NPM logic, where the importance of productivity and effectiveness is stressed [81], serving those managing the healthcare system and powerholders [89], or if the PRO is an instrument that finally brings about cultural changes and makes healthcare systematically patient-centric based on patients' needs and preferences [77,78,83]. This is a process that might result in the emancipation of the patients if PROs can adequately mobilise, educate, empower and involve patients in healthcare on an individual and a population level [97–100]. However, even if PROs are relevant, useful and actionable measures in clinical practice, the problem of measurability persists. Thus, according to Riiskjær, a healthcare system based on NPM's emphasis on measurability means that only measurable phenomena are taken into account, which is a problem considering the complexity of healthcare where elements that are less measurable or unmeasurable might be focal [81]. This issue leads to considerations on the true essence of the healthcare system, mirrored by PROs' increased integration of patients' HRQoL in healthcare [4,5], indicating a new direction; however, it is based on traditional quantitative method measures [5], resembling the conservatism of the healthcare system. Nonetheless, PROs, as a measure allowing subjective input from patients, can be considered a sort of golden mean, theoretically positioned in between objective process measures and unmeasurable phenomena. In this context, Ihde's description of technologies' universalistic character and cultural embeddedness is relevant [60,61]. Hence, a PRO resembles other technologies as universalistic and standardised tools, on one hand, and as cultural and contextual adaptable tools, on the other hand. This is an interpretation of PROs integrated into *PRO Elements* indicated by the category validated questionnaires (Figure 13) [5]. Therefore, even if PROs are standardised questionnaires, their use in different praxis and cultures might enable them to promote holism and effectiveness simultaneously in healthcare, depending on the specific PRO, culture and practice. Whether it is the holism or effectiveness aspects embedded in the functionalities and purposes of PROs that will dominate remains uncertain. However, based on the healthcare context in which EBM and NPM are hegemonic paradigms [81,87,88], which synergises with the traditional utilitarian interpretation of technology [60] and current utilitarian approach in healthcare [81], it is reasonable to assume that the effectiveness will be prioritised in the future. For this reason, awareness in this PhD project has been on PROs' participatory potential, functionalities, purposes, substance and patient experiences, subjects that will probably be even more important to examine in the future.

CHAPTER 7. CONCLUSION

The present PhD project contributes to the knowledge on a PRO in clinical practice after its digitalisation. Specifically, the project elucidates the association between PROs and patient participation, PROs' purpose and functionality, the type of elements constituting a PRO and citizens' experience with a PRO in a municipal context.

Conclusively, the findings from the six studies show that

- PROs and patient participation in clinical practice are associated in the development process, in the completion of questionnaires, in connection to patient empowerment and self-management, in the use of PRO data, in patient–clinician communication and in shared decision-making situations; moreover, they are affected by organisational and attitudinal matters (Paper I).

- Experts in a Danish context perceive a PRO as data collected and applied on an individual and/or a population level, which can be used either actively or passively. The experts believe that PROs are meant to improve the quality of healthcare; for example, PROs are meant to improve patient–clinician communication, treatment and decision-making in clinical practice. In this context, PRO use is also perceived as a praxis of its own. Furthermore, a PRO is the data meant to enable VBHC, to enhance the economic efficiency of the system and to facilitate a patient-centred healthcare system. A PRO is also seen as a technology, as the digitalised PRO facilitates distinctive applications (e.g. as part of a visitation system). Finally, what a PRO is depends on the context and disease area in which it is used (Paper II).

- Patients, clinicians and managers/politicians have different uses and benefits of PROs after the tools' digitalisation and integration into clinical practice. The overview provided by Table 6 identifies 33 different functionalities and links them to the relevant stakeholders (Paper III). Essentially, the use of PROs have become increasingly patient-oriented.

- A PRO after its digitalisation and integration into clinical practice has five overall purposes. Hence, it is used for research and drug testing, to improve the quality and economy of the healthcare system, as a way to realise a more patient-centred care approach, to drive the politicisation and democratisation of the healthcare system and to cause organisational and cultural changes (Paper IV).

- The elements constituting a PRO in clinical practice after its digitalisation, as illustrated by the interdisciplinary concept map *PRO Elements*, regard the validation of the PRO, who the developers are, the type of content built into the PRO, the type of measures used, how the PRO is mediated, who the respondents are, the type of data and the outcome produced (Paper V).

- Overall, newly diagnosed citizens with type 2 diabetes are satisfied with the use of PRO questionnaires and data. However, the specific PRO questionnaire examined needs to be adjusted to fit the needs of newly diagnosed citizens and more accurately mirror their disease situation. A PRO has an ambiguous impact; on one hand, it educates, motivates and empowers citizens, and on the other hand, it makes them feel anxious, frustrated and disempowered (Paper VI).

CHAPTER 8. IMPLICATIONS AND LIMITATIONS

IMPLICATIONS

The findings disclosed by the studies constituting the PhD project are useful scientifically, theoretically and in clinical practice. Hence, it is reasonable to claim that the aim of the project, to make a scientific contribution that might provide solutions to real-world problems, has been achieved in the short term, as validated by the study results. However, the impact of the results and conceptual inputs will be visible over the long term. Overall, the PhD project makes the following contributions to the field:

- An improved understanding of PROs' functionalities and purposes after their digitalisation and integration into clinical practice in a Danish and an international context. This part of the project unfolds the substantial complexity of PROs by clarifying how the functionalities and purposes of PROs are manifold.

- A clarification of the association between PROs and patient participation. A nuanced and detailed scrutinisation of these phenomena that might enable more concrete discussions and analyses on how PROs and patient participation affect each other in chronic care.

- An interdisciplinary and holistic reconceptualisation of a PRO. An interpretation of a PRO is closely linked to a PRO as part of clinical practice, making it useful in this context and across sectors and disciplines due to its interdisciplinary character.

- A conceptual map of the elements constituting a PRO in clinical practice. The map can be used when developing, applying, implementing and evaluating PRO tools. Similar to the reconceptualisation of PROs, the *PRO Elements* can also improve interdisciplinary collaboration and discussions of PROs.

- Empirical evidence on the PRO experience of newly diagnosed citizens with type 2 diabetes. As the study contributes knowledge on a specific group, the newly diagnosed findings can be used to modify the national diabetes PRO questionnaire and the PRO data can be used to better match the needs of this particular group.

LIMITATIONS

The findings of the PhD project are limited by several factors. First, the number of participants in the interview studies are 7 experts and 10 citizens, which might be perceived as rather low numbers. In the case of expert interviews [2], more participants could have been included, but as the included informants were main experts in a Danish context, the relatively lower count was deemed acceptable. Nonetheless, other relevant experts would have provided additional knowledge, which likely could have provided the study with even richer data. In the case of citizens [6], I was offered additional informants; however, I declined it, as at 10 interviews, clear tendencies and narratives were formed, and little new knowledge was obtained in the last interviews, indicating a point of saturation. Moreover, the spread of the informants' gender and age was satisfying; hence, no more informants were required. Nevertheless, more interviews would potentially have nuanced the findings and added new valuable points, which is why the number of participants is considered a limitation in these studies (Papers II and VI). Another limitation in this context was the lack of validation from experts and citizens, which might have strengthened the results. A general critique, applied to all studies comprising the PhD project, is that I have single-handedly analysed the entire data. Hence, in a phenomenological/hermeneutic vein, the potential of the data has only relied on my limited *horizon.* If the analyses and reading processes, in the scoping review, and the document analyses and analysis of the interview material were conducted in collaboration with others, the material might have opened up further and more aspects would have been elucidated. In other words, the quality of findings and data might have improved through collaboration, as more eyes are better than two. My supervisors did later in the process provide valuable critique on the findings; however, a lack of collaboration in the initial steps of the research process is a weakness of this project. In the study on the PRO experience of citizens with type 2 diabetes [6], their lack of knowledge of PROs and experience with patient–HCP consultations in a diabetes setting can be seen as a weakness in the study design, as it meant that they had no similar former experience to compare their PRO experience to. However, this can also be perceived as a strength as their lack of knowledge within the area ensured that their impressions of the PRO questionnaire and the use of PRO data in the consultation were authentic and unaffected by the former experiences. The lack of experience and knowledge also applied to me as a researcher in the field of PROs, as the PhD project was initiated. Before the PhD project, I had never used PROs, had never heard about them and was not educated within the healthcare area, which meant that in anthropological terms, I was a *stranger* in and to the field. Hence, even though I had some knowledge of the norms, values and scientific approaches within healthcare, I had no personal experience regarding the same. This is challenging, as a PRO is linked to healthcare and issues in this context; hence, my lack of knowledge and experience in this field limited me as a researcher and influenced potential findings. Hence, the reason why I prioritised involvement in several fields simultaneously during the PhD project was to strengthen myself as a researcher and improve the quality of the study findings. Too strong a relation with the field can also be an issue, as it limits what you might be able to disclose and discover as a researcher [71]. The fact that I have a background in political and social science and that the PhD project is positioned at the education of techno-anthropology are also what makes the findings in this PhD novel and valuable. Hence, the explicit focus on PROs' purposes, functionalities and constituting elements—the link between PROs and patient participation and interdisciplinary conceptualisations of PRO—are not subject fields I have located elsewhere in the PRO literature or research, which probably have surfaced because of my alternative background. This is a novel contribution that has faced some barriers when trying to publish the papers, which again probably comes down to different approaches to PRO and diverging scientific backgrounds. In connection to the study on the PRO experience of citizens diagnosed with type 2 diabetes, other contexts and methods were originally included. Thus, all interviews with patients in an outpatient setting and *think-aloud tests* were planned. The inclusion of patients from an outpatient clinic would have broadened the citizens' perspective on the diabetes PRO questionnaire, and the *think-aloud tests* would have elucidated user experience more authentically. This is a context and method that would have complemented the current PhD project, which is why their exclusion is considered a limitation. In terms of methods, a relevant limitation is a low focus on how a PRO actually functions in context, which is why the importance of such studies is emphasised in several locations in the present thesis. Nonetheless, when studying the connection between PROs and patient participation, a longer ethnographic study on how these phenomena are linked in clinical practice would have been highly valuable. Hence, the fact that this is not included in this project is a limitation, and hopefully an area I will get a chance to work with in the future. Additionally, patients' use of PRO data as a self-management tool in homely settings would be very interesting to study. The importance of real-life settings also applies to the concept map *PRO Elements*, which needs to be tested in practice to assess its usefulness and influence on the development, implementation, application and evaluation processes of PROs. The materials on which the scoping review and document analyses are based are also limited; hence, the inclusion of validation studies of PROs, knowledge from acute care, primary care studies and implementation studies would potentially have provided additional knowledge on PRO purpose, functionality and elements. Hence, the time and resources that typically limit the review studies have also functioned as a limitation in this PhD project. The application of quantitative studies could have complemented the study results. A mixed-method research design would strengthen the study findings. Therefore, the lack of quantitative approaches to the subject field is a limitation. Hence, as HCPs and citizens become more familiar with PROs, surveys containing questions on the issues examined in this project would add valuable knowledge to the field.

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