Patient-Reported Outcome Measures (PROMs) integrated in the follow-up of patients diagnosed with haematological cancers: A qualitative study of patients’ and health care professionals’ experiences
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PhD thesis

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PhD Thesis

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Stine Thestrup Hansen, January 2020
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DANSK RESUMÉ

Patientforeninger, forskere og politikere foreslår, at Patient Reported Outcome Measures (PROMs) implementeres i daglig klinisk praksis for at forbedre relationen mellem patienter og sundhedsprofessionelle. Integrering af PROMs formodes at bidrage til øget patientinvolvering, øget individualisering i pleje og behandling samt at kunne støtte de sundhedsprofessionelle i klinisk beslutningstagning. Indenfor det hæmatologiske speciale, kan øget patientinddragelse via PROMs potentielt forbedre kvaliteten i pleje og behandling af patienter diagnosticeret med hæmatologiske kræftformer. Patienterne udgør en heterogen gruppe med stor variation i sygdomsbiomarker samt behov for pleje og behandling. PROMs kan være et redskab for de sundhedsprofessionelle til at skabe forståelse af patienters fysiske og psykosociale tilstand under sygdom og behandling samt over tid. Løbende vurderinger fra patienten om egen helbredsrelaterede livskvalitet og tilstand kan hjælpe de sundhedsprofessionelle til at forstå patientens situation og ud fra dette initiere støttende tiltag for at lindre plagsomme symptomer forårsaget af sygdom og/eller behandling.

Internationalt findes der indenfor hæmatologi endnu ikke konkrete guidelines eller standarder for anvendelse af PROMs. Der mangler ligeledes erfaringer med PROMs overordnet og specifikt mangler viden om hæmatologiske PROM-instrumenter til klinisk anvendelse. Der foreligger også begrænset viden om hvordan anvendelse af PROMs opleves af brugerne. På den baggrund blev Ph.d. studiet, som er beskrevet i nærværende afhandling initieret.

Det overordnede formål med studiet var, at undersøge hvordan PROMs blev oplevet af brugerne (patienter, sygeplejersker og læger) i et hæmatologisk ambulatorium. Formålet blev opdelt i fire delstudier: 1) At undersøge hvordan patienter diagnosticeret med hæmatologiske kræftformer oplevede at deltage i et randomiseret PROM interventionsstudie, 2) At undersøge sygeplejerskers oplevelser når PROMs implementeres i klinisk praksis; 3) At undersøge lægers oplevelser når PROMs implementeres i klinisk praksis; 4) At generere en forståelse af de barrierer og muligheder PROMs repræsenterer i en klinisk hæmatologisk praksis baseret på studie 1-3.

Den kvalitative metodologi Interpretive Description suppleret med fokusert etnografi guidede studiet for at undersøge brugernes oplevelser med PROMs. Data blev genereret ved feltarbejde i ambulatoriet samt interviews med 16 patienter, 9 sygeplejersker og 13 læger. Analysen var baseret på en systematisk tekstkondensering og inspireret af Habermas teori om kommunikativ handlen.
Delstudie 1 viste, at patienterne sjældent oplevede PROMs blev anvendt af sygeplejersker eller læger i forbindelse med deres konsultationer. Alligevel var patienterne overbeviste om at deres data blev brugt til noget værdsfuldt i klinisk praksis eller i forskningsøjemed. Trods manglende dialog om de udfylde PROMs mellem læger/sygeplejersker og patienterne, fortsatte patienterne med at udfylde disse. Delstudie 2 viste, at sygeplejerskerne opnåede meget begrænsede erfaringer med anvendelse af PROMs under dette studie. De prioriterede opgaver som var krævet af systemet, hvilket resulterede i begrænset kapacitet til at udforske PROMs, da disse ikke kunne bringes i spil under de specifikke givne rammer. Sygeplejerskerne udtrykte, at PROMs havde potentiale til at støtte deres kliniske praksis fordi de fik ny viden om patienternes tilstand, og PROMs tydeliggjorde bl.a. den enkelte patients behov for understøttende behandling og pleje. Delstudie 3 viste, at for lægerne ledte implementeringen af PROMs ikke til integrering eller anvendelse af PROMs i patient-læge relationen. Lægernes anskuelser af PROMs var modsætningsfulde og todelte, enten støttende eller skeptiske overfor anvendelsen, men ingen af dem anvendte PROMs. Ud fra de oplysninger som lægerne fik via PROMs vurderede de patienternes oplevelser og tilfredshed som de væsentligste parametre. De resterende informationer blev for lægerne betragtet som irrelevante fordi de ikke havde rammer til at drøfte PROM besvarelserne i konsultationerne. Endelig viste delstudie 4, at på tværs af brugerperspektiverne herskede en ubestridt anerkendelse af prioriteringen af den hæmatologisk-biomedicinske agenda hvilket yderligere understøttes af sundhedssystemets krav. I møderne mellem sundhedsprofessionelle og patienterne var fokus på blodprover, sygdomsstatus samt behandling og dette fokus blev ikke udvidet til også at omfatte patienters øvrige symptomer og bivirkninger som blev identificeret via PROMs for eksempel obstipation. Derudover viste studie 4, at alle brugerne havde forskellige ønsker til hvad PROMs burde indeholde og have som formål for at fungere bedre i praksis.

Det kan således konkluderes, at brugerernes oplevelser af implementeringen af PROMs som ekstra tilgængelige data ikke resulterede i anvendelse af disse data. I stedet blev PROMs en slags pseuddata og bureaukrati, fordi patienternes bidrag ikke førte til handlinger fra de sundhedsprofessionelle trods behov for støttende behandling blev identificeret hos patienterne. Implementering af så omfattende instrumenter som PROMs i klinisk praksis er således en meget kompleks proces der kræver en deltagerinvolverende implementeringsstrategi.
ENGLISH SUMMARY

Patient organizations, governments, and researchers suggest implementing Patient Reported Outcome Measures (PROMs) in routine clinical practice to strengthen patient-professional relations, increase patient involvement, individualize patient care, and to support health care professionals in clinical decision-making. In haematology, including the patient’s voice through use of PROMs is a potentially suitable approach to improve the quality of care for patients diagnosed with haematological diseases, which represent a heterogeneous patient population. PROMs can be a tool to acquire an understanding of the patient’s degree of impairment, both physical and psycho-social, during haematological disease, including during treatment and over the long-term. Assessment of such functions can help identify a patient’s condition, allowing nurses and haematologists to alleviate the symptom burden caused by disease and/or treatment.

The international haematology community has not yet introduced specific standards or guidelines for application of PROMs, as experiences with haematology-specific PROMs are scant. Knowledge is limited on how PROMs are experienced by users, patients and clinicians in haematological clinical practice. With that background, the PhD study described in the current thesis was initiated to address some of these issues.

The overall aim of this study was to investigate how a short-form PROM in the electronic medical record system was experienced by users in a haematological outpatient clinic. The aim was divided into four studies: 1) To investigate how patients diagnosed with hematological cancer experienced participating in a randomized PROM intervention study, 2) To investigate nurses’ experiences when PROMs were implemented in clinical practice; 3) To investigate haematologists’ experiences when implementing PROMs in clinical practice; 4) To develop an understanding of the barriers and opportunities PROMs may present in clinical haematological practice, based on studies 1-3.

A qualitative framework guided the study, using Interpretive Description with a focused ethnographic approach, to explore experiences with PROMs in a haematological outpatient clinic. Data consisted of fieldwork and interviews, including 16 patients, 9 nurses and 13 haematologists. Analysis was inspired by Habermas’ social theory of communicative action, using systematic text condensation. For the fourth study, a combined data and method triangulation was applied to synthesize data.

In study 1, patients experienced that PROMs were rarely elaborated on by nurses and haematologists during their visits; however, patients were convinced that the data was either used for something
useful or in support of research. Despite lack of feedback, patients continued to complete PROMs also because they felt indebted to the institution for their treatment.

In study 2, the nurses’ practical experiences with PROMs were very limited. Nurses prioritized duties required by the system, resulting in a limited capacity to use and explore PROMs, as they were not actionable for nurses within this specific setting. Nurses also expressed that PROMs have the potential to support clinical practice by identifying previously unknown information about patients’ conditions and thereby identifying additional needs for supportive care.

Study 3 showed that for the haematologists, the introduction of PROMs did not lead to integration of or elaboration on PROMs in the patient-doctor relationship, rendering both the potential of PROMs and the instruments applied uncertain. The haematologists’ attitudes towards PROMs were antagonistic and dichotomous, either supportive of or resistant to their use. Within the short-form PROMS made available within the electronic medical record system, haematologists valued patient experiences and satisfaction as the most important outcomes. The remaining information was seen as mostly irrelevant to haematologists, who did not have the time or ability to address additional symptoms.

Study 4 examined all three different user group perspectives together and identified an unquestioned acknowledgement of the biomedical agenda set by the system, limiting the application of PROMs. Users had different preferences related to choice of PROMs and different objectives for the use of PROMs in clinical practice.

The overall conclusion of this study is therefore that simply introducing PROMs as available data in a haematological outpatient clinic did not result in utilization of the PROMs due to multiple reasons, and therefore the PROMs constituted pseudo-data and another layer of bureaucracy.

Implementing PROMs in clinical practice is a complex process that requires involvement of users as well as an implementation strategy.
PREFACE

Integration of Patient Reported Outcome Measures (PROMs) has grown significantly and at a steep pace in recent years in western countries. Patient associations and policy makers have pushed to standardize integration of PROMs in clinical care in response to research on PROMs that has proclaimed its benefits. This includes PROMs supporting assessment and identification of patients’ needs for care and treatment, increased patient involvement, support in clinical decision-making, and the potential to improve efficiency in healthcare.

While this may be the case in research, transferring PROMs into a pragmatic context may yield different results. Experiences with integration of PROMs in routine clinical practice and practical experiences transferring data from population to individual level are less represented. This PhD study constitutes an exploration of the experiences of patients, nurses and hematologists1 when implementing PROMs as additional data in an electronic medical record system at a haematological outpatient clinic for individual care and treatment. The current PhD thesis builds on my studies for applied practice, which were carried out at Zealand University Hospital in cooperation with the Department of Regional Health Research, University of Southern Denmark.

1 In this thesis, the terms haematologist and physician are both presented, as both refer to the specialized medical doctors employed at the department of haematology. General Practitioners (GPs) has been used to refer to medical doctors in primary healthcare services.
List of original papers

This PhD thesis is based on the following papers:

Paper I: “I Am Sure That They Use My PROM Data for Something Important.” A Qualitative Study About Patients’ Experiences From a Hematologic Outpatient Clinic. Published Ahead of Print, Cancer Nursing, 29 July 2019

Paper II: Nurses’ Experiences When Introducing Patient-Reported Outcome Measures (PROMs) in an Outpatient Clinic: An Interpretive Description Study. Accepted for publication, Cancer Nursing, 03 January 2020

Paper III: Haematologists’ Experiences Implementing Patient-Reported Outcome Measures (PROMs) in an Outpatient Clinic: A qualitative study for applied practice. Published, Journal of Patient-Reported Outcomes, 31 December 2019

Paper IV: The experiences of patients, nurses and haematologists when Patient-Reported Outcome Measures (PROMs) are implemented in a haematological outpatient clinic: A qualitative study. Draft for Journal of Patient-Reported Outcomes
Abbreviations

COSMIN  COncensus-based Standards for the selection of health Measurement INstruments
EORTC QLQ-C30  European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30
GPs  General practitioners
ID  Interpretive Description
OEQ  Outcomes and Experiences Questionnaire
PREM  Patient-Reported Experiences
PROM  Patient Reported Outcome Measures
RCT  Randomized Controlled Trial

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INTRODUCTION

Using PROMs to respond to patient needs might be a suitable approach to individualize and improve the quality of treatment and care for patients diagnosed with chronic haematologic cancers (1–3). Approximately 2,350 patients in Denmark are diagnosed with haematological cancer each year (4). Adult patients diagnosed with chronic haematological cancers constitute a considerable proportion of haematological cancer patients (5). Cancer causes serious consequences and sequelae for many patients (6–9). Lack of rehabilitation and supportive care may result in long-term psychosocial and physical after-effects (10,11). Physical consequences can include experiences of loss of control, increased risk of depression, anxiety about disease and death, insecurity, isolation, increased physical stress, or negative body image (12–14). Socially, the sequelae and consequences of the disease often manifest as changes in relation to family and network. Together, these circumstances can influence patients and their quality of life (15,16).

Research has shown that patients often experience that specialized physicians focus on the biomedical aspects of their disease: patients do not mention psychosocial needs to these physicians even though they are worried (14,17,18). In addition to the biomedical focus, patients express a desire for healthcare professionals to acknowledge them as whole individuals and actively discuss their lives and experiences of health and life with a disease (19–22). In a review concerning patient decision-making role preferences, it was found that patients wish to influence their care and treatment, but are not invited when these decisions are made (23). Patients request individual opportunities that support their individual needs (24–26).

The healthcare system has undergone substantial transformation in recent years. Society faces medical, demographic, democratic and socioeconomic challenges as more and more expensive treatments are introduced. At the same time, the elderly population constitutes a larger proportion within the healthcare system, demanding influence (23,27). The combination of these challenges requires innovative thinking for the healthcare system to accommodate and adapt, which is one reason to expand patient involvement (28–31). To develop a person-centred practice, it is essential that patients are listened to, taken seriously, and involved in relevant ways (23,32,33). That includes

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2The term *patient* used in the current study refers to persons receiving medical care or cared for by a doctor or nurse in the context of the healthcare system (161). Initially, patients are referred to in general; within the study patients are those individuals at the outpatient clinic diagnosed with haematological cancer.
healthcare professionals being familiar with patients’ lifeworld perspective and experiences of health, worries, and requirements so they can better support and help the individual (34). Such practices are expected to strengthen the targeted involvement of patients (16,35).

One proposed solution to reinforce individualized care in the healthcare system is the introduction of PROMs (30,36). Use of PROMs is regarded as an approach to promote patient involvement, as application of PROMs has the potential to improve patient-clinician communication and interaction (37–39). Furthermore, PROMs are suggested to be incorporated into clinical practice as a tool to systematically incorporate the patient’s own knowledge (29,40). Therefore, the Danish government mandated that PROMs should be implemented broadly in routine clinical care in the Danish healthcare system, starting with the cancer specialities, among others (41).

Policy and the flourishing of PROMs in Denmark

The growth of PROMs in Danish healthcare is partly a result of developments in the Danish Healthcare Quality Programme that was introduced in 2010 (42), together with international experiences of the use of PROMs (36). The Danish Healthcare Quality Programme aimed to ensure continuous development of the quality of care to improve patient pathways and to prevent unintended events in the healthcare system (42). The fundamental objective of the programme was to involve the end users in healthcare decisions within hospital departments. Later on, in 2015, a new quality programme for 2015 through 2018 was launched, which included the systematic use of cross-sector PROMs, with the aim of directly influencing treatment decisions and ensuring quality of care (43). Such data should include patient-reported symptoms, self-assessed health, and treatment experiences, and should enable assessment of the effect of a treatment or health intervention.

In 2016, the Danish Patients association published the ‘Programme PRO’ report, a guide to how PROMs can promote better treatment and quality of care in the Danish healthcare system through using PROMs across all potential clinical domains and all health sectors (27). This report recommended use of the term PRO or PRO data to focus on the patient’s outcome as the most important and useful element, not the measure. Despite these recommendations, I will use the term

3 The term lifeworld perspectives is an epistemological foundation for the caring science based on Edmund Husserl's theory of the lifeworld (162,163). The approach recognizes the patient as the main expert on their life situation, focusing on their everyday life, particularly in terms of illness and well-being.
PROMs, as Patient-Reported Outcomes is always a measurement with an instrument constituting the outcome (44). Based on the Programme PRO report, the Danish government decided to advance the development of PROMs to a national level by allocating resources in the financial agreement for 2017 (41). Furthermore, a national PROM steering committee was established, aiming to support the standardization and broad application of PROMs in all sectors throughout the health care system. The members of the National Steering Group for PRO includes the Ministry of Health, Danish regional government, Local Government Denmark, the Danish Health Data Authority, the Danish Health Authority, and the Danish Patients association. The steering group is now in charge of standardizing PROM questionnaires and establishing guidelines as well as contributing to knowledge-sharing on the use of PROMs in clinical practice and quality development (45).

More recently, the Danish Ministry of Health published a Digital Health Strategy in 2018 stating that PROMs are essential to the quality of treatment and that application of PROMs should be foundational(29). Despite these efforts, the systematic use of PROMs is still a developing concept (46): there is no national consensus as yet on which PROMs should be used, in what format, how to deal with cross-sector compatibility, hospital IT systems, the current legal restrictions on the joint use of health data prescribed by the General Data Protection Regulation (47), or how to ensure the psychometric quality of the measures (48,49).

**PROMs in function**

PROMs are 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” (50). This is an umbrella term (see Figure 1) that covers a spectrum of potential types of measurements, from health conditions as symptoms, side effects, functional level, and physical and social status (49,51), to Patient-Reported Experience Measures (PREMs) which report on patient experiences of structures, processes, satisfaction and experience of treatment (44,52).

Previously, PROMs were mainly used secondarily for governance or to measure effectiveness in clinical trials (50) but development and research on PROMs has now moved towards integration in clinical practice settings for individualized use (53–55), in Denmark also referred to as ‘active’ or ‘passive’ application of PROMs (27). The concept of PROMs in clinical settings includes that the patients routinely report on their health and experiences over time, which provides insight for
healthcare professionals to individualize care, as the PROMs can be used actively in dialogue and in decisions within the patient-healthcare professional relation (56).

PROMs are collected through questionnaires developed for use in clinical research or practice (30). The questionnaires can be generic, dealing with general aspects of illness such as pain, daily activity, and well-being, or they can be condition-specific questionnaires dealing with problems linked to a specific disease (57). Regardless of what type of PROMs are used, the PROM instrument is always chosen by the host at the receiving institution, which means that the variation of possible outcomes is predefined, and that PROMs represent a filtered view of the patient (46,58).

According to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist, which was developed for use in systematic reviews of PROMs, any measurement has some degree of error to consider (48). This includes risk of bias in measurement properties and methodological quality. For instance, consideration should be given to the instrument’s construct, which is the explicit, underlying and specific characteristics intended to be covered by the measure; the instrument’s measures, scales or tools used to collect data; validity concerning whether the instrument samples all the relevant or important content and whether instruments are answered differently by different groups of respondents with the same health status; reliability, which refers to the extent to which a measure yields the same result each time it is administered (if reliability is low, the instrument is less able to show changes); the instrument’s responsiveness and sensitivity to change, which refers to the ability to detect changes in the measures associated with a change in the condition of the patient (59). This exemplifies how there are a number of requirements that any instrument intended to collect information from patients should meet if PROMs are to be meaningful and allow for valid inferences (49).

In tandem with developing technology, PROMs have in recent years moved towards electronic or ePROMs and real-time data collection (40). Others use the term telePRO, which covers outpatient individuals’ reports of symptoms and health from home before or instead of visiting the outpatient clinic (60). PROM tools have become increasingly interactive, for example moderating questionnaires subsequent to patient answers, so-called computerized adaptive testing (61). However, this is a technically complicated feature which is still only used on a limited basis in Denmark, as the development of PROMs and healthcare technology has not reached a level sufficient to implement adaptive measurements yet.
**PROMs in cancer care**

Within the cancer field, efforts have been made to integrate PROMs in hospital settings as part of individualized clinical care (54, 63-66). In Denmark, the Danish Cancer Society initiated the programme “Partnership on PRO,” which ran from 2016 until 2019 and included research projects in the five regions of Denmark, including the present study within the Zealand Region. The programme’s overall objective was to develop evidence-based knowledge about the use of PROMs in cancer care and to improve treatment and follow-up of patients diagnosed with cancer (66). Another operator of PROMs in Denmark is the AmbuFlex/WestChronic PRO system, which was introduced in 2004 and has been continuously updated (47). AmbuFlex has developed several PROM solutions within oncological care settings (60). In the haematological field, research on the use of PROMs for individualized care is limited and knowledge of users’ experiences are scant (67–71).
STUDY AIMS

The overall aim of this study was to investigate whether a short-form PROM in the electronic medical record system is experienced as meaningful by patients, nurses and haematologists, with the PROM including information about patients’ self-assessed health-related quality of life, experiences, physical functioning and symptom burden. According to Ravn, ‘meaning’ consists of two essential characteristics: 1) a subjective aspect, or the non-objective meaning experienced by individual humans, and 2) a contextual aspect of humans’ lived experiences within the world. Together, the characteristics form the definition: “A phenomenon is meaningful when the individual human experiences the phenomenon to be part of a whole, wider context” (72). In this study, meaning is comprehended as whether the nurses and haematologists experience getting more information about patients’ conditions and experiences, and whether this leads to initiation of additional actions which in theory would not occur during standard consultations. For the patients, meaning is perceived as more personal: what is meaningful to the individual patient cannot be generalized, as this too easily becomes an unintended normative perspective (46). In order to explore these issues and perspectives, the study consisted of four sub-studies, each specified below.

The following aims are addressed:

Study I: The aim of this study was to investigate how patients diagnosed with hematologic cancer experience participating in a randomized PROM intervention study.

Study II: The aim of this study was to investigate the nurses’ experiences when PROMs were introduced in clinical practice in a haematological outpatient setting.

Study III: The aim of this study was to investigate haematologists’ experiences when implementing PROMs in clinical practice in an outpatient setting, as part of a multimethod intervention study.

Study IV: Based on studies I-III, the aim of this study was to develop an understanding of the barriers and potential opportunities presented by PROMs in clinical haematological practice.
METHODS

In this chapter, I introduce the overall methodology, methods and theory applied to create the foundation of this thesis. First, I will elaborate on the composition of the multimethod project the current PhD study is part of. Second, I present the qualitative study, including methodology and theoretical framework. Finally, I will expand on the data construction process and clarify considerations and decisions made prior to and during the research process.

The multimethod project

This PhD study was performed as a practical and methodologically independent study in a larger multimethod project: multimethod studies “include the use of more than one method of data collection or research in a research study or set of related studies” (see Figure 2) (73). The overall aim of the multimethod project was to explore different aspects of how PROMs were integrated in an outpatient clinical setting with adult patients diagnosed with chronic hematologic cancer. The multimethod project was initiated as a combined implementation and research approach to PROMs, aiming to improve patient care by focusing on patient involvement, supportive care, and communication during meetings at the outpatient clinic. Implementation was acknowledged as a process:

Implementation is part of a diffusion-dissemination-implementation continuum:

diffusion is the passive, untargeted and unplanned spread of new practices;
dissemination is the active spread of new practices to the target audience using planned strategies; and implementation is the process of putting to use or integrating new practices within a setting. (74,75)

The multimethod project involved two studies, one Randomized Controlled Trial (RCT) and another a qualitative study, which the current thesis reports. Myself and another doctoral student were employed to prepare doctoral studies based on the two separate studies. Both of us were involved in the organization of the RCT study, which commenced October 2016. As part of employment as a doctoral student in the department, I was responsible for the qualitative study. Meanwhile, I was assigned with tasks related to the RCT, including inclusion and randomization of patients, introduction of the PROMs to the staff, and other administrative issues.

The RCT study includes statistical analysis of the amount of initiatives provided by healthcare professionals within supportive care; if the introduction of PROMs increases or reduces the number of contacts with the department and paraclinical investigations; and if the introduction of PROMs
affects patients satisfaction. The RCT included patients according to the study inclusion criteria described in Figure 2.

Figure 2. Flowchart of the multimethod project "PROMs Integrated in the Follow-up of Patients Diagnosed With Hematologic Chronic Cancer" (76)
Patients were included for a two-year period and randomized into three study groups (see Table 1). In group 1, the hypothesis was that the shared PROMs would be used in some way (unspecified) to initiate supportive care and rehabilitation for the patients. In group 2, the hypothesis was that asking the patients to complete PROMs would make patients reflect on their own condition, which could then be discussed during consultations and potentially lead to initiation of supportive care and rehabilitation. No hypothesis was linked to group 3, the control group. The RCT project is ongoing and will be published separately.

**Table 1. The three randomization groups in the multi-method project**

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM data were available to the nurses and the haematologists in the electronic medical record system</td>
<td>PROM data were not available to the nurses and the haematologists</td>
<td>A control group that followed the departments’ standard procedures; that is, patients were not asked to complete a PROM</td>
</tr>
</tbody>
</table>

**Patient characteristics**

Patients included in the multimethod study were diagnosed with Myeloproliferative neoplasms, Chronic lymphocytic leukemia, Myelodysplastic syndromes, indolent lymphoma or myelomatosis (see Appendix 1 for specifications on diagnosis). The diagnoses embrace heterogeneous diseases and chronic conditions which for most patients imply reduced life expectancy (8,77). Treatments vary from ‘watch-and-wait’ or ‘active surveillance’, which means that sometimes the patient does not need treatment straightaway (78,79). Instead, the patient is actively monitored and checked until treatment is needed. Treatment may also be medical, e.g. different forms of chemotherapy and/or maintenance treatment (77,80). Therefore, as the patients’ diseases develop differently and patient trajectories vary, the representation of side effects from the disease and treatment varies and so do patients’ needs for supportive care and rehabilitation (5,81). These patients have in common that they will be followed at the department of haematology for regular control, visiting the outpatient clinic according to individual needs, between once a week and once a year. At the visit, patients meet nurses and haematologists who monitor their disease, pharmacological treatment, and condition, according to the Danish Follow-up Programme on Chronic Myeloid Diseases (34), the National Cancer Plan IV
(82), and local guidelines; this includes rehabilitation and supportive care. Thus we find this patient group appropriate to investigate experiences with PROMs (67).

**Collection of PROMs**

PROM data was collected and stored via the web-based data collection platform EvidoInsight developed by Dansk Telemedicin A/S, in which patient participants were registered. Patients who were randomized to group 1 were invited by e-mail to complete PROMs one week before their scheduled visit to the haematological outpatient clinic. The PROM questionnaires were accessible via patients’ own smartphone, tablet or PC due to a responsive web design secured by two-step verification for data security (see Appendices 2 and 3). To make the study accessible to as many patients as possible, a paper form was offered as an alternative. This version allowed patients with no internet or compatible device to be included in the study. These patients were supplied with paper questionnaires (see Appendices 4 and 5) and pre-paid envelopes. When receiving the returned paper questionnaires at the haematological department, the data was typed into the EvidoInsight system and handled electronically afterwards (see Appendix 6). 17 patients out of the 146 in group 1 and 2 chose the paper form.

**Rationale for the choice of PROMs used**

The choice of questionnaire was influenced by the target group and the construct: chronic haematologic cancers are a heterogeneous group of chronic conditions with different trajectories, and the PROM instruments were chosen to reflect patients with a variety of disorders. The multimethod study aimed to integrate PROMs in clinical practice as guided by the Danish National Guidelines on cancer treatment (34,82). The questionnaires used were pre-developed, and the psychometric content had been tested and validated by the questionnaire’s authors. However, the questionnaires were not tested or validated for this specific setting, nor with this specific construct, nor for this specific patient group. This study neither concerns nor provides a validation process or psychometric analysis of the instruments applied, but focuses on the users’ experiences related to the introduction of PROMs.

**The questionnaires**

The PROM questionnaires used for the multimethod project were the Danish versions of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Version 3.0 (EORTC QLQ-C30) and the Outcomes and Experiences Questionnaire (OEQ) (see Appendix 4
and 5). Both questionnaires were loaded into the EvidoInsight system, allowing patients to complete the PROMs electronically.

The EORTC QLQ-C30 questionnaire consists of 30 items and 15 domains: one global quality of life domain; five functional domains including physical, role, emotional, cognitive and social functioning; nine symptom domains including fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties (83). The domain scores were calculated according to the EORTC short form and translated into a scale of 0-100. A high score represented a high Health-Related Quality of Life for functional domains, and a low score presented a low degree of symptoms for symptom domains (83).

The OEQ questionnaire consists of 11 items within the domains of communication, information, involvement, responsiveness to individual needs, and discussion of worries and fear. Scores range from 0 to 18, with high scores indicating a good experience (84). The OEQ was translated, adapted and validated; the translation was tested for understanding and adjusted during two rounds with two different independent focus groups consisting of patients diagnosed with hematologic cancers (76). The validation was guided by the “Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO)” (85). When the patient had completed the PROMs, the EORTC QLQ-C30 was condensed into a short form embedded in the EvidoInsight system. For group 1, the short form was then typed into the electronic medical record system for availability to nurses and haematologists. To make the information easily available to nurses and haematologists, the values were specified as to whether the PROMs found that functioning was reduced, unchanged or increased; and whether the symptom burden was worsening, unchanged or improved since the last PROM completion. The OEQ was loaded in the medical record system in full, as it is a short questionnaire (see Table 2).
Research Project
PROMs integrated in the follow-up of patients diagnosed with chronic haematological cancer

PROMs completed by a patient on 18 September 2019

### EORTC QLQ-C30 Questionnaire

<table>
<thead>
<tr>
<th>Scale</th>
<th>Score</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global health status/Quality of life</td>
<td>42</td>
<td>(Reduced)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>47</td>
<td>(Reduced)</td>
</tr>
<tr>
<td>Role functioning</td>
<td>33</td>
<td>(Reduced)</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>83</td>
<td>(Reduced)</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>100</td>
<td>(Unchanged)</td>
</tr>
<tr>
<td>Social functioning</td>
<td>67</td>
<td>(Unchanged)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>67</td>
<td>(Worsening)</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>0</td>
<td>(Unchanged)</td>
</tr>
<tr>
<td>Pain</td>
<td>33</td>
<td>(Worsening)</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>33</td>
<td>(Worsening)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0</td>
<td>(Unchanged)</td>
</tr>
<tr>
<td>Appetite loss</td>
<td>33</td>
<td>(Worsening)</td>
</tr>
<tr>
<td>Constipation</td>
<td>33</td>
<td>(Worsening)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>0</td>
<td>(Unchanged)</td>
</tr>
<tr>
<td>Financial difficulties</td>
<td>0</td>
<td>(Unchanged)</td>
</tr>
</tbody>
</table>

*Note: A high score for a functional scale represents a high/healthy level of functioning whereas a high score for a symptom scale or item represents a high level of symptomatology or problems.*

### OEQ Questionnaire

<table>
<thead>
<tr>
<th>Scale</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients’ reports of their experiences in the department of haematology</td>
<td>16</td>
</tr>
</tbody>
</table>

*Scores range from 0 to 18. High score indicates a good experience*

**Question**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How helpful has your most recent visit to hospital been in dealing with the problem(s) you came to hospital for?</td>
<td>Helpful</td>
</tr>
<tr>
<td>How would you now rate the problem(s) you recently came to hospital for?</td>
<td>The same</td>
</tr>
<tr>
<td>How helpful was your most recent visit to hospital in helping you manage any aspects of the problem(s) that continued after you left hospital?</td>
<td>Helpful</td>
</tr>
<tr>
<td>How would you rate your health now as a result of your hospital visit?</td>
<td>A little better</td>
</tr>
<tr>
<td>When you had important questions to ask staff, did you get answers that you could understand?</td>
<td>Yes, always</td>
</tr>
<tr>
<td>How helpful was the information you were given about your treatment and condition at your most recent hospital visit?</td>
<td>Helpful</td>
</tr>
<tr>
<td>Were you involved as much as you wanted to be in decisions about your care and treatment at your most recent hospital visit?</td>
<td>As much as I wanted to be</td>
</tr>
<tr>
<td>How much did hospital staff respond to your individual needs during your most recent hospital visit?</td>
<td>At all times</td>
</tr>
<tr>
<td>Were you able to discuss any worries and fears with staff during your most recent hospital visit?</td>
<td>As much as I wanted</td>
</tr>
<tr>
<td>Did the different people treating and caring for you work well together to give you the best possible care?</td>
<td>Yes, always</td>
</tr>
<tr>
<td>Overall, how would you rate the outcome of your most recent visit to hospital?</td>
<td>Good</td>
</tr>
</tbody>
</table>
Introduction of PROMs to the outpatient clinic staff

Prior to the inclusion of patients, the nurses and haematologists at the outpatient clinic were offered one-hour sessions on the overall study design, its purposes, how to identify PROMs in the electronic medical system, and how to interpret the PROM data. Me and my doctoral student colleague facilitated the sessions, which were repeated twice in order to inform as many nurses and haematologists as possible. My colleague responsible for the RCT, who is a medical doctor, was also responsible for the sessions with the haematologists. I was responsible for the qualitative part and facilitated sessions with the nurses. During the multimethod project, the haematologists held two sessions in which haematologists could volunteer to explain to their colleagues how they used PROMs in their consultations with patients.

The nurses and haematologists were encouraged to integrate the information provided within the PROMs during conversations with patients, in clinical decisions, and for individualized care as recommended by the Danish National Guidelines on cancer treatment (34,82). In addition, a newsletter on this topic was written and distributed via e-mail to all nurses and haematologists at the department.

After the patients had consented to participate they were randomized into the three previously described study groups (see Table 1). The patients and their primary haematologist were then informed by e-mail about which group the patient had been randomized to. The nurses were not individually informed about patients’ randomization group, because no primary nurse contact arrangement is established at the outpatient clinic. Therefore, nurses only had PROMs available if they appeared at the electronic medical record system. The haematologists and nurses consulted patients from all three groups. If the patients had not responded when PROM questionnaires were sent out, the patients were reminded to complete the PROMs and help was provided with technical issues if relevant. However, not all the PROMs that were sent to the patients were completed; this will be evaluated within the RCT study. The ongoing flow of facilitating the PROMs for patients, nurses and haematologists was a shared responsibility for me and my colleague doctoral student.

Qualitative study

A qualitative research methodology was chosen in alignment with the aims of the study, to explore patients’, nurses’ and haematologists’ experiences with PROMs in their natural social context, clinical practice, and to inform clinical knowledge. In the following sections I will elaborate on the
sample, setting, methodology, data construction and analysis applied in this study. The process of fieldwork will be especially elaborated in detail. This has been an important phase within my personal development as a researcher, but no discussion of this issue took place within the previously published studies due to word limitations.

**Settings**

The setting for the multimethod study was a specialized haematological outpatient clinic at Zealand University Hospital in Denmark, providing the opportunity to explore users’ experiences with PROMs, including patients, nurses and haematologists. In this thesis, different terms are used when elaborating on the field. ‘Fieldwork’ is used as an overall term covering activities related to data construction in the haematological outpatient clinic (the field), and ‘field study’ refers to a specific period of data construction.

The haematological outpatient clinic

The outpatient clinic is located at the hospital and shares staff and management with the haematological ward. The physical environment for the outpatient clinic consists of a large waiting room, 10 consultation rooms allocated for haematologists, and 2 nursing sections, each with the capacity to treat 10 patients at the same time.

The departments’ values focus on research and actively incorporating research in clinical practice to provide research-based treatment and care (87). This includes a person-centred practice and user involvement, embracing the perspectives of patients and clinicians (87,88). Previously, the department investigated PROMs in a pilot study, for which the EvidoInsight platform was developed (2).

The department has produced local guidelines for nurses and haematologists on rehabilitation and follow-up procedures for patients diagnosed with haematological cancer (see Appendix 7 and Appendix 8). The guideline on rehabilitation includes the definition of rehabilitation from the World Health Organisation: “Rehabilitation is a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment” (88,89).

The guideline for patient follow-up further prescribes:

Patients’ trajectories are to be individually planned and differentiated. Follow-ups will focus on potential relapse of disease, side effects to treatment, rehabilitation
and psychosocial support. Involvement of patients and relatives is required and the process of matching expectations is mandatory. The initiatives are to be clearly described, including which initiatives are provided by the department and which are provided by the primary healthcare system or others.

Both guidelines are based on the Danish National Guidelines for cancer treatment (82) and prescribe a shared, interdisciplinary responsibility for nurses and haematologists. Thus the introduction of PROMs was intended to support person-centred rehabilitation and follow-up activities as well.

**Haematologists’ consultations**

Physicians performing consultations at the haematological outpatient clinic are specialized and experienced within this specialty. Some are medical assistants, some are senior registrars and some are chief physicians. Most are permanently employed, though the senior registrars are in a specialization education scheme. This means that there is a continuous renewal among department haematologists.

Patient consultations are standardized to last 20 minutes, including documentation. In the multimethod study, no extra time was allocated regardless of which group the patient was in. Each haematologist is responsible for a number of patients. Within the department’s guidelines, their role is described thus:

> The responsible haematologist has the overall medical responsibility for patient’s individual trajectory. This includes diagnostics, pharmaceutical treatment, information, requests from patients, relatives and authorities plus timely reaction to biomedical investigations including blood tests, clinical lab tests, pathology and imaging. (90)

**Nurse Consultations**

Patients are referred to consultation by a specialized haematology nurse by departments’ haematologists. Nurses are involved in care and treatment of patients in all phases. Instrumental responsibilities include fulfilling medical prescriptions, which may include taking medical histories; performing examinations; providing intravenous therapy, immunotherapy, chemotherapy or blood transfusions; performing blood tests; and assisting biomedical research (91). The nurses’ responsibilities also include haematological nursing care, which in the department is described in a
local Framework on Nursing. The framework states that haematology nursing should aim to be interactional and involve caring for individuals with a whole-person approach, including initiating person-centred rehabilitation and supportive care; educating and empowering patients and their families on how to live with and manage their blood disease; understanding patient’s needs for mind, body, spirit, emotions and environment; using expertise and clinical intuition to provide care; and promoting a healthy lifestyle for the best possible well-being or quality of life in the patient’s specific situation (87).

**Participants and sampling**

Participants were 16 patients, 9 nurses and 14 haematologists who were purposefully selected. Details on the participants are specified in Table 2 and furthermore within papers I, II and III. Patient participants were recruited from the RCT study, representing the three randomized groups, to reflect the three different forms of consultations and patients’ gender and age. Recruitment of nurses and haematologists followed the patient participants, as nurse and haematologist participants were those whom the patients met throughout their visit on the day when being observed by the present researcher. The patients’ visits were pre-booked and patients visited either a haematologist, a nurse, or a haematologist followed by a nurse.
### Table 2. Patients, haematologists and nurse participants included in the qualitative study

<table>
<thead>
<tr>
<th>Patients</th>
<th>Gender</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Intervention</th>
<th>Consulted by</th>
<th>Study phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1*</td>
<td>Male</td>
<td>74</td>
<td>Polycythemia vera</td>
<td>Control</td>
<td>N1</td>
<td>F1</td>
</tr>
<tr>
<td>P2</td>
<td>Female</td>
<td>73</td>
<td>Waldenström macroglobulinemia</td>
<td>Control</td>
<td>H2</td>
<td>F1</td>
</tr>
<tr>
<td>P3*</td>
<td>Male</td>
<td>85</td>
<td>Myelodysplastic Syndrome</td>
<td>PROMs available</td>
<td>H1</td>
<td>F1</td>
</tr>
<tr>
<td>P4</td>
<td>Female</td>
<td>71</td>
<td>Follicular lymphoma</td>
<td>Control</td>
<td>H3</td>
<td>F1</td>
</tr>
<tr>
<td>P5</td>
<td>Female</td>
<td>74</td>
<td>Myeloproliferative neoplasms</td>
<td>PROMs available</td>
<td>H4</td>
<td>F1</td>
</tr>
<tr>
<td>P6*</td>
<td>Male</td>
<td>68</td>
<td>Chronic lymphocytic leukemia</td>
<td>PROMs not available</td>
<td>N3 + H5</td>
<td>F1</td>
</tr>
<tr>
<td>P7*</td>
<td>Male</td>
<td>78</td>
<td>Myelodysplastic Syndrome</td>
<td>Control</td>
<td>H6</td>
<td>F1</td>
</tr>
<tr>
<td>P8*</td>
<td>Male</td>
<td>72</td>
<td>Follicular lymphoma</td>
<td>PROMs available</td>
<td>H7</td>
<td>F1</td>
</tr>
<tr>
<td>P9*</td>
<td>Male</td>
<td>71</td>
<td>Essential thrombocytethemia</td>
<td>PROMs available</td>
<td>N4 + H8</td>
<td>F2</td>
</tr>
<tr>
<td>P10*</td>
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<td>75</td>
<td>Myelofibrosis</td>
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<td>H6</td>
<td>F2</td>
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<tr>
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<td>Mantle cell lymphoma</td>
<td>PROMs not available</td>
<td>N7 + H9</td>
<td>F2</td>
</tr>
<tr>
<td>P12</td>
<td>Female</td>
<td>71</td>
<td>Waldenström macroglobulinemia</td>
<td>PROMs available</td>
<td>N6 + H10</td>
<td>F2</td>
</tr>
<tr>
<td>P13*</td>
<td>Male</td>
<td>76</td>
<td>Chronic lymphocytic leukemia</td>
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<td>H11</td>
<td>F2</td>
</tr>
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<td>P14*</td>
<td>Female</td>
<td>77</td>
<td>Polycythemia vera</td>
<td>PROMs not available</td>
<td>H12</td>
<td>F2</td>
</tr>
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<td>P15</td>
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<td>PROMs available</td>
<td>N1</td>
<td>F2</td>
</tr>
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<td>70</td>
<td>Follicular lymphoma</td>
<td>PROMs not available</td>
<td>H13</td>
<td>F2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Haematologists</th>
<th>Gender</th>
<th>Educational status/ Haematological experience</th>
<th>Study phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1</td>
<td>Male</td>
<td>Medical assistant &gt; 5 years</td>
<td>F1</td>
</tr>
<tr>
<td>H2</td>
<td>Male</td>
<td>Medical assistant &gt; 5 years</td>
<td>F1</td>
</tr>
<tr>
<td>H3</td>
<td>Female</td>
<td>Medical assistant &gt; 10 years</td>
<td>F1</td>
</tr>
<tr>
<td>H4</td>
<td>Male</td>
<td>Senior registrar</td>
<td>F1</td>
</tr>
<tr>
<td>H5</td>
<td>Male</td>
<td>Medical assistant &gt; 15 years</td>
<td>F1</td>
</tr>
<tr>
<td>H6</td>
<td>Male</td>
<td>Medical assistant &gt; 10 years</td>
<td>F1, F2</td>
</tr>
<tr>
<td>H7</td>
<td>Male</td>
<td>Medical assistant &lt; 5 years</td>
<td>F1</td>
</tr>
<tr>
<td>H8</td>
<td>Male</td>
<td>Medical assistant &gt; 10 years</td>
<td>F2, INT</td>
</tr>
<tr>
<td>H9</td>
<td>Female</td>
<td>Medical assistant</td>
<td>F2</td>
</tr>
<tr>
<td>H10</td>
<td>Male</td>
<td>Medical assistant &gt; 10 years</td>
<td>F2</td>
</tr>
<tr>
<td>H11</td>
<td>Female</td>
<td>Senior registrar</td>
<td>F2, INT</td>
</tr>
<tr>
<td>H12</td>
<td>Female</td>
<td>Senior registrar</td>
<td>F2</td>
</tr>
<tr>
<td>H13</td>
<td>Male</td>
<td>Senior registrar</td>
<td>F2</td>
</tr>
<tr>
<td>H14</td>
<td>Male</td>
<td>Medical assistant &lt; 5 years</td>
<td>INT</td>
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</table>

<table>
<thead>
<tr>
<th>Nurses</th>
<th>Gender</th>
<th>Haematological experience, years</th>
<th>Experience as a nurse, years</th>
<th>Study phase</th>
</tr>
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<tbody>
<tr>
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<td>8</td>
<td>28</td>
<td>F1, F2, FG</td>
</tr>
<tr>
<td>N2</td>
<td>Female</td>
<td>10</td>
<td>17</td>
<td>F1, FG</td>
</tr>
<tr>
<td>N3</td>
<td>Female</td>
<td>7</td>
<td>11</td>
<td>F1</td>
</tr>
<tr>
<td>N4</td>
<td>Female</td>
<td>18</td>
<td>18</td>
<td>F2</td>
</tr>
<tr>
<td>N5</td>
<td>Female</td>
<td>4</td>
<td>14</td>
<td>FG</td>
</tr>
<tr>
<td>N6</td>
<td>Female</td>
<td>7</td>
<td>14</td>
<td>F2</td>
</tr>
<tr>
<td>N7</td>
<td>Female</td>
<td>3</td>
<td>3</td>
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<tr>
<td>N8</td>
<td>Female</td>
<td>5</td>
<td>7</td>
<td>FG</td>
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<tr>
<td>N9</td>
<td>Female</td>
<td>11</td>
<td>11</td>
<td>FG (S)</td>
</tr>
</tbody>
</table>

F1 refers to data from Field Study 1, F2 refers to data from Field Study 2, FG refers to data from Focus Group Interview and INT refers to data from the in-depth interviews. * Patients accompanied by a relative (S) on sick leave
Methodology

Interpretive Description

Interpretive Description (ID), with a focused ethnographic approach, guided the study and was initially chosen as part of the study’s strategy (92,93). ID is an inductive methodology developed to explore clinical problems that arise from practice disciplines, with the objective to generate insights that inform clinical practice (94,95). ID acknowledges the theoretical and practical knowledge that researchers bring to a project, answering practice-oriented questions grounded in disciplines with an applicability mandate (92).

The methodology draws upon established qualitative research techniques from ethnography, grounded theory, naturalistic inquiry, and phenomenology, but differs by compromising “methodological orthodoxy” (94,96). Instead, the methodology focuses on the importance of explicit research logic and flexibility, permitting researchers to apply and combine the necessary pragmatic strategies to fully answer the research question (96,97). ID studies are distinguished from generic qualitative studies due to their epistemological standpoint, as ID is positioned as a philosophical alignment within the interpretive, naturalistic orientation, acknowledging the constructed and contextual nature of human experiences and shared perspectives of reality (98). ID cannot be placed firmly at any endpoint between objective reality and subjective impression but is placed somewhere in the middle. Hence, ID draws upon the full spectrum of factual material and social construction to develop meaningful and relevant understanding and knowledge of ideas central to applied disciplines such as healthcare professions (92). The composition of an ID study is guided by certain required and distinctive features, including: scaffolding the study, framing the study, strategizing a credible study, entering the field, constructing data, making sense of data, and conceptualizing findings. The result is a coherent, conceptual description containing understandings and illuminations of clinical phenomena, characteristics, patterns and structures in order to improve practice (99).

The methodology does not provide users with a stepwise procedure to research. However, it does prescribe quality features and how to maintain sufficient rigor to ensure academic credibility. These include epistemological integrity, representative credibility, analytic logic, interpretive authority, moral defensibility, disciplinary relevance, pragmatic obligation, contextual awareness, and probable truth (92). From an ID perspective, the key to quality is primarily found within the internal logic of purpose, process and context that turns into a coherent and convincing account (100). In this process, ID advocates an ongoing, concurrent data construction and analysis which allows the initial analysis to inform the subsequent data collection (99). This important process is justified through the
researcher’s audit trail, which includes preliminary findings and rationale for methodological
decisions made along the way (92). The audit trail for this study was incorporated into my log book, in
which I tracked decisions and reflections during the study from the very beginning when
scaffolding the study. The log book is still an active tool which will probably be used until the
completion of the larger multimethod study.

I chose ID methodology for this study for several reasons: 1) the nature of the phenomenon I wanted
to investigate, which called for a qualitative approach; 2) my personal background as a nurse based
in clinical practice, which informs my clinical knowledge and epistemology; 3) ID offers a pragmatic
and flexible approach for inquiry, which seemed beneficial, as it was impossible to predict potential
findings, suitable sources and relevant theory. Furthermore, ID seemed to be a rational choice for me
as a novice researcher, as the methodology guides the researcher through the qualitative research
process, from defining the research question, to research design, through fieldwork analysis,
interpretation and application of the results. It was also key to generate knowledge for clinical practice
in my own field if possible, knowledge which might not be accessible to external researchers.

In the case of the present study, I have endeavoured to better understand the implementation of
PROMs in clinical practice from the perspective of the user groups, the patients, nurses and
haematologists. The implementation of PROMs in the outpatient clinic represented a new form of
data that was added to existing clinical practice. I did not know how PROMs would be used, if they
would be used, what they would be used for, if they were relevant to users, or how PROMs would
exist in the context of the clinic. This was a complex clinical phenomenon involving interactions and
structures between and among patients, nurses and haematologists. Knowledge about clinical practice
with PROMs can inform and guide future implementation of PROMs at the specific department and
elsewhere, both nationally and internationally.

**Focused Ethnography**

According to ID, observations of human behaviour and interviews are central mechanisms in the
research process, helping to discover the impact of contextual events on the matter being studied,
aligned with a constructivist and naturalistic orientation to inquiry (92).

Inspired by classic ethnography but with a rationale of study limitations in clinical practice, a focused
ethnography by Knoblauch was chosen to support the data construction process (93). Focused
ethnography is an applied research methodology that focuses on specific situations where individuals
are involved in relationships or shared experiences (101). Focused ethnographies can serve as a meaningful and useful application of studies in healthcare settings, to investigate care and care processes by generating data on a specific topic of importance to individual clinicians or clinical specialties. According to Knoblauch, such studies presuppose that the researcher has an intimate knowledge of the field in order to understand the language of the culture, or one’s own ‘society’ (93). Elaborating on this, Van Maanen describes that “To write an ethnography requires at a minimum some understanding of the language concepts, categories, practices, rules, beliefs, and so forth, used by the members of the group studied” (102). Further characteristics of focused ethnography are:

(a) Focus on a discrete community or organisation or social phenomena
(b) Used in academia as well as for development in healthcare services
(c) Involvement of a limited number of participants
(d) Problem-focused and context-specific approach
(e) Participants usually hold specific knowledge
(f) Episodic observation
(g) Conceptual orientation of a single researcher (103).

In this study, fieldwork with focused ethnographic observations was carried out during consultations when patients from groups 1, 2 and 3 visited nurses and haematologists at the outpatient clinic. The fieldwork included the following: observations, focusing on the interactions between the healthcare professionals and the patients, during outpatient consultations at the outpatient clinic; field notes; and interviews with patients, nurses and haematologists (individual and in focus group) to develop a comprehensive understanding of user experiences with PROMs. The focus changed along the way as I generated and analysed data; the data analysis generated preliminary findings that informed subsequent data construction. Focused ethnography provided a constructivist frame aimed at eliciting the perceptions, meanings, and experiences of patients, nurses and haematologists, and therefore would develop rich descriptions in line with ID (92).

**Habermas’ Critical Theory**

To accompany the ID methodology, a framework inspired by Habermas’ critical theory was utilised. Critical theory was chosen after the first fieldwork and interviews, as I noticed indications of implicit structures, rationales and relationships related to power and oriented toward the system (104,105), concepts foundational to Habermas’ theorization.
The German philosopher and sociologist Jürgen Habermas became well-known in the 1960s as the leading light of the second generation of the Frankfurt school theorists (106). His roots are in the tradition of G.W.F Hegel’s dialectical philosophy, whose main assumption, shared by Karl Marx, was that “human beings form or define the world around them via their mental and physical activity” (106). Habermas’ critical theory on the nature of social change in the context of global capitalism may be understood as a further development of this first generation of Frankfurt theorists. The Frankfurt “school” was a group of philosophers and cultural critics who worked in the period before and after the Second World War for the Institute for Social Research based in Frankfurt (106).

Habermas’ critical theory is a social theory oriented toward critiquing and changing society as a whole. The goal of critical theory is not only to determine what is wrong with contemporary society, but to help transform society for the better by identifying progressive aspects and tendencies within it. Habermas is interested in institutional structures and the concept of the public sphere because he saw it as the origin of the ideal democratic political concept, and as the source for the basic morals and values that nourish and maintain democracy, including equality, liberty, rationality and truth (104,105).

Distinctive features of critical theory

System and lifeworld

According to Habermas, modern societies comprise two basic spheres: the lifeworld and the system. Lifeworld and system are the seats of communicative and instrumental action, respectively. The lifeworld is a concept describing the everyday world we share with others. It represents informal domains of social life such as family, household, culture, and everyday encounters with other people, where communicative actions and social relationships take place. In contrast, the system refers to economy or state structures, rule-governed elements and established patterns of instrumental action. Systems enact rational, purposive or strategic actions (105).

Habermas acknowledges the contributions of the system to the social life of the lifeworld, but points out the inherent danger of integration with the system. Systems institute and reinforce patterns of action and can prevent humans from reflecting on the end results of such actions. Modern society is thus in a fragile situation, caught between system and lifeworld, and as the domain of the lifeworld shrinks, ‘social pathologies’ arise and lead to instabilities and crises (104,105).
Communicative action, strategic action and the communicative space

Habermas distinguishes between communicative action, on the one hand, and instrumental and strategic action on the other. Instrumental action is when an individual does something as a means to bring about a desired end; strategic action is a kind of instrumental action whereby one realizes one’s own goals through the actions of other people. Both differ from communicative actions. The concepts of communicative action and discourse constitute a central link between Habermas’ pragmatic theory of meaning and social and moral theory. Communicative actions are linguistic interactions where speech acts contain validity claims concerning clarity, truth and justification, which are openly criticisable and discursively changeable (104,105). The discourse is communication that reflects the consensus in the context of action. Habermas argues that communicative and instrumental actions are distinct types of actions, but they are basic and irreducible to other types. The distinction between the two is both conceptual and real. There are two ways in which action can be understood and two ways in which real humans can interact in the social world. According to Habermas, the spaces in which communicative action occurs are limited in modern society because it has become primarily rational and orientated towards strategy, with open debate stifled by the concern to ‘get the job done’ (104,105).

Operationalization of power

The notion of power is a focal point for Habermas, who uses his theory of communicative action to critique power in modern societies. According to Habermas, power exists at different levels among humans, as communicative actions and purposive-instrumental actions; among these are ways of thinking, speaking and organizing (105).

Habermas criticizes power within the political economy and also the socio-cultural sphere, both constituting problematic power and domination in late capitalist societies. This concerns inequalities and exploitation in the production sphere but also power operationalized within rationality in the socio-cultural sphere, which instrumentalizes human actions (105).

Habermas distinguishes between legitimate, reasoned power based on the consensus achieved in communicative action, versus illegitimate, forced power. Legitimate power is connected to reason while illegitimate power is linked to force and implies a problem of coercion for the humans involved. In his critique, Habermas stresses the importance of keeping a balance in power and limiting the system from taking over (104,105).
The relevance of Critical Theory

In this study, I explore the experiences of patients, nurses and haematologists related to the introduction of PROMs. I argue that there is a practical tension between the required roles and actions that nurses and haematologists are required to take in everyday practice, and the communicative action intended to be introduced through PROMs, a method of improving person-centred care. It seems fair to claim that due to a number of forces in contemporary delivery and management of health services that the distinctive contribution of healthcare professionals has become less visible and that bargaining units and regulators are increasingly focused on practical tasks rather than what defines a practice or discipline such as nursing (107). In framing this argument I found it reasonable to assume that use of PROMs does not essentially concern the interactions and subjective preferences of the patients, nurses and haematologists, but rather is a result of a number of causal mechanisms (92), including actions and rationales as a result of social system structures and power within the healthcare system (104–106). I found that critical theory informed the empirical material and allowed me to explore in this study the experiences, actions, rationales and underlying mechanisms related to clinical practice.

Data construction

I carried out the fieldwork between March 2017 and December 2018 at the haematological outpatient clinic at Zealand University Hospital (see Figure 3).

| Figure 3. Fieldwork and data construction at the haematological outpatient clinic |
|-------------------------------------------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Data Material/Time                              | 2016    | 2017    | 2018    |
|                                                 | Q1      | Q2      | Q3      | Q4      | Q1      | Q2      | Q3      | Q4      |
| Audio recordings of the consultations + interviews with patients, nurses and haematologists |         |         |         |         |         |         |         |         |
| Focus group interview with nurses               |         |         |         |         |         |         |         |         |
| In-depth interviews with haematologists         |         |         |         |         |         |         |         |         |
| Multimethod project                             |         |         |         |         |         |         |         |         |
|                                                 | 10/16-1/6/20 |
| Epic Launch 25/11 *Focus group interview 12/10-2018 **In-depth interviews 12/11, 14/11, 18/12 |
The introduction of PROMs at this hospital was conducted simultaneously with a large restructuring of the hospital’s information technology, including launching Epic, a multipurpose electronic medical record system (108). During the launch of Epic, no fieldwork was planned as this period was allocated for the clinicians to focus on implementation of the new system. The fieldwork was planned based on the patients in the multimethod study and when they were to appear at the outpatient clinic. However, as clinical practice and working with people is changeable, patients’ visits were cancelled several times for different reasons and new plans were made. Mostly, patient visits were cancelled by the outpatient clinic nurses and haematologists because patients’ blood tests were acceptable, obviating the planned visit. Once, a visit was cancelled as the patient was in the intensive care ward. As the aim was to investigate patients’, nurses’ and haematologists’ experiences with PROMs in clinical practice, the primary data construction took place in study participants’ natural social context: clinical practice was the inductive, concurrent, multi-perspective data construction and analysis for the three studies (see Figure 4). These multiple perspectives formed a method triangulation which sought to illuminate what constitutes truth about PROMs in the clinical setting and to overcome bias that might occur from single-method approaches.
Figure 4. Flowchart of the data construction and analysis within the qualitative study

**Initial Research Questions**

| Patients’ experiences with PROMS | Nurses’ and Haematologists’ experiences with PROMs | How do the two perspectives interrelate? |

↓

Development of the initial observation and interview guide

↓

**Field study 1**

8 Patients
7 Haematologists
3 Nurses

↓

Analysis

↓

**Research questions adjusted**

| Patients’ experiences with PROMs | Nurses’ experiences with PROMs | Haematologists’ experiences with PROMs | How do the perspectives interrelate? |

↓

Adjustment of the observation and interview guide

↓

**Field Study 2**

8 Patients
7 Haematologists
4 Nurses

↓

Analysis

↓

**Findings**

| Patients experiences | Nurses’ experiences | Haematologists’ Experiences |

Development of the Focus Group Interview guide

↓

Adjustment of Interview guide

↓

**Focus Group Interview**

4 nurses

3 Haematologists

↓

Analysis

↓

**Findings**

| Nurses’ experiences | Haematologists’ experiences |

Findings Nurses’ experiences (Paper II)

Findings Haematologists’ experiences (Paper III)

↓

Analysis

↓

**Findings**

User Experiences (Paper IV)
Entering the field

The fieldwork was conducted as participant observations at the haematological outpatient clinic, to enter and engage in the world of the study participants (92,109). The outpatient clinic is part of the department of haematology where I have been working as a nurse since before the start of my doctoral studies. I was acquainted with the nurses and haematologists at the outpatient clinic as they had been my colleagues for 4 years.

During my fieldwork, my insider position helped me gain access to the field. When a patient participant had consented to participate, meaning that I could follow them during their consultations, I explained to the nurse and/or haematologist consulting with the patient on that specific day that the patient was a participant in the PROM study and that I would like to observe PROM usage in the patient’s consultation. In one instance a nurse denied me access to a consultation, explaining that she felt intimidated by my presence, and due to personal reasons she wished to refrain from participation. In that situation, another nurse volunteered to switch patients so I could follow the patient without interruption. In this case, my presence and participation in the field strongly influenced the field, with the consequence that the patient was consulted by a nurse other than the one planned. The rest of the nurses and haematologists agreed to my participation after the objective had been introduced and my participation explained during the teaching sessions at the outpatient clinic; most of them did not seem surprised by my presence. The nurses and haematologists consented to participate and most indicated that if the patient had consented to my participation it was fine for them as well. My query to nurses and haematologists about participation during their consultations constituted a brief talk, and the I thus became aware at an early, informal stage of the clinicians’ views and opinions of PROMs. For instance, one of the haematologists expressed that I could participate during the consultation, but that he did not intend to use the PROMs. These early contacts with nurses and haematologists were very short, as the clinicians are often very busy in the morning preparing for the day. At one point, I tried to contact the clinicians the day before, so as not to disturb them in the ‘rush hour’, but I learned that the time they had to prepare led to practices such as nurses switching patients, which was an unintended and undesired outcome: I needed to participate in status quo clinical practice.

The patient participants were contacted upon arrival at the outpatient clinic. I met them in the waiting room and presented myself as a nurse researcher. I had already spoken to most of the patients during the inclusion process for the multimethod study, and patients thus referred to me as being a familiar face. The patients all welcomed my participation during their visit. I briefly told the patients that I
was investigating how PROMs are used during clinic visits and that my main role was to observe. No patient declined to participate; instead they rather expressed appreciation that their case could be interesting to research.

Before the consultations, I studied the patients’ electronic medical record. If the patient had completed PROMs, I read the results in the electronic medical journal and wrote down issues which drew my attention. These could be specific issues on the PROM outcomes such as changes in the scores or issues leading to questions. If the patient had not completed PROMs, I only read the existing notes in the electronic medical journal. During the fieldwork, I specifically paid attention to how/if PROMs were elaborated on and what constituted the content of the consultation (see the Observation Guide, Appendix 9).

The fieldwork was predominantly used to observe the interactions of patients, nurses and haematologists in clinical practice, specifically focusing on PROMs; initially there was also a focus on whether there were differences between the three groups of 1) PROMs available, 2) PROMs completed but not available and 3) control group. Later, the focus was narrowed to experiences related to the introduction of PROMs, as no difference was observed among the three study groups. For the nurses and haematologists, I first aimed to investigate their experiences as one joint aim to capture ‘clinician’ experiences. This was with the rationale that practice would be interdisciplinary, with close collaboration on PROMs based on the multimethod project description. This aim changed after the first round of fieldwork and analysis, as the preliminary findings indicated a fragmented practice with very different perspectives on PROMs among nurses and haematologists. This resulted in the separation of the two perspectives.

**Field notes**

As part of the focused fieldwork, field notes were taken in a notebook as a way of recording what I observed and reflected on (103,110). During the fieldwork, I sketched in my notebook how the patients, patients’ relatives and health care professionals placed themselves in the room. I described the relationship between the patient and the clinician, what happened, and specifically how the patient was placed in respect to the clinicians. How did they interact during the visit, what did the clinician and patient do? How much time was spent looking at the computer? What body language could be observed? How long did the appointment take (see Appendix 9)? The field notes during patient visits were quite brief, mainly involving keywords or short sentences on the phenomena investigated, the atmosphere, emotions, reactions or my positioning when relevant. Immediately following the
fieldwork, I wrote down all thoughts and reflections on the situation experienced; these notes could be superficial, descriptive, analytical or reflective (110). The field notes formed an initial in-field pre-analysis (110); though the notes were not perceived as empirical data, they still formed part of the analysis and helped me recall the situation and my thoughts later during analysis (92).

**Interviews with patients, nurses and haematologists**

Observations of patient consultations were followed by interviews with individual participants, including patients (and relatives, if any), nurses and haematologists. In these interviews, specific observations were discussed (103), but also broader perspectives on the PROM application, or lack thereof (see Appendix 10 for the interview guide). The interviews took place at the haematological outpatient clinic in a quiet room.

Due to practical considerations, the patients were interviewed first so as to avoid delays. Afterwards, the nurse and/or haematologist who had been involved was interviewed. The interviews with patients were mainly regulated by patients’ time constraints, so these interviews often allowed for time to unfold questions. Interviews with nurses and haematologists took place in between their scheduled consultations with patients, however, leaving limited time. The nurse or haematologist was always asked when was the best time for the interview. No specific time was set for these interviews: instead, the time was controlled mainly by clinicians. The interviews with haematologists were especially very short, but the haematologists communicated and reflected in depth on the questions asked.

The full interview process with nurses and haematologists is described in the following section. The interviews were audio recorded, anonymized, and transcribed into text using NVivo software.

**Reflections on the field**

In the Interpretive Description methodology, fieldwork is not simply conducted but rather generated by the researcher, situating the self within the research role (92). This work calls for critical reflection on the researcher’s positioning, degree of participation, and ability to disregard the professional lens from one’s practice discipline (92,111). ID prescribes that “The task of the participant observer is to rigorously and systematically ensure that the lens through which you are looking is open, transparent, and clear, and the quality of your research product will depend entirely on how convincingly you can show that you accomplished that” (92). A recent review of Danish ethnographic research concludes that focusing on the role of the researcher and being an insider seems to be implicit and clarification on these issues is necessary to enhance the quality of such research (111). Van Maanen also argues
that such narratives are often overlooked by authors, and personal subjectivity becomes moot (102). Thus, to provide transparency on the focused ethnography and the process of entering the field as a novice fieldworker, this section contains a digest of some of the reflections tracked in my log book, which was written after the first period of fieldwork. These considerations mainly focus on the researcher-patient relation in the field and how I as a novice researcher was striving to develop ethnographic sensibility and reflexivity (112,113).

My very first experiences in the field led to reflections on interactions. After the first two sessions of fieldwork, I sensed that patients did not provide me with the full spectrum of their perspectives. According to Coffey, who focuses on fieldwork related to representation and identity, the ethnographer’s emotional tensions are important within fieldwork: emotions are part of the researcher’s sensibility and reflexivity needed to develop ethnographies (114). Therefore, I reflected upon this experience and feeling, noticing that patients’ answers were very short, their body language conveyed scepticism and they did not show interest in interacting with me. Was it because of my introductory instructions in the waiting room, where I communicated to them that I mainly planned to observe? Or was it something about my appearance? I did not know, but this hunch was present. At this point, I experienced that it was difficult to gain insight into the patients’ perspectives. I discussed the issue with my supervisors, who were experienced in fieldwork, and returned to the literature on theory of fieldwork in clinical practice.

My experience of a lack of interaction with patients caused me to reflect that fieldwork is more than entering the room and being present; certainly for the interviews after the fieldwork, my gut feeling told me that Pandora’s box remained closed to me. The focused ethnographic approach had to be supplemented with a wider understanding of how to enter social settings and establish relations in the field studied. I had done this a thousand times as a nurse at the department, why was this difficult as an ethnographic observer? If the patient did not invite me into their stories, then how would I gain insight to their lifeworld and perspectives?

According to Emerson, the objective of ethnographic studies is to adapt to the world that is being studied in order to better understand what is experienced as meaningful and important: this happens by establishing relations (110). In my focused ethnographic setting, the establishment of relations was a challenge due to the circumstances. The fieldwork was time-intensive: some patients arrived very late, and the establishment of a relationship took place in the waiting room where many other patients were waiting and passively listening. Thus, the challenge was to make room for patients’
confidence and not, even if perhaps unintended, trample on my own and the patients’ boundaries. I needed to pose trust rather than insecurity (102,113).

In the theoretical literature, it is discussed whether is it possible to enter the field and ‘only observe’ without influencing the field (109). Generally, there is consensus that researchers or ethnographers are only included in social associations through actively participating (115,116). One cannot and should not attempt to be a ‘fly on the wall,’ as no observer can be completely neutral in relationship to the phenomenon observed. Transparency about how the researcher influenced is rather important (117). Spradley defines a continuum of grades of participation, and posits a link between the degree of engagement and the researcher’s involvement (109). I realized that my theoretical, fixed ideas about what constitutes focused ethnography and fieldwork in theory had to become more flexible and my participant role had to be more engaging and participatory in order to make room for trust. During the subsequent fieldwork I began to show more interest, offering small talk about the patient’s journey to the hospital that day, or other issues to soften the atmosphere. Denzin describes the beginning relation as essential, as clinicians at the hospital meet patients in a fragmented manner in the hospital setting. Entering patient experiences happens through sharing narratives and letting humans express their views (118). Narratives may be necessary in field relations, which includes balancing between intimacy and distance in relation to the study participants, both to gain trust but also to rise above the researcher’s own preunderstanding (119). At the same time, field relations are characterized by phases: as the researcher and the study participant becomes familiar with each other, the relation develops. Furthermore, the researcher becomes more familiar with the field and develops as well (102). In my case I might have appeared insecure as fieldwork was a new discipline to me. During my latest fieldwork, I strove to be more active and engaged during the sessions. I experienced that when participating more actively, patients tended to enter into dialogue with me in a rather more narrative form. This led to more substantial and rigorous data. Sometimes, as I was waiting with the patients in the waiting room before their consultation, these situations gave rise to the most personal narratives.

The development of my ethnographic self

Fieldwork starts from where we are: the subjective personality is part of the research and is negotiated within the field (92,114). Cruz and Higginbottom state in their adaption of focused ethnography that fieldwork will not generate good data and interesting analyses without personal investment (101). On a practical level, such practice required awareness of my subjectivity in the fieldwork, being both an
experienced nurse in the field and at the same time entering my new role as a novice researcher, also described as a distinction between ‘being’ and ‘seeing’ (102). During fieldwork, this dual role challenged me; as an insider, I was acquainted with my previous colleagues and knew the haematological specialty very well. Though unintended, this also sometimes made me sympathize with the nurses and haematologists. Thus, a specific focus on bias, presumptions and prejudices was taken (92). On the other hand, my new role as an outsider became more apparent as I built experience in fieldwork, resulting in reflections, questions, and a critical analytic approach to practice (113). This was an ongoing shift, calling for awareness of my subjectivity and positioning as a researcher in the field of study (113), which was very honestly discussed and reflected on with my supervisors. An example was how I, as an insider nurse, had previously experienced the highly interdisciplinary practice of working with haematologists, and yet one nurse declined to participate in my observation session. What I saw through the ethnographic lens was a fragmented practice with scant interdisciplinary content. In the following section, I will provide an example of how my personal development into an ethnographic self took place.

Fieldwork is personal and emotional identity work, and the construction and production of self and identity occurs both during and after fieldwork, as practical, intellectual and emotional accomplishments (114). The following example involves a rather practical but also identity-focused issue regarding my choice not to wear my nursing uniform during field studies. Initially, I decided to wear my nursing uniform and name tag during fieldwork, as I wanted to be considered as part of the staff (120). That changed. Due to my experiences in the first sessions of fieldwork, including lack of interaction, I doubted the appropriateness of my uniform. I interpreted patients’ reactions as a result of them seeing me as part of the outpatient staff, which had been my goal. But during the fieldwork, I experienced patients asking for e.g. assistance with pharmacological treatments or if the infusion pump had stopped. Responding to such inquiries blurred my focus during the fieldwork (121). Therefore I decided to test fieldwork wearing civilian clothing, though still wearing my name tag. In this way, patients could see that I was employed, and I started to present myself as a nurse researcher. After that, my appearance seemed to be accepted more in the way I intended, giving me the ability to focus on the fieldwork. Also, I changed and developed my position and skills as a novice researcher (113).

Lastly, a move towards entering the researcher role was the realization that fieldwork is a learning process (92,112,122). As a novice researcher, after I had entered the field ‘on my own’ during the first period of fieldwork, I decided to join an experienced researcher on fieldwork at the beginning of
the second period. She was the department’s research leader and at the same time one of my doctoral supervisors. This constituted researcher ‘triangulation’ as she was a co-researcher in the fieldwork (123,124). She came up with inputs and ideas, and supplemented the process. With this set-up I received feedback on the process and we shared reflections on the field. I learned from her appearance and the way she presented herself how flexible fieldwork and the researchers’ role can be (117). The joint fieldwork was highly developmental and inspirational for me; learning from a confident researcher provided me with the skills and capability to situate myself within my researcher role.

Data analysis
ID does not prescribe a rigid data analysis process but relies on the pragmatic obligation to work data beyond initial descriptive claims towards interpretations that will illuminate the phenomenon investigated in a new and meaningful manner (99). Analysis is about making sense of what has been observed and heard—an explorative process where questions are continuously posed to the data and answers are sought to generate explanations supported by theory (125).

In this qualitative study, data analysis was inductively performed concurrently with data construction as a process aimed at making sense of data (see Figure 4). I transcribed all the audio recordings continuously during the data generation process. This allowed me to reflect on the material and take preliminary analytic notes. Analysis was conducted on the transcribed textual data in Danish. Transcribed interviews and field notes were uploaded to the qualitative software program NVivo with data grouped to each participant in cases with affiliations. NVivo was used to ease the work in regard to the large amount of data, as the software allowed linking different data sources and facilitating replication by making procedures explicit and transparent. Since ID does not prescribe a singular technique for data analysis, my analysis was inspired by content analysis and systematic text condensation to explore and develop data from the descriptive to the analytical (126). The analysis included the following phases: 1) comprehending data by coding, 2) synthesizing meanings, 3) theorizing relationships, and 4) recontextualizing data into findings (92,127).

Analysis was performed three times when new data material was generated (see Figure 5). Each time, the total dataset was pooled and previous codings were revised as new understandings occurred and focus changed. Textual data sources used for the analysis were the consultations and interviews in transcribed form. Field notes were used to inform data and to confirm or challenge the analysis. Observations and field notes informed the analysis and illuminated what occurred in clinical practice,
especially the consultation’s focus if it was not the PROMs, and elucidated contextual information on the clinical environment as the specific setting (92,123,125). Analysis for study I, II and II was performed in similar manner.

Comprehending data by coding
I approached the data by reading all of the transcripts and the matching field notes to get an overview beyond my initial impression during the transcription phase and to become familiar with the data (92,123). Data was reviewed several times, starting with a brief coding, sometimes even without naming the coding groups, only grouping them, aiming not to categorize the early understanding (92). I conducted the initial coding process and my supervisors were involved later in the analytical process.

Synthesizing meanings
The initial coding led to a second and deeper coding aiming to critically appraise relationships between details in the material and the whole (126). At this stage, each consultation was categorized as to whether PROMs were used in consultations or not, and data was sorted according to the study aim. At this stage, a lot of codings were identified, but through focusing on the aims, irrelevant data was sorted out (92). The condensing of the text and the content analysis focused on patients’, nurses’ and haematologists’ experiences and reflections due to the introduction of PROMs.

Theorizing relationships
As the previous codings were mostly descriptive, the next level was an analytical approach to text chunks and specifying meanings in citations, querying the data material to answer questions that could
be supported by theory (92,126). Finding patterns and themes was a more creative process. At this stage, working in the NVivo programme seemed to limit options for exploring the data in depth, a limit which could have led to potentially premature conclusions or interpretations (92). Therefore, nodes and text chunks of interest or thematic issues were printed on paper and grouped in categories and emergent themes. The analysis at this stage was characterized by synthesizing meanings and theorizing relationships across data whenever potential relationships within the data became apparent. At this stage, questions were constantly asked about the textual content from the transcripts to stimulate a critical appraisal, such as “What do I see?” and “Why do I see that?” (99). Three times throughout the data analysis, coding and themes were presented to the supervisors, resulting in revision of codings and meanings, a critical appraisal of arguments, discussions and theorizing of perspectives that supported me in conceptualizing causality and revealed credible and meaningful findings.

Recontextualizing data into findings
The last stage of the analysis process was to transform thematic patterns into interpreted, disseminated, conceptualized findings (92) concerning patients’, nurses’ and haematologists’ experiences when PROMs were introduced at the outpatient clinic. These were reported in papers I, II and III.

The interpretive description of user experiences when introducing PROMs
Based on data from studies I through III, a final analysis was conducted to develop an understanding of the barriers and opportunities PROMs may present in clinical haematological practice. The analyses included two distinct approaches, searching for new representations (124). First, the study results from the three user group perspectives were compared and discussed with my co-authors, considering potential similarities and differences, and adding the context structure and interpretation of the transverse findings. Second, the full dataset was reworked and codings which had previously been excluded due to reduced relevance were grouped into themes for comprehending, synthesizing, theorizing, and recontextualizing (123). Through this final analysis, a rigorous and comprehensive understanding was developed, leading to new themes.
ETHICAL CONSIDERATIONS

The study adhered to the principles defined by World Medical Association in the Helsinki Declaration (128) and the International Council of Nurses Code of Ethics for Nurses (129). The multimethod project was registered at ClinicalTrials.gov with identifier NCT03056469 (see Appendix 11) and approved by the Danish Data Protection Agency, associated with journal number SUH 658-45 2016 (see Appendix 12). The National Committee on Health Research Ethics approved the study with no reason for further ethical review (see Appendix 13).

For inclusion, all patients were informed verbally and in written form about the multimethod study, and about voluntary participation, anonymity and confidentiality (see Appendices 14 and 15). Patients consented in writing if they decided to participate in the multimethod project (Appendix 16). I contacted patients included in the multimethod study who were potential participants for the qualitative study, and then again in person when the patients arrived at the outpatient clinic for consultation. To confirm patient consent, I asked the patient’s permission to participate during their consultation, as there could be situations where my participation would be inappropriate. Furthermore, patients were reminded about their rights to decline participation.

Nurses and haematologists provided oral informed consent to participate in this qualitative study. The department’s leaders relied on the stance that research is everybody’s business and participation in research is an obligation when employed at the department. However, clinicians were always asked for informed consent to participate and no one was forced to participate if they declined. On two occasions clinicians refused to participate; this was registered, as was the reasoning. So that all informants may maintain anonymity and be able to speak freely, I have not specified details such as age for the nurses and haematologists included in the study.

After the fieldwork, a debriefing was held with the patient participants, as emotional subjects can occur during observations or interviews (130). Several times it happened that patients became emotional, with tearful eyes during the interviews. Therefore, I always allocated plenty of time to talk with patients after the audio recorder was turned off, to make sure that the patients departed in a comfortable state. In some cases, I experienced that patients addressed questions about physical issues to me like constipation. In those cases I gave advice if possible, or referred the patient to contact their responsible haematologist.
As the study was ongoing, we discussed ethical considerations with the steering group regarding justification of the lack of use of PROMs as found in this qualitative study. However, the decision was made to continue the intervention and fieldwork as the intervention was considered safe, and such experiences were important to explain challenges and guide future practice with PROMs.

During inclusion of patients, I became aware that the multimethod study was not suitable for all patients. Patients who declined participation explained reasons such as dyslexia; lack of mental and physical resources; concurrent association with other hospital departments; or lack of arrangement to participate such as no smartphone, no internet or too long a distance to a mailbox (for the paper form). A previous paper about exclusion regarding PROMs noted similar problems: people with disabilities and low literacy are systematically excluded from PROM studies (131). In the multimethod project, we included one patient with dyslexia who wished to be included. We made an agreement with the patient that he could complete the questionnaires by phone. The patient withdrew from the study after completing two questionnaires because the completion was too complex by phone. Though the current qualitative study does not provide analysis on participants’ background, there were indications throughout the inclusion phase that the set-up of the multimethod project might not be inclusive for vulnerable or socioeconomically disadvantaged patients. Such indications represent ethical challenges due to lack of equal access for projects aiming to involve patients (131).
FINDINGS

The four papers of the PhD study each represent significant portions of this qualitative study. The findings are briefly presented in this section. Further elaboration is offered in papers I, II, III and IV.

Study I

“I Am Sure That They Use My PROM Data for Something Important.” A Qualitative Study About Patients’ Experiences From a Haematologic Outpatient Clinic

This study aimed to investigate how patients diagnosed with hematologic cancer experience participating in a randomized PROM intervention study, including invitation to participate, completion of the PROM questionnaires, and subsequent visits to the outpatient clinic (76). Three main findings were identified: “PROMs are in the service of a good cause,” “The questions are not really spot on,” and “PROMs are sometimes used for something” (see Figure 6). Put together, these themes represented an understanding of the experiences of patients diagnosed with haematological cancers when PROMs were introduced into the haematological outpatient clinic.

“PROMs are in the service of a good cause” referred to patients’ experiences regarding the study invitation period. The theme “The questions are not really spot on” represented patients’ retrospective reflections about completing the PROMs, and the theme “PROMs are sometimes used for something” related to patients’ experiences during their visit at the outpatient clinic. During the fieldwork, no patients were seen to use or include their PROM responses in their dialogues with the professionals (76).

Figure 6. Flowchart of the Introduction (Green), Process (Blue) and Findings (Grey) for the PROM intervention. Phases illustrate that patients’ experiences were linked to activities (76).
**In the service of a good cause**

*Contributing to research*

For the patient participants, contributing to research was found to be an underlying premise. Patients expressed their willingness to contribute to research, including developing the system and the importance of and motivation for their participation in research. The patients felt they contributed to a larger cause, and thus they were not critical of the use of their PROMs, but assumed that PROMs represented an evaluation that could help the clinic or future patients. The patients did not perceive that the assessment was intended to benefit their own treatment or condition (76).

*Paying back*

Patients expressed feelings of gratitude toward the department for their treatment and potentially prolonged lives. Having the opportunity to give something back when contributing to the hospital’s research was regarded as important and meaningful to patients. Some of the patients connected their reflections on this issue to concerns regarding how much longer the department would keep them in the system despite their advanced age or progression of their illness (76).

**The questions are not really spot on**

*Do these questions concern me?*

During the field study, some patients stated that they were struggling to identify with the questions on the questionnaire, or that the issues did not relate to their disease or life situation. In the interviews, several participants expressed that the questions had no relevance to their situation or haematologic disease and the visit (76).

*Completing PROMs was not easy*

Some patients stated that it was difficult to answer the questions in the PROMs because of practical issues with the paper form or technical problems with the electronic version. For instance, practical problems could include confusion regarding the instructions for the paper form, which were not intuitive for some patients, and therefore they did not know how to complete them correctly. Others expressed that they found it hard to make a decision about which response category to choose because they felt there was a lack of response options that would allow their answers to be accurate. Another problem reported was that questions were unclear or irrelevant, to the extent that answering was not possible (76).
PROMs are sometimes used for something
Patients mostly experienced that their PROMs were not mentioned by nurses and haematologists during the consultations, and some felt insecure about whether the nurses and haematologists used their PROMs. Some patients assumed that haematologists and nurses would automatically incorporate the PROM data in the assessment of their condition. Patients did not expect to have a conversation about their answers or to get feedback on their PROM data during the consultations. Only one patient reported that his haematologist talked about his answers to the items in the PROMs during the visits observed, but this situation did not promote a discussion of what was important to the patient (76).

Study II

Nurses’ Experiences When Introducing Patient Reported Outcome Measures (PROMs) in an Outpatient Clinic: An Interpretive Description Study
This study investigated nurses’ experiences when PROMs were introduced in clinical practice in a haematological outpatient setting as part of a multimethod intervention study. The two main findings were “PROMs are only used when there is time – which there rarely is” and “PROMs cannot be used without a strategy, just because they are present.”. Together, these themes represented an understanding of nurses’ experiences when introducing PROMs at the haematological outpatient clinic (86). “PROMs are only used when there is time – which there rarely is” was found to have three separate subthemes, including “Nurses need to prioritize patient flow,” “Use of PROMs could strengthen nursing practice,” and “Nurses face a dilemma.” These findings represent an assembled interpretation of nurse practices with PROMs. The theme “PROMs cannot be used just because they are present” was identified as an underlying premise for nurses’ motivation to use PROMs. If nurses were not given a specific strategy on how to include PROMs, they continued their standard practice. The interpretation was represented by two subthemes: “PROMs were not easily available” and “Wishing for a strategy” (86).

PROMs are only used when there is time – which there rarely is
Nurses need to prioritize patient flow
Nurses characterised their clinical practice as very busy, and reported they often had to prioritize their duties as they could not manage all of them. The nurses changed their plans on patient responsibilities ad hoc, and explained that this was done with consideration for maintaining patient flow in their
clinical practice, so that patients were not unduly delayed by waiting times. Both times a shift was observed, patients had completed PROMs, but they were not mentioned during the meeting (86).

**Use of PROMs could strengthen nursing practice**

During fieldwork, one nurse actively incorporated information from PROMs during a meeting with a patient, though she did not make the patient aware, as she asked questions related to PROMs indirectly. During the remaining fieldwork, PROMs were rarely used by the nurses. When asked about the use of PROMs during the focus group interview, a nurse explained that she was increasingly trying to use the PROMs, as she had experienced situations in which PROMs identified important problems she was not aware of. Then, as the nurses reflected upon the potential of PROMs, they broadly agreed that PROMs could probably strengthen nursing practice, but that they did not have any experiences of use of PROMs in their everyday practice (86).

**Nurses face a dilemma**

During the focus group interview, the nurses expressed they had very limited or no experience using PROMs, but reflecting upon PROMs, nurses did see potential. This was a conflict that nurses experienced when prioritizing: nurses had to choose between what had to be done, such as instrumental treatments, and ‘nice to do’ duties, including use of PROMs and exploring patients’ needs for supportive care (see Figure 7) (86).

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**Figure 7. Characteristic Dichotomies in Nurses’ Practice Inspired by Habermas and McCormack (86)**
PROMs cannot be used just because they are present

PROMs were not easily available

Throughout the fieldwork, nurses reported that finding PROMs in the electronic medical record system was a challenge. Nurses repeatedly failed to find the patients’ PROMs even though data was available. Nurses stated that PROMs were drowning in the electronic information flow and stated the importance of PROMs being easy to find. Nurses requested that patients’ completion of PROMs should be adjusted to patients’ meetings with nurses as well as haematologists, as some patients had more meetings with the nurses (86).

Wishing for a strategy

In this study, the nurses did not use the PROMs in their daily practice but said that they wished the department would prescribe a strategy for the use of PROMs. Nurses proposed that providing a strategy or systematizing nurses’ use of PROMs would support nurses’ prioritization of PROMs, as mandatory use of PROMs required by the leaders would make it permissible for nurses to spend time using PROMs, which speaks to institutional implementation issues (86).

Study III

Haematologists’ Experiences Implementing Patient Reported Outcome Measures (PROMs) in an Outpatient Clinic: A qualitative study for applied practice

This study aimed to investigate haematologists’ experiences when implementing PROMs in clinical practice in an outpatient setting, as part of a multimethod intervention study.

The haematologists views on PROMs were characterised as distinct, fairly antagonistic, and dichotomous (see Figure 8). Overall, haematologists resistant to the application of PROMs were experienced haematologists, mainly males. Haematologists supporting the application of PROMs were younger, both male and female (132). No haematologists were observed to articulate PROMs during observed consultations, through according to the haematologists that did not necessarily mean that they did not refer to the PROM notes. Across all consultations, primary focus remained on the haematological agenda, such as blood test results and medication. The haematologists, who during the interviews declared intentions of using the PROMs, viewed PROM information as additional information or pseudo-data, not necessary to be mentioned in the patient-doctor interaction (132). The main theme identified in this study, “Against PROMs”, represented an assembled interpretation of haematologists’ experiences with PROMs that were not supportive of their clinical practice:
“PROMs address information irrelevant to haematologists but relevant to patients’ general practitioners (GPs)”, “Use of PROMs is time-consuming”, “PROMs are unnecessary” and “PROMs are difficult to use”. The second main theme “Supportive of PROMs” arose as haematologists expressed that PROMs had or could have a supportive function in their clinical practice. The theme consisted of three subthemes: “A better impression of patients’ conditions”, “PROMs can increase practice efficiency”, and “Patients’ experiences are important” (132).

Against PROMs

**PROMs address information irrelevant to haematologists but relevant to patients’ general practitioners (GPs)**

One of the most prevalent statements by haematologists was that PROMs provided patient information irrelevant to haematology, but rather relevant to patients’ GPs. Consequently, the haematologists may have indicated to patients that the department was not interested in patients’ overall health; a discussion of such might have monopolized the brief time allotted to consult on patients’ hematological diseases. The consequences of a PROM could thus lead to more harm than good. Some haematologists assumed a single-profession perspective, not considering PROMs as a multidisciplinary tool to be used within the department (132).

**Use of PROMs is time-consuming**

Some haematologists identified the PROM layout in the electronic medical record journal as problematic and lengthy because too much data was reported in light of the time available. Consequently, haematologists did not read the PROMs report in the electronic medical record journal (132).

**PROMs are unnecessary**

Most haematologists simply stated that they did not use PROMs as the data was not useful for consultations. A few had very strong feelings against the introduction of PROMs, one explaining that PROMs limited his freedom to speak with the patients and that the tool was a barrier to proper communication. One haematologist argued that the art of person-centred care centres rather on the art of conversation, not relying on PROMs, and that patient consultations should focus on knowing the human, not the data (132).
PROMs are difficult to use

Some haematologists expressed simply not knowing what to do with the PROM data. These haematologists were not observed to elaborate on the PROMs in any way during the consultations. These proceedings was interpreted in several ways: not only are PROMs difficult to use, but there may also be a lack of training on PROMs, or an expression of uncertainty about PROM measurement validity (132).

Supportive of PROMs

A better impression of patients’ conditions

The theme was identified as haematologists reflected on the potential of PROMs and how the data could provide new information before patient visits. One haematologist expressed that PROMs with patients’ blood test data could provide pre-knowledge that could potentially be integrated during haematologists’ preparation, as a pre-assessment of patients’ conditions. Some haematologists expressed a high level of confidence in the result reported, not questioning if the PROMs measured the patient’s situation accurately or how the data were presented (132).

PROMs can increase practice efficiency

A few haematologists who mostly supported the use of PROMs reflected on the Danish healthcare authorities’ decision that PROMs are to be implemented in the treatment of all cancer patients. The haematologists related the suggestion to practice and how this approach could potentially be supportive for patients and the department in future practice (132).

Patients’ experiences are important

Apart from the theme ‘PROMs address information irrelevant to haematologists and relevant to general practitioners’, the issue that most haematologists addressed (including those both supportive of and resistant to the introduction of PROMs) was the part of the PROM reporting on patient experiences and satisfaction with their visits at the department. Haematologists reported that patients’ assessment of their treatment and care assisted in evaluating their own practice, and that patient experiences were highly important (132).
Study IV

Patients, Nurses and Haematologists Experiences when Patient Reported Outcome Measures are introduced in a Haematological Outpatient Clinic: A Qualitative Study

The aim of this study was to develop an understanding of the barriers and potentials PROMs may have in clinical haematological practice, based on studies I through III.

“Structural similarities influencing adoption of PROMs” and “Different perspectives on the potential of PROMS” were the two main findings. The theme “Structural similarities influencing adaption of PROMs” was separated into three subthemes: “The haematological agenda rules”, “Relations are fundamental before adoption of PROMs” and “Structure holds the system”. These findings represent an assembled interpretation of transverse contextual underpinnings related to PROMs.

The theme “Perspectives on the potential of PROMs” was found as transverse issues dealing with influential perspectives on PROMs. The interpretation was divided into three subthemes: “The choice of PROM instrument is of utmost importance”, “PROMs call for action” and “Contradictory preferences” (133).
Structural similarities influencing adoption of PROMs

The haematological agenda rules

The most prominent theme in the data was the haematological agenda, shown as a focus on patients’ laboratory tests, pathology, and imaging, all of which permeated clinical practice and patients’ everyday life. Haematological treatment and assessment of a patient’s condition was highly concerned with cell status and moderation of cells within medical treatment. This led to a higher focus on biomedical outcomes rather than on patients’ experiences and alleviation of symptom burden caused by the disease or treatment. The haematological agenda was a barrier as it often overruled the potential use of PROMs (133).

Relations are fundamental before adoption of PROMs

A similar perspective among patients, nurses and haematologists was the fundamental importance of relationships to build trust, a priority which was valued higher in consultations than application of PROMs. There was some variety, as patients relied on the clinic appointment and the importance of meeting the same haematologist or nurse each time. The haematologists’ experiences were that relationship-building won over PROMs. Nurses mostly expressed that relations and continuity were a necessity to work with PROMs (133).

Structure holds the system

Although nurses and haematologists worked in the same environment, their practices were fragmented, as seen in their rationale of action mainly being controlled by professional obligations, relying on the system. Patients mainly expected to be informed about their disease status by the haematologist, while nurses provided their treatment. Haematologists were mostly restricted to the occasion of a patient consultations and the very specific aim of the consultation, such as if the patient were booked for a general follow-up or to be informed about test results. These were structures and rationalities of action holding the system, guided by nurses’ and haematologists’ obligations within their profession in the outpatient clinic (133).

Perspectives on the potential of PROMs

The choice of PROM instrument is of utmost importance

The specific PROM instrument used influenced the clinical adoption, depending on the user. This meant that information gained from the PROMs mostly lacked relevance to users including patients
and haematologists, while nurses expressed that the specific instrument was highly relevant to provide information about patients’ condition. Though nurses believed that information in PROMs was relevant, there was a potential pitfall due to uncertainty when transferring PROMs to individual care, as outcomes could be false. Nurses could fail to notice the most important information about the patient, as PROMs not reflecting patients’ conditions could lead to potentially harmful situations related to data-driven decisions. The individual professionals’ assessment of PROMs relevance was a barrier to interdisciplinary initiation of supportive care (133).

**PROMs call for action**

A shared finding among the patients, nurses and haematologists was that PROMs call for action by clinicians, and PROMs were intended to initiate communication and alleviation of symptoms, not to simply remain as data. Despite this shared assumption, there was a lack of action on PROM data, as nurses and haematologists did not have a procedure incorporated during implementation, meaning that use of PROMs was not monitored, and completing PROMs did not lead to increased reflection or requests from patients (133).

**Contradictory preferences**

Regarding the potential of PROMs, patients, nurses and haematologists had different preferences of which PROMs were relevant, dependent on the objective of the consultations. Nurses had a mindset towards providing supportive care as a core nursing discipline, but the institutional system only allowed nurses to perform treatment. The haematologists’ preferences were to monitor the disease status and adjust treatment, two tasks for which the PROMs lacked relevance. These contradictory preferences and the lack of convertibility of responsibility to initiate supportive care left some patients aware of unmet needs. Other patients could not identify with the PROM questions and wished to abstain from completing PROMs, or asked for the opportunity to write free-text responses to the hospital. Nurses faced a professional dilemma, dealing with missed care due to their professional obligations, while haematologists relied on the responsibility of haematological agenda. These contradictory preferences complicated the implementation of PROMs (133).
DISCUSSION

Findings

This thesis comprised four studies investigating patients, nurses, and haematologists and their synthesized experiences when PROMs were introduced in a haematological outpatient clinic. Combined, these perspectives represent a nuanced interpretive description for applied practice. The main finding related to PROMs was that there was no difference among the three intervention user groups, as PROMs were hardly used in haematology clinic consultations. Thus consultations within the control group did not differ from the group whose PROMs were available to clinicians or the group whose PROMs were completed but not available. Therefore, the focus changed from exploring differences among the three groups to an exploration of the premises of PROMs, including context, reasons, rationales and structures in clinical practice. In this section these findings are discussed in context of the existing literature on PROMs to develop implications for further implementation of PROMs in routine clinical care (92).

The introduction of PROMs

Before the multimethod project began, the department had not worked with PROMs in routine care. Therefore, the nurses and haematologists at the department had no previous experience with PROMs in clinical practice. Within the multimethod project, the implementation was characterized as an early phase dissemination-implementation strategy (75,134). The implementation strategy did not prescribe concrete actions for clinicians to perform, how to act on the PROMs, what scores to respond to, or what should be initiated. The main focus in the teaching session for the nurses and haematologists was to introduce the PROMs into clinical practice. Considering implementation as “the process of putting to use or integrating new practices within a setting” (75), one can question whether PROMs could be said to be implemented, since this qualitative found PROMs were hardly used in the intervention groups. Therefore, as the qualitative study progressed, implementation was renamed ‘initial phase implementation’ rather than implying that a full implementation had taken place (75,134).

In retrospect, the department’s approach to PROM implementation may have been naïve or not taken seriously enough. In literature, implementation is often described as a complex process proceeding through stages which cannot be skipped (74,75,134,135), and that knowledge brokering such as
translating knowledge or research into clinical practice is complex (136,137). Related to PROMs, unless knowledge is put into action, the potential benefits of PROMs cannot be realised (138).

There are suggestions on how to work with implementation within the field of applied disciplines. These include conceptualising implementation stages, and essentially prescribing a change in researchers’ and clinicians’ roles to allow greater involvement and to activate clinicians as participant designers or implementation drivers, allowing greater involvement and greater potential dissemination (74,134,135,139). Furthermore, the accomplishment of relating PROMs to an agenda of patient involvement demands more engagement of patients during implementation, such as in selection of PROM instruments (46). Evaluating the multimethod study, the PROM implementation could have been supported in advance by a step-wise implementation strategy, including activation of users to make PROMs more feasible and convenient to use.

**Different preferences in PROMs**

By synthesizing the different user perspectives in the fourth study, it became clear that users had different preferences for PROMs. Comparable results are previously described. In a review of PROMs’ influence on the patient-clinician relationship, it was found across a range of clinical settings that clinicians experienced PROMs as a constraints rather than something supportive of communication, and therefore as something which interfered with the relationships with patients (39). A study on PROMs in patients diagnosed with epilepsy in outpatient follow-up consultations identified ambivalence toward PROMs, as clinicians viewed their potential to both improve and impair quality of care (140). In this qualitative study, haematologists valued their relationships with patients more than they valued the use of PROMs. Brewster et al. found that clinicians experience measurement tools as being socially situated; their use is linked with the clinician’s work of managing patient relationships, which influences how measurement tools are used in clinical practice (141).

Literature suggests that when implementing PROMs in routine clinical practice, management needs to consider how PROMs can be introduced in a way that supports rather than disrupts the clinician-patient relationship (36,142–144). That involves giving clinicians considerable freedom in how and when they use PROMs and acknowledging that it is the conversation that PROM completion prompts, not just the score, which potentially supports patient care (39). The experiences of departments’ managers could have been a fourth relevant perspective to investigate in this qualitative study.

The findings on patient experiences did not reveal any evidence that patients believed PROMs were introduced to improve their individual trajectories, though they were informed about this in the patient
information material when selected for inclusion in the multimethod project. Langstrup criticises that little attention is given to patients’ work of providing PROM data and that the terminology “sharing data” rather than “producing data” invokes an implicit ethic of sharing (46). Meanwhile, little attention is given to the task of providing data as “patient work” (46). Such a critique becomes relevant when patients’ PROMs are not used and PROMs become a layer of pseudo-data. In a previous study of patient experiences related to PROMs, it was found that patients did not necessarily feel it was appropriate to discuss functional status and HRQL aspects with the physician, similar to the current qualitative study, where physicians did not perceive health-related quality of life was within their purview (145). Another study on communication in cancer care found that patients can feel emotionally supported without explicit emotional talk within oncology consultations because they perceive physicians as experts who have the knowledge and authority to treat them (19). These findings indicate that future work with PROMs should aim to specify patients’ needs and wishes related to PROMs in specific settings.

For the nurses, PROMs were observed to be used once, thus practical experiences with PROMs were scant. When the nurses reflected on the potential of PROMs during the focus group, they were encouraging, saying that PROMs should be part of future nursing practice and that the information addressed in the PROMs was of high relevance to nursing practice.

Previous studies have found that when incorporating PROMs in nurse-led consultations, nurses reported that relational use of PROMs increased visibility of quality of life concerns, led to positive developments within relational care, and furthered their capacity as relational care providers (146). Another study with nurses caring for patients needing in-home dialysis found that PROMs informed nurses’ practice and changed care (147). Likely similar to my findings from the haematology clinic experiences, some studies have also found that nurses perceived PROMs as introducing an ‘interactional strangeness’(39). Due to the findings on nurses’ (lack of) experiences in my study, and reflections on their potential, further research is needed to provide knowledge on nurses’ practical experiences of PROMs in haematological care settings.

Where are PROMs heading?
The findings from this qualitative study address users’ doubts about PROMs. The nurses requested a strategy for the use of PROMs. Some haematologists did not know what to do with the PROM data available; others thought that the PROMs addressed information relevant to patients’ GPs. Another consideration is whether PROM data is available to the right clinicians at the right time, as the nurses
in this qualitative study requested availability of PROMs for their own practice, not only for patient visits with haematologists. These findings call for institutional leadership and decisions on how PROMs are intended to be used; which clinicians are responsible for reviewing PROMs; what action schemes are expected or possible in response to the PROMs; and what the future practice on PROMs should be. A previous study suggests these types of concerns can be addressed as part of a framework for PROMs implementation, and the authors propose a model for joint use of health data (148).

PROMs are intended to add different aspects in clinical practice, such as clinical decision-making (149), person-centred care and empowerment (47), effectiveness (29), and a screening or assessment tool to monitor symptoms and quality of life (150). All of these aspects actively involve the patient in decisions about care and treatment (24,151). The underlying understanding is linked with concepts such as autonomy, equality and co-determination, reflecting the 20th-century view of humanity in healthcare (49,152). Patient involvement as a philosophical stance is premised on humans as thinking subjects with rights, expectations and feelings, rather than focusing on a disease as an object to cure and treat (153). Patients have a right to participate in decisions related to their own life and health and involvement in clinical care has become a necessary consequence of this right (154). Whether these visions are compatible with haematological practice, and whether PROMs are a possible answer, remains uncertain in the results of this qualitative study, as PROMs were not fully implemented.

In an ethnographic study about the emerging politics and practices of PRO Ms in the Danish public healthcare system, Langstrup finds that elaboration on PROMs in the Danish healthcare system is discursive and normative (46). Danish healthcare authorities articulate PROMs as “meaningful”, suggesting that meaningful data work can be established when data furthers a clinical logic and a normative vision of patient involvement in clinical trajectories (46). Such normative articulation foreshadows challenges in making data work meaningful for patients and health professionals. The problem is transforming passively-used PROMs into “active” PROMs in routine care, when routine care does not consider the situatedness of the data (46). Langstrup states “The rhetorical insistence that the data work with PRO should be “meaningful” will not in itself ensure that only meaningful data work follows or that all actors experience it as such in daily practices of healthcare and everyday life” (46). According to Ravn, a phenomenon is meaningful when an individual realizes how the phenomenon is part of a wider context. A phenomenon which the individual is not able to comprehend as part of a relevant wider context is experienced as pointless (72). Considering this definition, patients in this qualitative study might have seen PROMs as meaningful since they (the patients) assumed that their PROMs contributed to research and care for other patients. For the nurses, the
PROMs were not used as they were not mandatory, though they might have potential to become meaningful as nurses believed that PROMs added new and relevant information about the patient. For the haematologists in this study, PROMs might not be meaningful, as the PROMs were not used, and the PROMs were rather unnecessary to some. On the whole, the introduction of PROMs in this qualitative study was not perceived as meaningful to users in the specific setting. For some, PROMs had potential so become meaningful; to others, the introduction of PROMs was not desired.

**Research process and methodology**

In this discussion, I will focus on different aspects of the study related to the research process and methodology. This relates mainly to the qualitative study, but addresses issues related to distinctive parts of the multimethod project as well.

As part of the applied qualitative methodology, reflexivity has been considered throughout the study in terms of how the research process might have influenced or limited the findings (96,113). This included constant attention to and reflection upon my preconceptions about the field investigated (92). When the multimethod project initially began, I had high expectations and was very enthusiastic about the introduction of PROMs and how this could potentially change or influence practice. I regarded the future launch of EPIC mostly as a potential challenge related to the introduction of PROMs. Then, as the study progressed, it was a surprise to see that the main issue of my focus, usage of PROMS in the different intervention groups, did not occur at all and that some clinicians expressed that PROMs were not helpful. The introduction of PROMs and the contextual clinical practice proved much more complex than I thought. This was a phase characterized with feelings of frustration, disappointment and anger as I did not understand why users would not explore the possibility of using PROMs. At the same time, I was surprised that clinicians were so honest with me and entrusted me with their sincere experiences, involving me during their clinical practice. Along the way, I changed my view and frustration transformed into more constructive curiosity about the clinicians’ rationale; I also became interested in the practice I had observed and wished to accurately represent the realm of user experiences. It was challenging to recognize and reflect upon my own presumptions and biases as a researcher and nurse, although it was necessary to do so when conducting and interpreting a study that strove for integrity of process (92).

Various qualitative scholars have described general principles for the evaluation of qualitative research, providing a critical perspective to assess the overall quality of the research conducted (96,155–157). Evaluating products of interpretive description relates to general principles (92),
though Thorne prescribes four crucial evaluation criteria, including epistemological integrity, representative credibility, analytical logic and interpretive authority (92). The quality related to these criteria is assessed and described in the following section.

**Interpretive description evaluation criteria**

*Epistemological integrity* is ensured when there is a defensible line of reasoning from basic assumptions to the results and the methodological rules by which decisions about the research process are described and explained (92). This strategy was pursued in this qualitative study as it was grounded in alignment with the interpretive naturalistic orientation, acknowledging the constructed and contextual nature of human experiences and shared perspectives of reality. This was investigated through a focused ethnographic approach to gain insights about the users’ experiences, and analysed drawing on critical theory. The approach demonstrated pragmatic meaning on not only what was obviously said or observed, but retrieved rationales, actions and structures to understand clinical practice with social and contextual influences. In all, the methodological decisions assisted the epistemological integrity of the study.

*Representative credibility* involves that the theoretical claims of the studies presented are consistent with the manner of sampling for the phenomenon under study (92). To enhance representative credibility we sampled participants through purposeful and strategic sampling to reflect maximum variation of user perspectives (92). Personal-level and methods-level triangulation was applied throughout the investigation to recognize knowledge beyond a single person’s perspective (92,123). The approach chosen generated data which allowed the formulation of findings useful to answer the study aims.

The *analytic logic* criterion refers to the researcher’s responsibility to reflect a logic with explicit reasoning and that the decision-making process throughout the study is accessible. In this study, we have strived to visualize and argue for the process and logic of scaffolding mainly within the papers, where the rationale for the study related to each of the users’ perspectives are described. Furthermore, from the very beginning of the study, an audit trail (92) was conducted within my log book which recorded notes ad hoc on assumptions, preunderstandings, decisions, reflections related to the study. The fourth requirement of interpretive authority relies on *trustworthiness* (92). Throughout the study, I have explicated hypotheses and preunderstandings and clarified my role as a researcher in order to grasp my intentions in revealing knowledge and to enhance interpretive authority.
Overall design and validity

To my knowledge, this is the first qualitative study to explore introduction of PROMs in a haematological outpatient setting. Thus it has provided novel insights and knowledge on experiences for applied practice. The qualitative study was performed in the very beginning of the multimethod project and a crucial question to ask is whether the results would be different if the study was repeated later in the process of the multimethod project. To answer that question, some considerations are necessary. Clinical practice is certainly a changeable sphere. First of all, the haematologists performing consultations in the outpatient clinic change over time, as some are employed temporarily during their education; furthermore, we know from this study that haematologists’ experiences with PROMs are highly individual. For the nurses, the qualitative study period was characterised by massive resignation and some of the nursing staff changed as well. Therefore, the representation of clinicians’ perspectives may potentially change. However, the very experienced haematologists would remain. Second, the launching of Epic influenced clinical practice much more than we predicted. Namely, the leaders announced that staff participation in research had to be delayed as the main focus was to be the implementation of Epic and ensuring the safety of patient care trajectories. However, the first period of fieldwork was conducted before the launching of Epic, and during this period the PROMs were not used. Furthermore, the PROM note in the electronic medical record did not change. Therefore, my findings might not have been influenced by the launching of Epic. Overall, we do not have reason to believe that findings would be very different if the study was started later.

In the multimethod project, the EORTC QLQ-C30 questionnaire was applied. The findings indicate that the instrument might not be the best suited to the task, as patients struggled with the content while nurses and haematologists had divergent experiences. A recent review of quality-of-life instruments in haematology identified that in such settings, 30 different instruments were reported to be used and none of them were developed for integration in clinical care; the EORTC QLQ-C30 questionnaire was among the instruments found to be used (150). Eventually, a new instrument, the haematological malignancy patient-reported outcome (HM-PRO) was developed for patients with haematological malignancies in routine clinical practice. This instrument should be considered in future PROM work in this setting. Regardless of which PROMs are used in future clinical practice, the instrument should be tested and validated to the specific setting and aim (48,49,58). Furthermore, whatever PROM instrument is chosen, it can never cover every individual patient’s condition or what is the most important to the individual. A possible solution to this could be to add a free text response space for patients, which others have done, leading to conversation about what is written there (158). Another
possibility is to use narrative interventions, an approach which seems feasible in managing psychosocial and existential problems (159), or to use a person-centred care framework which also aims to strengthen patient-professional communication (25,160).

Study limitations are described within papers I through IV; however, there is an additional issue which we have rarely touched upon concerning the patients’ relatives. Relatives are generally understood to be a resource for patients in the healthcare system (33). Once during the study, I became aware that a patient had not completed the PROMs herself; her spouse had completed it, answering questions for the patient. There is no perfect solution for how to incorporate relatives in future PROMs work, but most patients are accompanied by relatives to the hospital and their role should be considered.

A final consideration goes to the overall set-up. In the best of all worlds, the qualitative researcher ought not to have been involved in the administration of the multimethod RCT study at all. Having the roles of introducing, teaching, investigating and evaluating might not have been an optimum solution as I shifted roles. This set-up was, however, a very pragmatic solution to complete the multimethod project, and at the same time the qualifying condition which allowed me to investigate the field.
CONCLUSIONS

The overall aim of this study was to investigate whether a short-form of PROMs in the electronic medical record system, including information about patients’ self-assessed health-related quality of life, experiences, physical functioning and symptom burden, is experienced as meaningful by users, including patients, nurses and haematologists.

We found that patients were challenged by the content of the PROM questionnaires being used. Patients found some items irrelevant, and some themes and items were missing, as were some response options. Although the PROM data was rarely elaborated on by the nurses and haematologists during patient consultations, the patients continued to complete the PROMs because they were convinced that the PROMs were either used for something valuable or were in support of research, or because they felt indebted to the institution for their treatment. The contribution of study I is the finding that patients diagnosed with haematologic cancers do not necessarily experience the use of the particular PROMs applied as supportive to their individual trajectories or experience that it provides room to unfold their lifeworld perspectives. Patients perceived completion of PROMs meaningful only insofar as they contributed to research and future patients.

Nurses’ practical experiences with PROMs when introduced in clinical practice were very limited. Nurses prioritized mandatory obligations according to the system’s rationale, which resulted in a limited capacity to use and explore PROMs. The PROMs were not actionable for nurses within the specific setting. PROMs might have potential to support nurses’ clinical practice, as PROMs could add new information about patients’ conditions and could identify needs within supportive care. This study’s contribution to current research on the use of PROMs is that simply introducing PROMs does not necessarily actuate the potential of PROMs due to multiple reasons.

For haematologists in this study, the introduction of PROMs did not lead to integration of patient information or clinician elaboration on PROMs, leaving uncertainties about the potential of PROMs and the instruments applied. The haematologists’ attitudes toward PROMs were characterized as antagonistic and dichotomous, either supportive of or resistant to their use. Haematologists reported that patient experiences and satisfaction were the most valued outcome, while the remaining information from the PROMs was mostly irrelevant to haematologists, who did not have the time or ability to address additional symptoms.

Across the different user experiences when introducing PROMs to the haematological clinical practice was an unquestioned commitment to the haematological agenda as the norm within the
system, leaving PROMs unexplored. We found structural similarities influencing adaption of PROMs and different perspectives on the potential of PROMS. Nurses and haematologists had different preferences related to choice of PROM content and different objectives with PROMs in clinical practice.

For the nurses, the PROMs were not important enough as they were not used: however, PROMs might have potential to become meaningful. For the haematologists in this qualitative study, PROMs might not be meaningful, as the PROMs were not used, and were seen as rather unnecessary to some. On the whole, the implementation of PROMs in the current multimethod project was hardly perceived as meaningful to users.

**PERSPECTIVES**

**Implications for practice**

- PROMs are here to stay, as the Danish Government and the national Danish steering group on PRO have decided to establish guidelines for standardized use of PRO data across geographical sectors and treatment plans, as part of the 2019-2022 Danish Digital Strategy.
- No PROM can ever cover all of a patient’s possible conditions or individual issues. If PROMs are for individual care, questionnaires should include a free text entry space, allowing the patient to voice individual concerns. Another solution could be the use of narratives or a person-centred framework, if aiming for individualized care.
- It is the conversation and initiatives that PROM completion prompts, not just the score, which potentially supports patient care. Patients do not experience PROMs being used during their own trajectory unless the clinicians discuss the PROMs in a meaningful way with the individual patient during consultations.
- PROMs might not be applicable to all patients, for instance patients with dyslexia and multiple diseases might easily be excluded.
- The implementation of PROMs at the haematological outpatient clinic led to identification of some discrepancies between the guidelines for rehabilitation and how responsibilities were interpreted and prioritized by haematologists and nurses. In some cases, that left patients with unresolved concerns. Such discrepancies should be addressed in future practice.
• Departments should carefully consider if, where and how PROMs may be meaningfully implemented in future haematological clinical care settings. Decisions should be made in the local context, including patients, nurses, haematologists and management perspectives.

Implications for Research

• Critical studies investigating the contribution of PROMs in routine haematological care are lacking.

• Future work on PROMs within the haematological outpatient clinic setting could investigate facilitators and barriers for PROM implementation. This might be part of a future PROM implementation study.

• The evaluation of the multimethod project’s RCT study should aim to assess if the implementation of PROMs changes the number and type of supportive care interventions, the number of paraclinical interventions, and the number of contacts between patients and the department of haematology.

• Future efforts should be made to identify or develop PROM instruments that oblige the perspectives of patients, nurses and haematologists, focusing on the very specific aim of integration in haematological clinical practice.

• PROMs are still a developing concept and thus awareness of measurement properties, psychometric pitfalls, and weaknesses linked with the approach is highly needed. Future PROM instruments should be psychometrically tested, adjusted, and validated within specific patient groups and settings to ensure content reliability and relevance.
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Haematologists’ experiences implementing patient reported outcome measures (PROMs) in an outpatient clinic: a qualitative study for applied practice

Stine Thestrup Hansen, Mette Kjerholt, Sarah Friis Christensen, Bibi Hølge-Hazelton and John Brodersen

Abstract

Background: The patient-doctor relationship is crucial to provide person-centred care, allowing the alleviation of symptom burden caused by disease or treatment. Implementing Patient Reported Outcome Measures (PROMs) is suggested to inform the decision-making process and lead to initiation of care. Yet there are knowledge gaps regarding how meaningful it is to incorporate PROMs in clinical settings. The aim of this study was to investigate haematologists’ experiences when PROMs were implemented in an outpatient setting.

Methods: Fourteen participant observations, 13 individual interviews and three in-depth interviews were conducted with haematologists, guided by the qualitative methodology Interpretive Description. Analysis was inspired by Habermas’ critical theoretical framework.

Results: The haematologists included were characterised by dichotomous experiences with PROMs, either resistant to or supporting their implementation. None were observed to elaborate on PROMs during consultations: instead, primary attention was spent discussing the hematological agenda dictated by the system.

Conclusion: The use of PROMs for individualized care was linked with extensive uncertainties and PROMs were not requested by the haematologists. To improve individualized care, other approaches may be more suitable. If PROMs are to be incorporated into future clinical practice, they should be tested to the specific patient group and involve relevant users.

Keywords: Qualitative study, Haematology, Patient reported outcomes, EORTC QLQ-C30, OEQ, Applied research

Background

Efforts have been made by the European Hematology Association Scientific Working Group and the American Society of Hematology to develop a conceptual framework for Patient Reported Outcome Measures (PROMs) integration in clinical haematology care [1, 2]. The framework builds on the assumption that the patient-doctor relationship is crucial in providing holistic, patient-centred care and alleviating the symptom burden caused by the disease or treatment. PROMs can help identify symptom burden and inform the decision-making process, leading to initiation of supportive care [1–3].

Internationally, PROMs are recognized as a means for patients to provide information about their quality of life, symptoms, and experiences of care [4–6]. PROM assessments have the potential to introduce the patient’s perspective into clinical processes [7, 8] via self-report instruments completed by the patient but chosen by the institution [2, 9, 10]. This approach is attracting growing attention by patient organisations and by public health
authorities seeking to promote and standardize the use of PROMs in clinical healthcare settings as new health technology aims to provide person-centred care at a lower cost [11–14]. Hence integration of PROMs in clinical practice has been described as the next step, as previous studies have found that the use of PROMs in routine medical care is associated with improved patient-physician communication, enhanced shared decision-making, improved symptom management, and greater satisfaction with care, as well as improved overall quality of life [4, 5, 15]. However, a critical appraisal of PROMs is lacking: adoption of PROMs from clinical research into clinical practice has potential pitfalls, as PROM data used to describe groups in research should differ from PROMs used to reflect patients’ individual health [16]. Adaption of PROMs has also been linked to measurement uncertainties, including content validity (content relevance and content coverage) and the psychometric properties of the PROM(s) [17, 18]; inadequate measurement properties could potentially lead to clinicians using invalid outcomes when consulting with patients, which again could potentially be harmful and detrimental to the patient-doctor relationship. Important knowledge gaps remain regarding the complexity of PROMs usage and how to adapt them across different settings for routine clinical care [3, 4]. Despite an extensive volume of literature on the use of PROMs for routine clinical care, it is difficult to reach firm conclusions due to the broad variety of interventions within setting-specific studies [4, 19, 20]. Research is needed on the actual experiences of users of these tools [11, 15, 21, 22]. Therefore, the aim of this study was to investigate haematologists’ experiences when implementing PROMs in clinical practice in an outpatient setting, as part of a multimethod intervention study. For an overview of the multimethod study, visit Additional file 1.

Methods

Study design

This study was guided by the qualitative methodology Interpretive Description (ID), including a focused ethnographic approach [23], to fit the nature of the aim [24]. Use of this methodology was driven by the rationale and logic inherent to applied practice, permitting the researcher to apply and combine methods as needed during the research process to fully answer the research question and identify implications for practice [24]. Focused Ethnography, with participant observations, interviews, and in-depth interviews, was applied to enhance the setting-specific, problem-focused and short-duration consultations between haematologists and patients [25]. Finally, the theoretical framework on critical theory by Jürgen Habermas inspired the interpretation and discussion of the data.

The PROMs applied were the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Version 3.0 (EORTC QLQ-C30) [26] and the Outcomes and Experiences Questionnaire (OEQ) [27]. For additional information on the PROMs implemented, please visit Additional file 2. Completed EORTC QLQ-C30s were transferred into the electronic medical record system using a standardized short-form [28] while OEQs were transferred in full. A detailed description of the completion process is described by Hansen et al. [29].

Participants and setting

Thirteen haematologists performing consultations in a haematological outpatient clinic were included, sampled with maximum variation to reflect departmental variation in gender, age, educational background, experience, and ethnicity, striving to elucidate and generate data from different perspectives (See Table 1).

One month before the intervention study began, haematologists at the department were offered one-hour plenum sessions regarding the purposes and design of the multimethod project. These sessions were held by the researcher responsible for the intervention study, who also was a medical doctor. Sessions included information on how to identify and interpret the PROMs provided in the electronic medical record system. No prescription was provided on how to include PROMs or how to intervene using the information provided in the PROMs, and no clinician alerts were programmed into the medical record system due to the outcomes under examination in the study. Instead, PROMs were intended to be included as relevant to the individual haematologists’ assessment of patient conditions and therefore a part of the department’s existing guidelines for rehabilitation and supportive care for patients diagnosed with haematological cancer [30, 31]. The plenum sessions were repeated after 6 months. Meanwhile, newly employed haematologists received the same in-person informational sessions with the responsible researcher. The information provided at the plenum sessions was also incorporated in a newsletter and distributed via e-mail to all haematologists.

When haematologists consulted with a patient who had completed PROMs, the researcher requested permission to observe the consultation and to conduct a brief interview with the haematologist afterward. All of the haematologists asked consented to the consultation observation; one refused to be interviewed afterward, reporting lack of support in the use of PROMs. All 13 consenting participants were invited to the final in-depth interviews, as was one haematologist who had not previously participated: this last individual was invited strategically as he was engaged with use of PROMs. Two
invited haematologists consented to the final in-depth interview: one experienced haematologist and one younger haematologist. In total, 14 participant observations, 13 individual interviews, and three in-depth interviews were conducted with haematologists (one individual was observed and interviewed twice as he was filling in for a colleague). The patients who were present during the observed consultations had already granted consent for these sessions to be observed, as the patients had consented to the multimethod intervention study [29].

The study was conducted at a large outpatient haematology clinic located at a Danish university hospital. The introduction and implementation of PROMs at the hospital was conducted simultaneously with a large restructuring of the hospital’s information technology, including launching EPIC® [32], a multipurpose electronic medical record system.

**Data collection**

Data was conducted from March 2017 to December 2018, consisting of two rounds of participant observations alternating with analysis, and finally the in-depth interviews (see Fig. 1 and Table 1). During the two rounds of participant observations, no haematologists were observed to actively mention or incorporate PROMs, indicating the need for another data source to inform the research. The intention of the participant observations were to observe the haematologists’ attitudes to and use of PROMs in practice. It turned out that the haematologists did not use or refer to the PROMs, which could not have been explored without the observations. Therefore the in-depth interviews were planned, after which the total dataset was judged sufficient to provide answers on the research aim. ID does not seek data saturation, as it is impossible to achieve given human variation and diversity on a topic [33–35]. Instead, the key to quality within an ID study is the internal logic of purpose, process, and context that align into a coherent and convincing account which becomes sufficiently well developed to warrant reporting [24].

Participant observations were carried out by the first author, who was a nurse acquainted with many of the haematologists from a past 4-year tenure as a nurse in the outpatient clinic. Participant observations took place during haematologists’ consultations with patients in the clinic [36]. During the consultation, participant observations followed an observation guide [37]. Field notes were taken during observations and supplied to the researcher immediately after the session [38]. The subsequent interviews were short and focused, as they were conducted in between the haematologists’ consultations appointments, and aimed to explore haematologists’ experiences and reflections related to PROMs [39]. A semi-structured interview guide provided guidance, including descriptive, structural, and contrast questions [40]. The observation and interview guide was developed according to the guidelines of the Consolidated criteria for Reporting Qualitative Research (COREQ) checklist [41] by the first author and co-authors, focusing on investigating the haematologists’ experiences, motives and broader reflections on PROMs. Participant observations, interviews, and in-depth interviews were audio recorded, manually transcribed, and organized into electronic files in NVivo PRO™ [42]. In the presentation of findings, ‘H’ followed by an individual number refers to a specific haematologist (see Table 1). F1 refers to data from Field

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Data was conducted in the phases *15/03/17–16/08/17; 07/03/18–04/05/18; 12/11/18–18/12/18*
Study 1, F2 refers to data from Field Study 2, and INT refers to data from the in-depth interviews.

Data analysis
Data analysis was performed inductively, concurrently with data collection, as a creative and abductive process (see Fig. 1) [24, 43]. Observations and field notes informed the analysis to explain what occurred in clinical practice, the focus (if it was not the PROMs), and contextual information on the clinical environment as a specific setting [23, 44]. The analytical process resulted in a critical appraisal of arguments, discussions, and theorizing of perspectives, resulting in the conceptualization of causality and the revealing of credible and meaningful findings. The analytical process was initially performed in NVivo PRO” [42]. Additionally, in the final phases of analysis, data was printed on paper to provide a more creative and visualized exploration without locking data into predefined boxes. Moving quotations around in paper form helped to reveal new insights regarding meanings and relationships in the data. The analysis was performed in Danish to avoid language barrier limitations, and quotes translated into English for the presentation of findings.

Results
The haematologists included were characterised as having distinct, rather antagonistic, and dichotomous views on PROMs. Overall, haematologists resistant to the application of PROMs were characterized as experienced haematologists, mainly males. Haematologists supporting the application of PROMs were younger, both male and female haematologists engaged in medical specialization training, with a mindset predisposed towards practice development. These findings emerged during observations and interviews. No haematologists were observed to directly elaborate on PROMs during observed consultations. Across all observations, primary focus was on the haematological agenda, such as blood test results and medication. The haematologists, who during the interviews declared intentions of using the PROMs, viewed PROM information as additional
information or pseudo-data, not mentioned in the patient-doctor interaction. Two overall themes emerged from the analysis, discussed below.

Theme 1. Against PROMs
Through the analytic process, the first overall theme “Against PROMs” was explored and separated into four subthemes: 1) PROMs address information irrelevant to haematologists but relevant to patients’ general practitioners (GPs), 2) Use of PROMs is time-consuming, 3) PROMs are unnecessary and 4) PROMs are difficult to use. These findings represent an assembled interpretation of haematologists’ experiences with PROMs that were not supportive of their clinical practice.

PROMs address information irrelevant to haematologists but relevant to general practitioners
One of the most prevalent observations by haematologists was that PROMs provide patient information irrelevant to haematology. The haematologists interpreted some information as relevant to patients’ GPs. Consequently, the haematologists may have indicated to patients that the department was not interested in patients’ overall health; a discussion of such might have monopolized the brief time allotted to consult on patients’ hematological diseases.

These PROM completions form a serious range of problems. As haematologists, we are nerds in our field… We must be careful when opening up issues like constipation, [because] then we open up issues that we should not be involved with. If I start up solving issues which the patient is already handling with his GP, it will do more harm than good. Normally the patients know where to address their problems… If we ask all these questions with PROMs, patients might think that I can help them solve all sorts of things. But in reality the relevance for me is to control patients’ EPO treatment, which patients’ GPs cannot. With PROMs we end up talking about anything other than what we should… I guess that is the question – is constipation relevant to haematologists or is that an issue for the GP…? (H1, F1).

This quotation raises several issues. First, it is an ethical problem if PROMs identify issues haematologists cannot respond to. The consequences of a PROM could thus lead to more harm than good. Second, there is a lack of recognition on the part of the system of patient knowledge of where to discuss specific health problems, and lack of respect of the general practitioners’ domain. Finally, this haematologist assumed a single-profession perspective, not considering PROMs as a multidisciplinary tool to be used within the department.

Use of PROMs is time-consuming
Haematologists were asked about the presentation of PROM data in the electronic medical record system. Some identified the layout as problematic because too much data was reported in light of the time available.

I look at the PROM notes quite briefly. The first time I saw the PROM notes I studied the data more in detail. But the notes are so comprehensive that it takes far too long a time to interpret the data compared to the workflow we have. In the meantime, I imagine – maybe I have high thoughts of myself – that I can easily see if there is a problem relevant to me… The notes are standardized with a large volume but with less substance… I believe for some patients this is going to increase the amount of communication, which is unwanted to me, if I may say so… (H6, F2).

PROMs are unnecessary
During the interviews, haematologists related their experiences with PROMs. Most haematologists simply reported not using PROMs as the data was not useful for consultations. A few had very strong feelings against the introduction of PROMs, one explaining that PROMs limited his freedom:

I have to say, as a general rule I don’t use the PROMs. I don’t. I cannot see the intentions behind it. I meet patients that I have known for years throughout my clinical practice, and I ask them how they are doing, I ask about their symptoms. Patients can tell what’s on their mind. I don’t need to send patients a questionnaire to clarify these things, I don’t. I think that the patients are relatively uncomplicated, so why introduce a questionnaire between the patient and me? That does not make sense to me. Clinicians, both nurses and haematologists, have the ability to recognize personalities, and we talk to our patients in relation to that ability as we use our skills… I wish that we could get rid of these PROMs and focus on our work. (H8, INT).

This experienced haematologist argued that the art of patient-centred care centers rather on the art of conversation, not relying on PROMs, and that patient consultations should focus on knowing the human, not data.

PROMs are difficult to use
After the participant observations, the haematologists were asked about the usefulness of PROMS. A number of haematologists expressed simply not knowing what to do with the data. These haematologists were not
observed to elaborate on the PROMs in any way during the participant observations.

I have to say that I have not engaged with the PROM data. The note is quite long and it seems rather impossible to get an overall impression of the content. Concretely I don’t know what to do about it. (H13, F2).

I have previously worked with PROMs in clinical trials. But I have not tried to use PROMs on an individual level before, and I think it is difficult to take action on the information that I get. (H9, F2).

These quotations could be interpreted in several ways: not only are PROMs difficult to use, but there may also be a lack of training on PROMs, or an expression of uncertainty about PROM measurement validity.

Theme 2. Supportive of PROMs
The second overall theme “Supportive of PROMs” arose as haematologists expressed that PROMs had or could have a supportive function in their clinical practice. The theme consisted of three subthemes: 1) A better impression of patients’ conditions, 2) PROMs can increase practice efficiency, and 3) Patients’ experiences are important.

A better impression of patients’ conditions
The theme ‘A better impression of patients’ conditions’ was identified as haematologists reflected on the potential of PROMs and how the data could provide new information before patient visits. For example, patients’ blood test data were used during haematologists’ preparation as a pre-assessment of patients’ conditions.

The PROM data provides me with an impression of the patient’s condition before I see them here ... then I know how the patient is doing. Normally, we don’t know before the patient is coming and sometimes it is a disaster that is coming through my door. Of course, sometimes I can see it from the blood test as well, that this patient might not be doing well ... But sometimes the blood tests are normal, but the patients claim to feel awful. Then you have to identify the problem ... and sometimes the problem is a family-related issue, which has nothing to do with this. Such cases take a long time ... But when I have these data in advance, I have a better impression if there is a problem, so I am ready ... In that way PROMs are quite positive. (H11, INT).

This haematologist expressed a high level of confidence in the result reported, not questioning if the PROMs measured the patient’s situation accurately or how the data were presented [16, 17, 45].

PROMs can increase practice efficiency
Few haematologists who mostly supported the use of PROMs reflected on the Danish healthcare authorities’ decision that PROMs are to be implemented in the treatment of all cancer patients.

A part of this game or project with PROMs is how we can ensure that the patient is doing well, and, being fair, which patients can refrain from consultations. These patients are diagnosed with low-grade malignancies. So which patients could we ask these PROM questions, and then they don’t have to visit the hospital? With two of my patients I have thought that it was rather ridiculous that they had to show up, as the blood test were fine, everything was fine, and the patients were doing really well ... Some patients in this region travel from far away to get here for no reason, so I believe that it would make sense to reverse these consultations supported by PROMs. (H4, F1).

This haematologist related the suggestion to her own practice and how this approach could potentially be supportive for patients and the department.

Patients’ experiences are important
Aside from the theme ‘PROMs address information irrelevant to haematologists and relevant to general practitioners’, the issue that most haematologists, both supportive of and resistant to the introduction of PROMs, addressed during the interviews was the part of the PROMs reporting on patient satisfaction. Haematologists reported that patients’ assessment of the treatment and care provided assisted in evaluating their own practice.

The only part of PROMs that I use is the part about patients’ satisfaction ... If I had patients who were dissatisfied with the communication from me or my colleagues, then I guess it would be obvious through PROMs ... So patient satisfaction is bothering me and an issue that I am interested in when reading the PROM data ... And if the patient is dissatisfied then we can discuss that ... But I have never experienced that yet... (H6, F1).

Discussion
In the present study, the haematologists were characterized with two distinct attitudes towards PROMs: first, resistant to the use of PROMs, mainly expressed by haematologists who were critical of data-driven decisions
and applying an instrument to the art of conversation and patient-centred care. Second, younger hematologists mainly experienced PROMs as adding new and relevant information which could potentially lead to new types of consultations. However, these younger hematologists assumed that the PROMs were previously validated and utilised accurate measurement properties.

The outcome “patient satisfaction” was referred to as the most important outcome for the hematologists no matter their gender, experience and attitudes towards PROMs. The interest in satisfaction might be interpreted as hematologists fearing patient dissatisfaction and its consequences; this rendered PROM outcomes merely interesting as an evaluation of hematologists, rather than one relevant to patient care. Other studies have found that physicians fear receiving complaints as they were interpreted as ‘mistakes’ made within a highly competitive profession, something with largely psychological consequences for the individual hematologist and their future practice [46–48]. This fear of complaints exemplifies how the underpinning legislation and systems rule and influence hematologists’ practice.

Following a critical theoretical perspective and using ID to generate knowledge for practice, when interpreting these findings it is essential to contextualize the healthcare system hematologists operate in and to identify inherent control mechanisms ruling haematology practice [49, 50]. In Habermas’ framework, hematologists’ practices exist in tension between the system and the lifeworld (see Fig. 2). Hematologists themselves represent the system, as they are a profession controlled by legislation, organizational structures, guidelines, specialization, and, pragmatically, a daily schedule in the outpatient clinic with strict time limits to manage patient flow. Furthermore, the pre-defined and standardized context allows a very brief time for core duties such as updating patient condition status and treatment planning during appointments [2, 51, 52]. Consultations are thus dominated by the haematological biomedical agenda, one set and governed by the system, leaving hematologists with no choice regarding priorities during consultations. Time for communicative actions and exploring the lifeworld was limited to small talk between a few hematologists and their patients, such being the circumstances allowed by the system [49, 50].

PROMs were implemented in this department simultaneously with the implementation of a new mandatory electronic system. This may explain why some hematologists did not use the PROMs, instead following the system’s logic and prioritizing mandatory tasks, especially when the hematologist did not find PROMs useful. Some even regarded the introduction of PROMs as a top-down decision disrupting the patient-doctor relationship. A previous study on training clinicians to use PROMs found that a key issue limiting implementation was clinicians’ lack of knowledge on how to apply PROMs during clinical encounters [53]. Another implementation study pointed out the importance of stakeholder buy-in as a prerequisite to implementation, as individuals can play a critical role in helping to adopt usage of PROMs [54]. A defined, procedural framework might help clinicians value the information obtained from PROMs and understand that they can facilitate shared decision-making and person-centered

![Fig. 2 Characteristic Dichotomies in Hematologists’ Practice Inspired by Habermas and McCormack](image-url)
Comparing our study to this literature, the introduction of PROMs without a focus on stakeholder buy-in or procedural usage recommendations may have been naïve, which is a limitation to our findings.

Looking at the themes identified among those supportive of the use of PROMs, some are compatible with some existing knowledge, such as that PROMs potentially provide a better impression of patient conditions and can increase practice efficiency, and that patient satisfaction is important [2, 4, 15]. However, our findings were characterized merely as potential supportive features expressed by haematologists: concrete application of PROMs data was absent, rendering these findings uncertain.

A recent study aimed to determine if PROM data was a valuable tool to assess health-related quality of life (HRQoL) among patients diagnosed with multiple myeloma [58]. The study identified a range of methodological challenges: in order to make HRQoL meaningful, patients might adapt to changes in HRQoL over time, rendering the measurements unreliable, and also patients were liable to not complete PROMs as their disease progressed. These findings could be interpreted as lack of content validity, something that was also identified in the present study when analysing patients’ experiences with PROMs [29]. Another study from neurology investigated PROM-based outpatient follow-ups and concluded that use of PROMs could influence the patient–doctor interaction, increasing patient involvement; this was mainly related to pharmacologic treatment, but the study also found ambivalence among clinicians, as PROMs could both improve and impair the quality of follow-ups [59]. Comparing previous research with our results, a discussion about the value of PROM data is needed, as it appears that introduction of PROMs in clinical practice is linked with some disadvantages. Overall, the approach of using PROMs to identify patients’ individual needs and provide patient-centred care must be questioned, as the quantification of individual experiences through standardised questionnaires is linked with lack of content validity and inadequate psychometric measurement properties [16, 17, 45]. Also, the PROM instrument applied should be considered; in our study the instrument was associated with low content validity and lack of item consistency [45]. Patients did not find questions relevant to their disease and a large number of patients requested free-text entry boxes, indicating a lack of coverage, or that none of the responses were aligned with their situation, leading to potentially invalid responses [29]. The haematologists also did not find the outcomes relevant to their practice and did not understand the PROMs’ scope. Finally, one should be critical towards applying a quality of life questionnaire, as quality of life is not easily quantified through predefined items but rather more as an individual judgment of the value of life circumstances [60, 61]. This point was supported by haematologists in our study as they did not evaluate PROMs as adding precise information about the individual patients, a finding consistent with the imprecision of PROMs when used at the level of individuals and not a group of people [17]. Our findings elucidate how PROMs represent the system, adding another layer of bureaucracy and limiting haematologists’ possibilities for communicative actions, including supporting a patient-centred care culture [62]. This was contrary to the system’s rhetorical insistence on PROMs as meaningful data work [13]; PROMs became meaningless busywork with low legitimacy in some of the haematologists’ clinical practice [11, 21].

Conclusions

The introduction of PROMs in this hematological outpatient clinic did not lead to incorporation of patient information or clinician elaboration on PROMs in the patient–doctor relationship, leaving uncertainties about the potential of PROMs and specifically about the instruments applied. The haematologists were characterized by antagonistic, dichotomous attitudes toward PROMs, either supportive of or resistant to their use. Supportive haematologists were mainly younger, while resistant haematologists were more clinically experienced and critical of the subject the PROMs encompassed. Haematologists experienced patient satisfaction as the most important outcome, while the remaining information from the PROMs was mostly irrelevant to haematologists who did not have the time or ability to address additional symptoms.

Practice implications

First, if PROMs are to actuate their future potential within clinical haematology practice, clinicians and other stakeholders should be involved and engaged throughout the preparation stages, to improve adoption and to encourage support and usage. Second, future PROM instruments should be psychometrically tested, adjusted, and validated within the specific patient group to ensure content reliability and relevance. Finally, one should be aware of the pitfalls associated with adapting PROMs to improve an individualized approach in clinical practice. Other approaches, such as the patient-centred care framework [63], might be more appropriate when aiming to improve individualized care.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s41687-019-0166-6.

Additional file 1: Overview of the multimethod study.
Additional file 2: Additional information on the PROMs implemented.
Acknowledgments
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Authors’ contributions
STH was primarily responsible for the study conception and design, data collection, analysis and interpretation of data, visualization, drafting and revisions of the manuscript. BHH, MK and JB were responsible for the study conception and design, analysis and interpretation of data, and revisions of the manuscript. SFC were responsible for funding acquisition and editing the manuscript. All authors have approved the final version of this manuscript for publishing and agree to be held accountable for all aspects of the work.

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Availability of data and materials
The datasets generated and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
All study participants have provided informed consent and ethical clearance was obtained by the Danish Data Protection Agency (Journal no. 2008-58-0020) and the National Committee on Health Research Ethics approved the project (ClinicalTrials.gov: NCT03056469).

Consent for publication
The informed consent forms stated that patients and haematologists would not be identified if information about this study is published, and patients were informed that their comments would be reported anonymously prior to the interview. Patient quotes are reported anonymously.

Competing interests
The authors declare that they have no competing interests.

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References
"The experiences of patients, nurses and haematologists when Patient-Reported Outcome Measures (PROMs) are implemented in a haematological outpatient clinic: A qualitative study" is in the process of being published and is therefore omitted this thesis.
APPENDICES

Appendix 1  Specification of inclusion and exclusion criteria*
Appendix 2  Screenshots of the EvidoInsight software used for patient completion of the PROMs by phone*
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Appendix 4  EORTC QLQ-C30 Paper form questionnaire*
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*Appendix in Danish
### Appendix 1: Specification of inclusion and exclusion criteria

#### PROM Studiet – Specificerede inklusions- og eksklusionskriterier til RCT

**Overordnet** For at opnå en så homogen patientgruppe som muligt tages udgangspunkt i to af de hæmatologiske kræftpakkeforløb med "hæmatologiske cancerformer“ med et kronisk indolent sygdomsforløb uden kurative behandlingsmuligheder.

**Inklusionskriterier:** Nydiagnosticeret malign sygdom som indgår i kræftpakkerne for kronisk myeloid sygdom/maligne lymfomer/CLL defineret som kronisk indolent ikke-kurabel tilstand

Patienter med diagnoser som KAN indgå i studiet

<table>
<thead>
<tr>
<th>Forkortelse</th>
<th>Navn</th>
<th>Kode</th>
<th>Kommentar til inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPN</td>
<td>Myeloproliferativ sygdom/neoplasi</td>
<td>ICD-10 DD473</td>
<td>Alle</td>
</tr>
<tr>
<td>ET</td>
<td>Essentiel trombocytose</td>
<td>ICD 10 DD459</td>
<td>Alle</td>
</tr>
<tr>
<td>PV</td>
<td>Polycytæmia vera</td>
<td>ICD-10 DD474</td>
<td>Alle</td>
</tr>
<tr>
<td>MF/PMF</td>
<td>Primær myelofibrose</td>
<td>ICD-10 DD474</td>
<td>Alle</td>
</tr>
<tr>
<td>PrePMF =</td>
<td>Præmyelofibrose</td>
<td>D921</td>
<td>Alle</td>
</tr>
<tr>
<td>MDS</td>
<td>Myelodysplasisk syndrom</td>
<td>DD460-DD469</td>
<td>Alle</td>
</tr>
<tr>
<td>CLL</td>
<td>Kronisk lymfatisk leukæmi</td>
<td>ICD-10 DC911</td>
<td>Alle</td>
</tr>
<tr>
<td>FL</td>
<td>Follikulært lymfom</td>
<td>ICD 10 DC820-DC830</td>
<td>Næsten alle. Se *</td>
</tr>
<tr>
<td></td>
<td>Lymfoblastært lymfom</td>
<td>DC835</td>
<td>Næsten alle. Se *</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Symptom</th>
<th>Diagnosis</th>
<th>ICD-10 Code</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-celle lymfom</td>
<td>ICD-10 DC851</td>
<td>Næsten alle. Se *</td>
<td></td>
</tr>
<tr>
<td>WB</td>
<td>Waldenströms makroglobulinæmi</td>
<td>ICD-10 DC880</td>
<td>Næsten alle. Se *</td>
</tr>
<tr>
<td>MCL</td>
<td>Mantelcelle lymfom</td>
<td>DC831</td>
<td>Næsten alle. Se *</td>
</tr>
<tr>
<td>MZL</td>
<td>Marginalzone lymfom</td>
<td>830</td>
<td>Næsten alle. Se *</td>
</tr>
</tbody>
</table>

*Nogle patienter med et højt sygdomsstadie (typisk stadie 3.b eller 4) skal først igennem en primær behandling inden de kan inkluderes i studiet. Det kan f.eks. være R-CHOP, R-benda eller strålebehandling.

Patienter der sættes i en behandling som led i et kontrolforløb med f.eks Hydrea, Interferon, Vidaza, Rituximab, Imbruvica (ibrutinib) må gerne inkluderes i studiet.

**Patienter, der aldrig kan indgå i studiet:**

1. Myelomatosose
2. MGUS
3. De akutte leukæmi (AML/ALL)
4. HCL (Hårceleleukæmi)
5. DLBCL (diffust storcellet B-lymfom)
6. HL (hodgkins lymfom)
7. Andre aggressive lymfomer
8. ITP
9. Mastocytose
10. Hæmofili patienter

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Appendix 2: Screenshots of the EvidoInsight software used for patient completion of the PROMs by phone

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Appendix 3: Screenshots of the EvidolInsight software used for patient completion of the PROMs

The opening page for PROM completion

The questionnaire completion in progress
The questionnaire completion in progress

Termination of PROM completion
EORTC QLQ-C30 (version 3.0)

Vi er interesserede i at vide noget om Dem og Deres helbred. Vær venlig at besvare alle spørgsmålene selv ved at sætte en ring omkring det svar (tal), som passer bedst på Dem. Der er ingen "rigtige" eller "forkerte" svar. De oplysninger, som De giver os, vil forblive strengt fortrolige.

1. Har De nogen vanskeligheder ved at udføre anstrengende aktiviteter, som f.eks. at bære en tung indkøbslastse eller en kuffert?  
   Slet ikke | Lidt | En del | Meget
   1 | 2 | 3 | 4

2. Har De nogen vanskeligheder ved at gå en lang tur?
   1 | 2 | 3 | 4

3. Har De nogen vanskeligheder ved at gå en kort tur udendørs?
   1 | 2 | 3 | 4

4. Er De nødt til at ligge i sengen eller at sidde i en stol om dagen?
   1 | 2 | 3 | 4

5. Har De brug for hjælp til at spise, tage tøj på, vaske Dem eller gå på toilettet?
   1 | 2 | 3 | 4

I den forløbne uge:

6. Var De begrenset i udførelsen af enten Deres arbejde eller andre daglige aktiviteter?
   1 | 2 | 3 | 4

7. Var De begrænset i at dyrke Deres hobbyer eller andre fritidsaktiviteter?
   1 | 2 | 3 | 4

8. Havde De åndemød?
   1 | 2 | 3 | 4

9. Har De haft smerte?
   1 | 2 | 3 | 4

10. Havde De brug for at hvile Dem?
    1 | 2 | 3 | 4

11. Har De haft besvær med at sove?
    1 | 2 | 3 | 4

12. Har De følt Dem svag?
    1 | 2 | 3 | 4

13. Har De savnet appetit?
    1 | 2 | 3 | 4

14. Har De haft kvalme?
    1 | 2 | 3 | 4

15. Har De haft kædet op?
    1 | 2 | 3 | 4

Vær venlig at fortsætte på næste side.
### I den forløbne uge:

<table>
<thead>
<tr>
<th>Slet ikke</th>
<th>Lidt</th>
<th>En del</th>
<th>Meget</th>
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<tbody>
<tr>
<td>16. Har De haft forstoppelse?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. Har De haft diarré (tynd move)?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18. Var De træt?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19. Vanskeliggjorde smertes Deres daglige gøremål?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20. Har De haft svært ved at koncentrere Dem om ting som f.eks. at læse avis eller se fjernsyn?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21. Følte De Dem anspændt?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>22. Var De bekymret?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>23. Følte De Dem irriteret?</td>
<td>1</td>
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<td>3</td>
</tr>
<tr>
<td>24. Følte De Dem deprimeret?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>25. Har De haft svært ved at huske?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>26. Har Deres fysiske tilstand eller medicinske behandling vanskeliggjort Deres familielev?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>27. Har Deres fysiske tilstand eller medicinske behandling vanskeliggjort Deres omgang med andre mennesker?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>28. Har Deres fysiske tilstand eller medicinske behandling medført økonomiske vanskeligheder for Dem?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

### Ved de næste 2 spørgsmål bedes De sætte en ring omkring det tal mellem 1 og 7, som passer bedst på Dem

29. **Hvordan vil De vurdere Deres samlede helbred i den forløbne uge?**

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meget dårligt</td>
<td>Stærkere godt</td>
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</table>

30. **Hvordan vil De vurdere Deres samlede livskvalitet i den forløbne uge?**

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meget dårlig</td>
<td>Stærkere godt</td>
<td></td>
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</tr>
</tbody>
</table>
SÅDAN UDFYLDES SPØRGESKEMAET

Formålet med spørgeskemaet er at få tilbagemelding fra dig vedrørende dine oplevelser fra dit seneste besøg i hæmatologisk ambulatorium. Det vil give afdelingen mulighed for at identificere områder, hvor der, med udgangspunkt i dine oplevelser, bør sættes ind for at forbedre.

Sæt kun kryds i ÉT svar for hvert spørgsmål.
Hvis du kommer til at sætte krydset forkert, bedes du skravere det forkerte svar og sætte kryds i det korrekte svar.

![Table showing how to fill out the questionnaire]

På forhånd tak.
Sp. 1. Hvor gavnligt var dit seneste hospitalsbesøg med hensyn til at afhjælpe det problem eller de problemer, som du kom til hospitalet for?

☐ 1. Særdeles gavnligt
☐ 2. Meget gavnligt
☐ 3. Gavnligt
☐ 4. En smule gavnligt
☐ 5. Slet ikke gavnligt
☐ 6. Problemet/problemerne er blevet fuldstændigt løst

Sp. 2. Hvordan vil du nu vurdere det eller de problemer, som du for nylig kom til hospitalet for?

☐ 1. Meget bedre
☐ 2. En smule bedre
☐ 3. Uændret
☐ 4. En smule værre
☐ 5. Meget værre

Sp. 3. Hvor gavnligt var dit seneste hospitalsbesøg med hensyn til at håndtere de forskellige dele af det eller de problemer, som fortsatte efter at du havde forladt hospitalet?

☐ 1. Særdeles gavnligt
☐ 2. Meget gavnligt
☐ 3. Gavnligt
☐ 4. En smule gavnligt
☐ 5. Slet ikke gavnligt
☐ 6. Der er ingen problemer tilbage; alle problemer er blevet fuldstændigt løst

Sp. 4. Hvordan vil du vurdere dit helbred nu som følge af dit hospitalsbesøg?

☐ 1. Meget bedre
☐ 2. En smule bedre
☐ 3. Uændret
☐ 4. En smule værre
☐ 5. Meget værre
Sp. 5. Fik du forståelige svar, når du stillede vigtige spørgsmål til personalet?

☐ 1. Ja, altid
☐ 2. Ja, for det meste
☐ 3. Ja, nogle gange
☐ 4. Nej, aldrig
☐ 5. Ved ikke

Sp. 6. Hvor gavnlig var den information, du fik vedrørende din behandling og sygdom ved dit seneste hospitalsbesøg?

☐ 1. Særdeles gavnlig
☐ 2. Meget gavnlig
☐ 3. Gavnlig
☐ 4. Lidt gavnlig
☐ 5. Slet ikke gavnlig
☐ 6. Jeg fik ingen information, men ville gerne have haft det
☐ 7. Jeg havde ikke brug for information

Sp. 7. Blev du inddraget så meget, som du ønskede i beslutningerne vedrørende din pleje og behandling ved dit seneste hospitalsbesøg?

☐ 1. Så meget, som jeg ønskede
☐ 2. Mindre, end jeg ønskede
☐ 3. Overhovedet ikke, selv om jeg gerne ville
☐ 4. Overhovedet ikke, og jeg ønskede det heller ikke
☐ 5. Mere, end jeg ønskede

Sp. 8. Hvor meget reagerede personalet på dine individuelle behov under dit seneste hospitalsbesøg?

☐ 1. Hele tiden
☐ 2. For det meste
☐ 3. Nogle gange
☐ 4. Slet ikke
Sp. 9. Fik du mulighed for at drøfte dine bekymringer og din angst med personalet under dit seneste hospitalsbesøg?

☐ 1. Så meget, som jeg ønskede
☐ 2. For det meste
☐ 3. Nogle gange
☐ 4. Overhovedet ikke, selv om jeg gerne ville
☐ 5. Jeg havde ingen bekymringer eller angst

Sp. 10. Samarbejdede de forskellige personer, som behandlede og plejede dig, om at give dig den bedst mulige behandling og pleje?

☐ 1. Ja, altid
☐ 2. Ja, for det meste
☐ 3. Ja, nogle gange
☐ 4. Nej, aldrig
☐ 5. Ved ikke

Sp. 11. Alt i alt, hvordan vil du vurdere resultatet af dit seneste hospitalsbesøg?

☐ 1. Fremragende
☐ 2. Meget godt
☐ 3. Godt
☐ 4. Rimeligt
☐ 5. Dårligt
### De næste fem spørgsmål vedrører dit helbred i dag

*Markér ÉT svar for hvert emne ud for den sætning, som bedst beskriver din helbredstilstand i dag.*

<table>
<thead>
<tr>
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<tr>
<td>Jeg har en smule problemer med at gå omkring</td>
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<tr>
<td>Jeg har nogle problemer med at gå omkring</td>
<td>☐</td>
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<tr>
<td>Jeg har store problemer med at gå omkring</td>
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<td>Jeg har store problemer med selv at vaske mig eller klæde mig på</td>
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<tr>
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<tr>
<td>Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter</td>
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<td>Jeg har store problemer med at udføre mine sædvanlige aktiviteter</td>
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<tr>
<td>Jeg har nogle smerter eller ubehag</td>
<td>☐</td>
</tr>
<tr>
<td>Jeg har store smerter eller ubehag</td>
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<table>
<thead>
<tr>
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<tr>
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<td>☐</td>
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<tr>
<td>Jeg er noget angst eller deprimeret</td>
<td>☐</td>
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<tr>
<td>Jeg er meget angst eller deprimeret</td>
<td>☐</td>
</tr>
<tr>
<td>Jeg er ekstremt angst eller deprimeret</td>
<td>☐</td>
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Tak, fordi du udfyldte spørgeskemaet.
Overview, patients’ completion of questionnaires

Overview, adjustment of patients’ completion periods
Overview, patients’ last completions

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Temp. 1</th>
<th>Temp. 2</th>
<th>Pegtol. 1</th>
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<td>Test 3</td>
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Overview, patients’ completions continued
Appendix 7: Local guideline on rehabilitation in Department of Haematology

Hæmatologi ROS - Rehabilitering for hämatologiske patienter, ver. 2

1) Formål
   At beskrive den faglige indsats samt organiseringen af indsatsen for patienter med nedsat funktionsevne.

   Instruksen skal være vejledende for klinikeren til at identificere og intervenere patienters behov for rehabilitering.

   Formålet med rehabilitering i hæmatologisk regi er at forbedre og vedligeholde patientens funktionsevne fysisk, psykisk, socialt og intellektuelt med henblik på, at patienten bliver så uafhængig og selvstændende som muligt samt opnår et meningsfuldt liv.

2) Anvendelsesområde
   For patienter med forløb i Hæmatologisk Afdeling, Roskilde Sygehus. Indgår i fællesfaglig modtagelse i dagafsnit, ved læge-, behandlings-, og sygepleje-konsultationer, samt ved indlæggelsesforløb.

3) Fremgangsmåde
   3.1) Baggrund
       Flere overlever en kræftsygdom og flere lever længere med en kræftsygdom end tidligere. Der er et stort behov for at sikre, at mennesker, der har eller har haft kræft bliver hjulpet og støttet, så de bedst kan bevare deres funktionsevne, eller genvinde den så godt som muligt.

       Alle patienter, der har patientforløb i Hæmatologisk Afdeling skal have foretaget en vurdering af behov for rehabilitering. Behovsvurderingen og indsatsen bør anlægge et helhedsorienteret perspektiv på den enkeltes livssituation, ressourcer og behov.

       Hvert år får ca. 35.000 mennesker påvist en kræftsygdom i Danmark og ca. 15.000 vil de af kræft. I forhold til rehabilitering vil ca. 70 % (DK 155.000) af de patienter, der lever med kræft, selv kunne håndtere deres egne problemer sammen med de pårørende og med støtte fra fagprofessionelle. Ca. 25 % (DK 55.000) vil have behov for en professionel ledet indsat, og ca. 5 % (DK 11.000) vil have behov for en særlig indsat.

   3.2) Identifikation af behov for rehabilitering
       Rehabiliteringsbehovet skal vurderes hos:

   http://d4.regj.intern/Doks/dokument.asp?DokID=329500&q=Indtast%20s%C3%B8g... 24-09-2019
- Patriner der er diagnosticeret eller henvist til afdelingen med begrundet mistanke om en hæmatologisk kraftsygdom
- Patriner, der har overlevet en kraftsygdom
- Patringerens pårørende og efterladte

I forbindelse med samtalen med patienten ved fællesfaglig modtagelse foretager sygeplejersken eller lægen en systematisk og nuanceret vurdering af behovet for en rehabiliterings intervention.

Hypoterg foretrukne områder er lig:

<table>
<thead>
<tr>
<th>Behovsområde</th>
<th>Problemer/vanskeligheder</th>
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<tbody>
<tr>
<td>Fysisk</td>
<td>• Smerte, åndenhed</td>
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<tr>
<td></td>
<td>• Manglende appelt, vægttab, kvalme</td>
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<td></td>
<td>• Tarhed/svamp i munken, synkebesværs</td>
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<td></td>
<td>• Forstoppelse, diarræ, inkontinens</td>
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<tr>
<td></td>
<td>• Nedsat muskelraft, beveglighed og fysisk</td>
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<tr>
<td></td>
<td>funktionsniveau</td>
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<tr>
<td></td>
<td>• ADL, nedsat funktion og begrensninger</td>
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<td>i udførelse af daglige aktiviteter</td>
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<td></td>
<td>• Savnproblemer</td>
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<td></td>
<td>• Træthed</td>
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<td>• Seksualitet</td>
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<td>• Angst, depression</td>
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<td>• Hukommelses- koncentrationsbesværs</td>
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<td>Socialt</td>
<td>• Fastholdelse af jobbet, forsergelser</td>
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<td>• Relationer til pårørende, nære i</td>
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<td>børnefamiiler</td>
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<td>Eksistenselt/ændelig</td>
<td>• Manglende anerkendelse fra omgivelserne</td>
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<tr>
<td></td>
<td>• Tørhed, skyld, skam</td>
</tr>
<tr>
<td></td>
<td>• Manglende accept af ændret identitet,</td>
</tr>
<tr>
<td></td>
<td>livsomstændigheder og udsigter</td>
</tr>
<tr>
<td></td>
<td>• ensomhed</td>
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(Kilde: Gisela Hansen et al. 2011; Johnsen, 2008; Johnsen, 2009)

I forlængelse skal lægen/sygeplejersken løbende evaluere, justere og/eller foretage ny vurdering af patientens behov. Det er en faglig vurdering, der afgør, hvor ofte rehabiliteringsplanen evalueres/revurderes, dog ved længerevarende indlæggelse dog min.

I forlængelse skal patienten og/eller forretningspartner forlænges vurdering, hvis det vurderes, at der er behov for ny vurdering.

I forlængelse forstås, at den fagprofessionelle i dialog med patient vurderer patientens situation indenfor ovennævnte områder sammen med patienten. Vurderingen tager i overordnet patientens egen vurdering i forhold til habituelt kontra aktuelt, samt i validerede redskaber i forhold til emneområderne, som afdelingen har valgt at anvende.

(link til sygeplejefaglige planer)

3.3) Udarbejdelse af plan

Udarbejdelse af plan sker, når der indenfor områderne i figur 1 er fundet et eller flere problemer, hvor patienten har oplevet funktionsstab, og hvor der kan måles en funktionsnedgang.

Planen skal indeholde

• Problemformulering

http://d4.regj.intern/Doks/dokument.asp?DokID=329500&q=Indtast%20s%C3%B8g... 24-09-2019
• planlagte handlinger
• mål
• evaluering/revurderings behov

Ved behov for strættende samtales i forhold til rehabilitering henviser lægen eller sygeplejersken patienten til sygeplejekonsultation i ambulatoriet.

*Målet for patientens rehabilitering er at re-integrere patienten i hverdagslivet efter kræftdiagnosen og behandling af denne.

For alle patienter, der indgår i kræftpakke forløb, skal der foreligge enten en rehabiliteringsplan eller en vurdering i forhold til en rehabiliteringsplan.

3.4) Pårørende rolle
Pårørende til kræftpatienter har en støttende rolle for patienten i hele forløbet.

De pårørende kan selv have behov for rehabilitering i forløbet, da det kan være belastende at være pårørende. De pårørendes behov kan opstå på baggrund af træthed/udmattelse, sevnforstyrrelser, dårligt fysisk helbred, dårlig emørselsstabil stand m.v.

Psykiske konsekvenser af at være pårørende kan være stresssyntomer, angst og måske depression.

Lægen eller sygeplejersken kan henvise den pårørende til samtaler i sygeplejerskeambulatoriet, hvor den samlede rehabiliteringsplan lægges. De pårørende får et selvstændigt forløb.

Det er vigtigt at have særlig opmærksomhed på barn til kræftsyge. Barnene kan opleve social stigmatisering og en ændring af egen rolle i sociale relationer – også uden for familien. I disse tilfælde skal afdelingen sørge for at tilbyde henvisning til Børne- og Ungdomspsykolog.

4) Ansvarsforhold
Sygeplejersken og lægen, der foretager den fællesfaglige modtagelse af patienter, er ansvarlige for at indfange de pårørende i starten af patientforløbet.

Kontaktsygeplejerske/-læge er ansvarlige for at vedligeholde/revurdere planen for rehabiliteringsindsatsen.

Sundhedsfagligt personale, der har kontakt med patienten, er ansvarlig for at udføre planens handlinger.

Sygeplejerske og læge, der har kontakt med patienten, har ansvaret for at inddrage pårørende i forløbet.

Afdelingsledelsen er ansvarlig for implementering.

Det er den enkelte medarbejders ansvar at kende og anvende instrukser.

5) Dokumentation
Kontaktsygeplejerske og sygeplejerske er ansvarlig for, at diagnoseteamet udarbejder en tverrfaglig rehabiliteringsplan for alle patienter.

Sygeplejersken skal i sygeplejedyrden dokumentere afdækningen af fysiske, psykiske og sociale forhold, identificere rehabiliteringsområder og oprette indsatsområder for identificerede områder.

6) Definitioner/Søgeord
WHO's definition (www.who.int/topics/rehabilitation/en/) of rehabilitering:

http://d4.regi.jtern/Doks/dokument.asp?DokID=329500&q=Industri%20%20%20%20B8g... 24-09-2019
Rehabilitering af mennesker med nedsat funktionsevne er en række af indsatser, som har til formål at sætte den enkelte i stand til at opnå og vedligeholde den bedst mulige fysiske, sanseæg, intelleguelle, psykologiske og sociale funktionsevne. Rehabilitering giver mennesker med nedsat funktionsevne de redskaber, der er nødvendige for at opnå uafhængighed og selvbestemmelse." - Sundhedsstyrelsens oversættelse maj 2010


7) Referencer

- Virksomhedsgrundlag for Roskilde-Køge sygehus
- "Nationale anbefalinger for sundhedspersonalets møde med påvirket avlsfødt patient", sundhedsstyrelsen 2012
- Behandling af den elektivt henviste patient i somatikken
- Regionale retningslinjer: Patientjournalen
- Fagspecifik journalføring
- Indledende sygeplejeudredning, sygehus Nord, dok. nr. 247957
- Sygeplejefaglig journalføring
- Lægefaglig journalføring udarbejdes
- Lægefaglig journalføring udarbejdes
- Sekretærfaglig instruks udarbejdes
- Sygeplejekonsultation, henvisning til sygeplejekonsultation under udarbejdelse
- Psykolog, henvisning til psykolog i Hæmatologisk afdeling

Standard DDKM for Sygehuse 2. version
1. 3.02 Patientjournalen
2. 7.07 Behandling af den elektivt henviste patient
2.15.01 Rehabilitering

Revisions historik

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http://d4.regj.intern/Doks/dokument.asp?DokID=329500&q=Indtast%20s%C3%B8g...  24-09-2019
Appendix 8: Local guideline on follow-up in Department of Haematology

1) **Formål**
At beskrive effektueringen af opfølgingsprogrammer for de fire hovedgrupper af hæmatologiske cancersygdomme i Hæmatologisk afdeling.

2) **Anvendelsesområde**
Læger og sygeplejersker ansat i Hæmatologisk afdeling, Roskilde sygehus.

3) **Fremgangsmåde**
Sundhedsstyrelsen og regionerne har udgivet opfølgingsprogrammer for de fire hovedgrupper af hæmatologiske cancersygdomme: **Opfølgingsprogrammer – kreativmarked** (Se hvert opfølgingsprogram under Bilag).


Udarbejdelse af opfølgingsplan og efterfølgende effektuering af indsatser varetages i tæt samarbejde mellem patientens kontaktpersoner (læge, sygeplejerske, sekreter). Den tværfaglige indsatssplanlægges i opfølgingsplanen og kontaktlægen og kontaktsygeplejersken sikrer en kontinuerlig dialog med henblik på koordinering og løbende nødvendige justeringer af indsatser.

Der tages overordnet udgangspunkt i Sundhedsstyrelsens opfølgingsprogrammer samt retningslinjer fra de ankelte DMCG'er, se **Danske Multidisciplinære Cancer Grupper samt under referencer**. Afdelingen følger således de nationalt rekommanderede opfølgingsfrekvenser og brug af diverse undersøgelser/analyser. Implementeringen bliver en del af sygehusstrategien "Patienten som partner". Afdelingen følger løbende op på implementeringen, idet følgende KPI'er monitoreres: 1. patienter som indgår i kreativmarked har en opfølgingsplan; 2. opfølgingsplanerne opfylder kriterierne defineret i denne retningslinje. Målopplysning er >90% for begge KPI'er. Ansvarlig for monitoreringen er forløbskoordinatøreren, der sikrer, at kontaktlæge/sygeplejerske informeres, hvis opfølgingsplan ikke er udarbejdet.

**Standardforløb for en nyhenvist hæmatologisk patient med malign diagnose er:**
1. Visitation (forløbskoordinatorer og speciallæger)
2. Udredningsprogram (kontaktlæge)
3. Efterstadie (kontaktlæge og kontaktsygeplejerske)

http://d4.regscj.intern/Doks/dokument.asp?DokID=474274&q=Indtast%20s%C3%B8g... 28-10-2019
4. Behandlingsfase (kontaktlæge og kontaktsygeplejerske)
5. Opfølgningssamtale (kontaktlæge og kontaktsygeplejerske)
6. Opfølgning frem til afslutning eller gentagne behov for ny udredning og nye behandlinger

Opfølgningsplan udarbejdes i forbindelse første besøg efter afsluttet primærbehandling. Hos patienter med kroniske forløb og forventet kontinuerlig behandling eller intet behov for behandling udarbejdes opfølgningsplan dog i forbindelse med "efterstadies". En mindretal af patienter diagnosticeres og behandles primært under indlæggelse. Eks. emtevis patienter med akut leukæmi, hvor hele det initiale forbipasserer i den stationære og semiambulante funktion. Her vil opfølgningssamtale med udarbejdelse af opfølgningsplan ske under indlæggelse eller ved semiambulant kontrol – senest i forbindelse med indlæggelse til sidste behandlingskur i primærbehandlingen.

Opfølgningsplanen skal dokumenteres i journalen og kodes med XR001 ("plan for opfølgning efter kræft"). Kodningen varetages af kontaksekspert i forbindelse med skrivning af opfølgningsplan i OPUS. Efterfølgende sender kontaksekspert opfølgningsplanen til egen læge i almen praksis.

Forlatskoordinationen sikrer i forbindelse med monitorering, at kodningen er foretaget. Dokumentationen sker ved, at kontaktlægen skriver et OPUS notat med overskriften "Opfølgningsplan" og de enkelte punkter i nedenstående skema er obligatoriske. Hvis behovsvurderingen konkluderer, at der ikke er behov for understøttende indsatser noteres dette.

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<td>Eks. &quot;Patient og pårørende informeret om opfølgningsplan og accepterer planen&quot;</td>
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<td>FMK og CAVE</td>
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</table>

http://d4.regj.intern/Doks/dokument.asp?DokID=474274&q=Indtast%20s%C3%B8g... 28-10-2019
4) **Ansvarsforhold**
Afdelingsledelsen har i samarbejde med afsnitssedelserne ansvar for implementering af opfølgningsprogrammer.
Læger og sygeplejersker har ansvar for at udarbejde opfølgningsprogrammer.

5) **Dokumentation**
Opfølgningsplan dokumenteres i Opus og ESD

6) **Definitioner/Søgeord**
Behandlingsplan: indeholder medicinsk behandlingsplan og rehabiliteringsplan

7) **Referencer**
Se bilag.
Acut Leukæmi Gruppen (ALG): Kliniske retningslinjer
Dansk Lymphom Gruppe (DLG): Kliniske retningslinjer
Dansk Studiegruppe for Kroniske Myeloide Sygdomme (DSKMS): Kliniske retningslinjer
Dansk Myelomatose Studiegruppe (DMSG): Kliniske retningslinjer

Bilag:
Opfølgningsprogram for akut leukæmi.pdf
Opfølgningsprogram for kroniske myeloide sygdomme
Opfølgningsprogram for lymphomkræft og kronisk lymfatisk leukæmi
Opfølgningsprogram for myelomatose

**Revisions historik**

<table>
<thead>
<tr>
<th>Version</th>
<th>Godkendt</th>
<th>Revisions information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>05.01.2016</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>09.12.2015</td>
<td></td>
</tr>
</tbody>
</table>
Observationsguide af konsultationssituation mellem patient og læge eller sygeplejerske

Beskrivende spørgsmål:
Hvem deltager i situationen?
Hvad er omstændighederne for situationen? (Hvor? Hvornår? Formål?)
Hvad sker som ikke produceres verbalt?

Interaktion mellem læge/sygeplejerske og patienten
Hvordan og hvem indleder samtalen?
Hvordan positionerer informanterne sig?
Hvad bliver gjort?
Hvad bliver sagt?
Hvordan er informanternes kropssprog?
Hvordan fordeler tiden indholdsmæssigt? Hvem er den mest talende part? Om hvad?
Skjult Dagsorden?

Observationer specifik om PRO-data
Inddrages PRO-data under konsultationen?
Hvis ja, hvem bringer PRO op? Hvordan? Hvad er konsekvensen?
Hvad fører en evt. drøftelse af PRO besvarelserne til?

Observationsguide – Fokusgruppe interview

Beskrivende spørgsmål
Hvem deltager i fokusgruppeinterviewet?
Hvad er omstændighederne for situationen? (Hvor? Hvornår? Formål?)
Hvad sker nonverbalt?

Gruppeinteraktionen
Hvordan og hvem indleder samtalen?
Hvordan positionerer informanterne sig? Siger nogle mere en andre? Er der nogen som er styrende eller nogle som ikke siger ret meget?
Hvad bliver gjort?
Hvad bliver sagt? Hvilke faglige termer anvendes?
Hvad sker nonverbalt?
Hvordan er informanternes kropssprog?
Hvordan bliver tingene sagt? Er der et hierarki?
Hvordan fordeler tiden indholdsmæssigt? Hvem er den mest talende part? Om hvad?
Skjult Dagsorden?
Appendix 10: Interview guides

Interview med patienter som informanter

Beskrivende spørgsmål (afdækker patientens basale viden)
Vil du indledningsvis fortælle mig hvad du fejler hvorfor du kommer her i hæmatologisk afdeling? (Giver forståelse af patientens oplevelse og forståelse af sygdommen og forløbet i afdelingen)
Blev der lagt en plan for hvad der skal ske fremadrettet ift. din sygdom?
Hvordan blev planen lagt?
Hvordan synes du konsultationen gik?

Strukturelle spørgsmål (områder eller felter som er basale for patienten)
Du deltager i undersøgelsen hvor du besvarer spørgeskemaer inden konsultationen. Jeg er interesseret i hvordan det går?
Oplevede du at sygeplejersken/lægen brugte oplysninger du har indsendt via spørgeskemaet?
Hvordan?
Hvad oplever du for tiden er det vigtigste for at vi kan hjælpe dig i ftf livet med sygdom?

Kontrastspørgsmål (Hvad pt mener med forskellige vendninger og begreber)
Nævnte du selv din spørgeskemabesvarelse? Hvorfor/hvorfor ikke?
Drejede samtalen sig om det som var vigtigst for dig lige nu?
Fandt du spørgsmålene i spørgeskemaet relevante ift din situation og sygdom?

Interviewguide med læge/sygeplejerske

Indledende information:
Interviewet her skal bidrage til forståelse af hvordan du som sundhedsprofessionel prioriterer indholdet i konsultationen med patienten og evt. hvordan du anvender patientens egne rapporterede helbredsoplysninger.

Beskrivende spørgsmål
Hvilke overvejelser gør du dig i forhold til hvad konsultationen skal indeholde?
Hvad synes du var det vigtigste at bruge konsultationen/situationen på?
Var der et gennemgående tema i konsultationen?

Strukturelle spørgsmål
Hvad er dit syn på anvendelse af PRO
Har du anvendt de PRO data som patienten har indberettet? Hvordan?
Gav de indberettede oplysninger mening da du talte med patienten – Var de relevante?
(studiegruppe 1)
Er PRO forenelig med den hæmatologiske dagsorden?
Hvad er dit syn på helhedsorienteret opfølgning (Jf. opfølgningsprogram (3))? Bidrager PRO til dette?
Appendix 10: Interview guides

Kontrastspørgsmål
Fordi patienten større indflydelse under konsultationen med forudgående PRO data? (studiegruppe 1 og 2)
Hvordan kom i frem til en plan for det videre forløb i afdelingen?

Interviewguide – Fokusgruppeinterview med sygeplejersker

**Fokus for interviewet er:**
1. sygeplejerskers prioritering af indholdet i konsultationerne
2. sygeplejerskernes oplevelser og opfattelser og fremadrettede forventninger med anvendelse af PRO i praksis.

Beskrivende spørgsmål
Har i fået erfaringer med PRO? Hvilke?
Er PRO en hjælp for jer som professionelle?
Er det i deres optik en hjælp for patient og pårørende?
Hvornår anvender de anvender/anvender de ikke PRO og hvorfor?
Hvad er potentialen ved PRO fremadrettet i jeres kliniske praksis? (Evt. Til sygeplejekonsultationer?)
I observationsstudiet så Stine flere gange at nogle sygeplejersker prioriterede samtale og behandling af patienterne før de læste journalerne, og altså ikke så ud til at anvende pro så meget- hvad tænker I om det?

Strukturelle Spørgsmål
Hvordan er PRO blevet brugt/ikke brugt?
Hvad er styrende for om PRO bliver anvendt?
Hvordan passer de eksisterende PRO notater ind i jeres konsultation? (Hav kopi med eksempel på PRO notat som kan tales ud fra)
Kan dette nye tiltag integreres i en travl praksis? (Betydningen af at integrere ny viden/tilgange i en travl praksis)
Hvilke rammer og vilkår er styrende for jeres prioriteringer når i jeres møde med patienterne?
Kender I til vision og strategi for sygeplejen på SUH og til strategi for sygeplejen på afdelingen?
Er det noget der indgår I jeres overvejelser og er hvordan ser I PRO understøtter/er i kontrast til disse (hvis de kender dem).

Kontrastspørgsmål
"Patienten først“ – Hvad betyder det og hvordan kommer det til udtryk i praksis?
Under observationerne var der flere situationer hvor i sygeplejersker byttede patienter – Hvorfor bytter i patienter?
Hvilken betydning får det for jeres praksis når i bytter patienter ”ad hoc“ i løbet af dagen?
(Hvordan) Kan i forestille jer at arbejde med patientrapporterede oplysninger fremadrettet?
Patient-Reported Outcomes Integrated in the Follow-up of Patients With Hematological Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03056469

Recruitment Status: Recruiting
First Posted: February 17, 2017
Last Update Posted: February 17, 2017

See Contacts and Locations

Sponsor:
Zealand University Hospital

Information provided by (Responsible Party):
Zealand University Hospital

Study Description

Brief Summary:
This study investigates if integration of patient-reported outcomes in the follow-up of patients with newly diagnosed, not curable, chronic hematological cancer changes the number and kind of supportive care interventions. Furthermore, this study investigates if the patients feel that they are more involved in a positive way when patient-reported outcomes are integrated in the follow-up of their cancer.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematological Cancer</td>
<td>Other: Completion of patient-reported outcome (PRO) questionnaires</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Detailed Description:
This is a multimethod study. It has a quantitative and a qualitative part. The patient-reported outcome questionnaire European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C-30) and the patient-reported outcome and patient-reported experience questionnaire The Outcomes and Experiences Questionnaire (OEQ) are completed by the included patients within one week before a patient-physician consultation at the outpatient clinic at one single department of hematology. Baseline is different for different patient groups: 1) for participants receiving a primary treatment baseline is defined as the first patient-physician consultation after the primary treatment ended, 2) for patients continuously receiving medical treatment baseline is defined as the first patient-physician consultation after starting medical treatment, and 3) for patients followed using a watch and wait strategy baseline is defined as the first patient-physician consultation after deciding the watch and wait strategy. Each patient completes the questionnaires for 2 years. The questionnaires can be completed online or on paper depending on the patients choice. Answers from both questionnaires are eligible to all health care professionals in the outpatient clinic in an internet based tool. A summary of scores from the EORTC QLQ C-30, and the answers and the score from the OEQ, are written in the medical record.

This study investigates, if use of the patient-reported outcome (PRO) questionnaires are useful in the assessment of the patients needs and health care providers decision making regarding supportive care interventions. It investigates, if completion of PRO questionnaires changes...
the number and kind of supportive care interventions.
Observations of patient-physician consultations and individual interviews with patients are used to capture the impact of the questionnaires on the consultations and patients evaluation of the use of the questionnaires.
This study also investigates if patients completion of PRO questionnaires and healthcare professionals use of the questionnaires in clinical decision making changes the number of contacts between patients and a department of hematology and the number of paraclinical interventions.

Study Design

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Interventional  (Clinical Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Enrollment</td>
<td>225 participants</td>
</tr>
<tr>
<td>Allocation</td>
<td>Randomized</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>Parallel Assignment</td>
</tr>
<tr>
<td>Masking</td>
<td>Single (Care Provider)</td>
</tr>
<tr>
<td>Masking Description</td>
<td>In one randomization arm the participants submit patient-reported outcomes, and the care providers have access to the patient-reported outcomes. In another randomization arm the participants submit patient-reported outcomes, but the care providers do not have access to the patient-reported outcomes. In the last randomization arm the participants are randomized to standard follow-up, do not complete PRO questionnaires and are thus controls.</td>
</tr>
</tbody>
</table>

Primary Purpose: Supportive Care
Official Title: Patient-Reported Outcomes Integrated in the Follow-up of Patients With Hematological Cancer
Study Start Date: September 2016
Estimated Primary Completion Date: March 2020
Estimated Study Completion Date: December 2021

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Care providers do have access to PROs</td>
<td>Patient-reported outcomes (PRO) questionnaires are completed at home within one week before a patient-physician consultation at the outpatient clinic. The questionnaires are submitted online or on paper depending on the participants choice.</td>
</tr>
<tr>
<td>Participants complete patient-reported outcome (PRO) questionnaires. Care providers do have access to the PROs and use them in clinical decision making.</td>
<td></td>
</tr>
<tr>
<td>Active Comparator: Care providers do not have access to PROs</td>
<td>Patient-reported outcomes (PRO) questionnaires are completed at home within one week before a patient-physician consultation at the outpatient clinic. The questionnaires are submitted online or on paper depending on the participants choice.</td>
</tr>
<tr>
<td>The participants complete patient-reported outcome (PRO) questionnaires. Care providers do not have access to the PROs.</td>
<td></td>
</tr>
<tr>
<td>No Intervention: Control group</td>
<td>Standard follow-up. The participants do not complete PRO questionnaires.</td>
</tr>
</tbody>
</table>

Outcome Measures

Primary Outcome Measures:
1. Supportive care interventions [ Time Frame: Three and a half year ]
   Number and kind of supportive care interventions are registered. Supportive care actions are defined as: a) a plan for rehabilitation, b) an intervention by a physiotherapist, occupational therapist, dietician, or social worker, c) consultation with a psychologist or talk with a priest, d) an intervention done by a general practitioner because of the hematological cancer after contact between the hematological department and the general practitioner, e) use of offers like group tasks etc offered by the Danish Cancer Society, or f) other supportive care interventions

Secondary Outcome Measures
1. Patients satisfaction with the interventions done by a department of hematology [Time Frame: Three and a half year]
   Patients satisfaction with the interventions done by a department of hematology are measured using a patient-reported experience questionnaire.

2. Impact of the use of PRO questionnaires on the consultation and patient satisfaction with and evaluation of the use of patient-reported outcomes in the outpatient clinic [Time Frame: Three and a half year]
   The impact of the use of PRO questionnaires on the consultation and patients satisfaction with and evaluation of the use of patient-reported outcomes in the outpatient clinic are investigated by observation of conversations between doctors and patients in the outpatient clinic, and furthermore investigated by individual interviews.

3. Contacts to the outpatient clinic at department of hematology [Time Frame: Three and a half year]
   All contacts between the patients and the department of hematology are registered. Are there more/less/equal number and kind of contacts to the outpatient clinic at department of hematology when using patient-reported outcomes compared to when not using patient-reported outcomes?

4. Paraclinical interventions [Time Frame: Three and a half year]
   All paraclinical actions ordered by the department of hematology are registered. Are more/less/equal number and kind of paraclinical interventions done when using patient-reported outcomes compared to when not using patient-reported outcomes?

Eligibility Criteria

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years to 100 Years (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Patients newly diagnosed with not curable, chronic hematological cancer
- ≥18 years old
- Oral and written informed consent

Exclusion Criteria:
- Participation in another intervention study
- Psychological or physiological conditions that may prevent compliance/adherence to the study
- Patients do not wish to be included in the study

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03056469
Contacts

Contact: Nana Brochmann, MD +4522833458 ext +4522833458 nmr@regionsjaelland.dk
Contact: Hans Hasselbalch, professor +4526223678 ext +4526223678 hans.hasselbalch@gmail.com

Locations

Denmark
Department of Hematology, Zealand University Hospital
Roskilde, Zealand, Denmark, 4000
Contact: Nana Brochmann, MD +4522833458 ext +4522833458 nmr@regionsjaelland.dk
Contact: Hans Hasselbalch, professor +4526223678 ext +4526223678 hans.hasselbalch@gmail.com

Sponsors and Collaborators
Zealand University Hospital

Investigators
Study Chair: Hans Hasselbalch, professor Department of Hematology, Zealand University Hospital, Vestmarkavej 9, 4000 Roskilde, Denmark

More Information
Go to

Responsible Party: Zealand University Hospital
ClinicalTrials.gov Identifier: NCT03056469 History of Changes
Other Study ID Numbers: REG-72-2016
First Posted: February 17, 2017 Key Record Dates
Last Update Posted: February 17, 2017
Last Verified: February 2017

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Keywords provided by Zealand University Hospital:
patient-reported outcomes
supportive care
clinical practice
hematological cancer

https://clinicaltrials.gov/ct2/show/study/NCT03056469?term=Patient...
DATABASEHANDLERAFTALE

vedrørende web-baseret system til at randomisere patienter og inddamle spørgeskemaer i projektet "PROM integreret i opfølgnings af patienter med hæmatologiske kærftformer" samt at høste spørgeskemasvar

For at sikre overholdelsen af de til enhver tid gældende regler om behandling af personoplysninger, herunder særligt persondataloven\(^1\) og dertil horende bekendtgørelser og vejledninger, har

Region Sjælland
Alléen 15, 4180 Sorø
CVR-nr. 29190658
Region Sjælland (dataansvarlig)

og

Dansk Telemedicin A/S
Robert Jacobsensvej 68, 2300 Kbh S
Nikolaj Humle
CVR-nr. 21728381
Dansk Telemedicin (databehandler)

indgået nærværende databehandleraftale som en del af aftalegrundlag af kontrakt nr. SUH 658-45 2016 (se bilag 1) om leverance af et web-baseret system til at randomisere patienter og inddamle patient-reported outcome measures (PROM) via spørgeskemaer samt opbevare PROM data i projektet "PROM integreret i opfølgnings af patienter med hæmatologiske kærftformer" (herefter "Hovedaftalen")

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\(^1\) Lov nr. 429 af 31.maj 2000 om behandling af personoplysninger med senere ændringer § 42, stk. 2 ifl. § 41.
hvor data fysisk behandles på følgende adresser, placering af servere:

Jay.net
Smedeland 32
DK-2600 Glostrup
http://www.jay.net

Intervion
Industriparken 20A
2750 Ballerup
http://www.intervion.com

1. Databehandlerens ansvar
Databehandleren handler alene efter instruks fra den Dataansvarlige og alene i det omfang, det er nødvendigt for, at Databehandleren kan opfylde sine forpligtelser i henhold til Databehandleraftalen. Databehandleraftalen er således en del af den Dataansvarliges instruks til Databehandleren.

Databehandleren forpligter sig til, til enhver tid, at overholde de danske såvel som Databehandlerens nationale lovgivningsmæssige krav vedrørende databehandling og datasikkerhed samt den Dataansvarliges informationssikkerhedspolitik med tilhørende retningslinjer i forbindelse med den databehandling, som udføres for den Dataansvarlige.

2. Databehandlerens opgave
Formålet med databehandlingen: Databehandleren udvikler et web-baseret system til at randomisere patienter og indsamle patient-reported outcome measures (PROM) via spørgeskemaer samt opbevarer PROM data fra projektet "PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer".

Databehandlerens opgave er at drifte det web-baserede system til at indhente patient-reported outcome measures (PROMs), og at hoste PROM data på servere.

Databehandlingen vil omfatte patienter med hæmatologisk cancer, som er tilknyttet hæmatologisk afdeling, Sjællands Universitetshospital.

Databehandlingen vil omfatte opbevaring af data i kategorien patient-reported outcome measures (PROM = patienternes vurdering af deres symptomer, helbred, funktionsniveau og helbredsrelaterede livskvalitet).

Uddybning af instruks til Databehandler - se venligst vedlagt kontrakt mellem hæmatologisk afdeling, Sjællands Universitetshospital og Dansk Telemedicin A/S (bilag 1).

3. Tekniske og organisatoriske sikkerhedsforanstaltninger
Databehandleren skal træffe de fornødne tekniske og organisatoriske sikkerhedsforanstaltninger mod, at oplysninger hændeligt eller ulovligt tilintetgøres, fortabes eller forringes, samt vedrørende "PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer"
mod, at de kommer til uvedkommendes kendskab, misbruges eller i øvrigt behandles i strid med loven.

Databehandleren forpligter sig til at overholde de til enhver tid gældende lovglivningsmæssige krav vedrørende behandling af personoplysninger. Databehandlingen skal derfor foregå i overensstemmelse med de til enhver tid gældende regler om behandling af personoplysninger, herunder særligt persondataloven og dertil hørende bekendtgørelser" og vejledninger.

Databehandler behandler oplysninger på den Dataansvarliges vegne og handler alene efter instruks fra den Dataansvarlige jf. bilag 1. Af instruksen fremgår minimumskrav til de fornødne tekniske og organisatoriske sikkerhedsforanstaltninger.

Databehandleren forpligter sig endvidere til at handle personoplysningerne i overensstemmelse med den informationssikkerhedspolitisik som den Dataansvarlige er underlagt jf. bilag 2.

Principperne og anbefalingerne i ISO 27001 med senere ændringer vil således på alle relevante områder skulle efterleves som ramme, i det omfang andet ikke fremgår af nærværende databehandlertaale.

4. Databehandlerens brug af Underdatabehandler

Databehandleren må ikke indgå aftaler med en Underdatabehandler om behandling af personoplysninger omfattet af denne databehandleraftale, medmindre den Dataansvarlige skriftligt har givet samtykke til aftaleindgåelsen. Den Dataansvarlige er berettiget til at stille vilkår for et sådant samtykke.

Databehandleren må endvidere ikke overføre eller tillade overførsel af personoplysninger til lande uden for EU og det Europeiske Økonomiske Samarbejdsområde uden den Dataansvarlige fores endvidere skriftlige samtykke.

Såfremt den Dataansvarlige har givet tilladelse til en overførsel af personoplysninger til lande uden for EU og det Europeiske Økonomiske Samarbejdsområde, påhviler det databehandleren at sikre, at data ikke overføres, før der foreligger et lovligt kontraktgrundlag for overførsel af personoplysninger til de pågældende lande herunder en direkte databehandleraftale mellem den Dataansvarlige og eventuelle Underdatabehandlerere beliggende i tredjelande.

Databehandleren skal i sin aftale med Underdatabehandleren sikre sig, at Underdatabehandleren som minimum kan opfylde de forpligtelser, som Databehandleren har påtaget sig ved denne databehandleraftale, for så vidt angår den behandling af personoplysninger, der varetages af Underdatabehandleren.


---

2 Se f.eks. Bekendtgørelse nr. 528 af 15. juni 2000 om sikkerhedsforanstaltninger til beskyttelse af personoplysninger, der behandles for den offentlige forvaltning med senere ændringer.

Vedrørende "PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer"

Såfremt Databehandleren anvender Underdatabehandler, skal oplysninger om denne fremgå af punkt 15.

5. Ad hoc arbejdspadser
I det omfang, databehandlingen sker fra ad hoc arbejdspadser (fjernarbejdspadser eller hjemmearbejdspadser) skal dette beskrives i punkt 15.

Såfremt Databehandleren foretager databehandling fra ad hoc arbejdspadser, skal Databehandleren sikre, at disse lever op til de sikkerhedsmæssige krav i denne Databehandleraftale med bilag samt Datatilsynets IT-sikkerhedsstekster herom.

Databehandleren skal blandt andet opfylde og dokumentere følgende:
- Beskrivelse af anvendt krypteret forbindelse mellem ad hoc arbejdspadsen og Databehandlerens/Dataansvarliges netværk
- Anvendelse af 2-faktor-autentifikation
- Databehandlerens interne instrukts til egne medarbejdere vedrørende ad hoc arbejdspadser

6. Tilsynsmyndigheder, audits og revisionserklæringer
Databehandleren skal på den Dataansvarliges anmodning give den Dataansvarlige tilstrækkelige oplysninger til at denne kan påse, at de nævnte tekniske og organisatoriske sikkerhedsforanstaltninger m.v. er truffet. Endvidere skal Databehandleren kunne dokumentere, at identificerede sårbarheder bliver imødegået ud fra en risikobaseret vurdering.

I tilfælde af, at den Dataansvarlige og/eller relevante offentlige myndigheder, særligt Datatilsynet, ønsker at foretage en fysisk inspektion (audit) af de foranstaltninger, som Databehandleren foretager i medfør af Databehandleraftalen, forpligter Databehandleren sig til - med et rimeligt varsel - at stille tid og ressourcer til rådighed herfor. Databehandleren forpligter sig på samme måde til at sikre, at sådanne audits også kan gennemføres hos dennes Underdatabehandler.


7. Underretningsplicht og assistance
Databehandleren forpligter sig til straks og skriftligt at orientere den Dataansvarlige om enhver afvigelser fra kravene i databehandleraftalen, f.eks.:

Vedrørende “PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer”
• ved enhver fravigelse fra givne instrukser
• ved enhver afvigelse fra det aftalte om tilgængelighed
• ved planlagte releases, opgræderinger, tests mv.
• ved enhver mistanke om brud på fortroligheden
• ved enhver mistanke om misbrug, fortabelse og forringelse af data
• ved enhver hændeligt eller uautoriseret videregivelse af eller adgang til personoplysninger
   gerne behandlet efter denne databehandleraftale

Databehandleren og dennes eventuelle Underdatabehandler e skal straks assistere den Dataansvarlige med håndtering af enhver henvendelse fra en registreret, herunder anmodning om indsigt, berigtigelse, blokering eller sletning, hvis de relevante personoplysninger behandles af Databehandleren.

Databehandleren og dennes eventuelle Underdatabehandler e skal assistere den Dataansvarlige med at overholde øvrige forpligtelser, der måtte påhvile den Dataansvarlige efter gældende ret, hvor assistance er forudsat, samt hvor assistance er nødvendig for, at den Dataansvarlige kan overholde sine forpligtelser.

8. Aftalens ikrafttræden og varighed
Databehandleraftalen træder i kraft samtidig med indgåelsen af Hovedaftalen som anført på side 1.

Databehandleraftalen ophører, når al behandling af personoplysninger i henhold til Hovedafta-
len er ophørt og Databehandleren har slettet data, jf. punkt 9.

9. Håndtering af data efter aftalens ophør
Databehandleren og dennes eventuelle Underdatabehandler e forpligter sig til at tilbagelever er og/eller slette personoplysninger, når databehandlingen i henhold til aftale med den Dataan-
svarlige ophører. Den Dataansvarlige skal oplyse Databehandleren om det tidspunkt, hvor da-
tabehandlingen skal ophøre. Det påhviler herefter Databehandleren at tilbagelevere og/eller slette personoplysningerne på det oplyste tidspunkt.

Sletning må ikke ske, før den Dataansvarlige skriftligt har godkendt den påtænkte frem-
gangsmåde for sletning.

Såfremt den Dataansvarlige ikke finder metoden tilstrækkelig sikker og i overensstemmelse
med gældende regler om behandling af personoplysninger, skal den Dataansvarlige meddele
Databehandleren hvilken metode, der kan anvendes i stedet. Der henvises til Datatilsynets it-
sikkerhedstekst ST3 fra 2014 med eventuelle opdateringer.

Når sletningen er foretaget, skal Databehandleren fremsende en skriftlig erklæring på, at data
er slettet som aftalt, inklusiv en beskrivelse af den anvendte metode.

Såfremt Databehandler eller dennes Underdatabehandler i forbindelse med konkurs eller lign-
ende ophører med at behandle personoplysninger for den Dataansvarlige, skal alle personop-
lysningerne straks leveres tilbage til den Dataansvarlige på en måde, der gør det muligt for
den Dataansvarlige at anvende disse fremadrettet. Herefter er Databehandler, dennes kon-

Vedrørende “PROM integreret i opfølgningen af patienter med hæmatologiske kræftformer”
kursbo eller lignende forpligtet til effektivt at slette oplysningerne fra egne systemer i overensstemmelse med ovenstående.

10. Tavshedsplict og fortrolighed
Databehandlerens ansatte, samarbejdspartnere, eksterne konsulenter og vikarer mfl. vil i forbindelse med behandlingen af fortrolige oplysninger være omfattet af de regler om tavshedsplict, som gælder for ansatte i den offentlige forvaltning. Der henvises til forvaltningslovens § 27 og straffelovens §§ 152-152 f.

Det påhviler Databehandler og dennes Underdatabehandler at informere egne ansatte, samarbejdspartnere, eksterne konsulenter og vikarer mfl. om udstrækningen af tavshedspliciten og om konsekvenserne ved en eventuel overtrædelse.

Databehandleren skal holde personoplysningerne fortrolige, og er således alene berettiget til at anvende personoplysningerne som led i opfyldelsen af sine forpligtelser i henhold til denne databehandleraftale og instruks.

Databehandleren påtager sig endvidere at begrænse adgangen til personoplysningerne til de medarbejdere, for hvem det er nødvendigt at behandle personoplysninger for at kunne opfylde Databehandlerens forpligtelser over for den Dataansvarlige.

Databehandlerens forpligtelser om tavshedsplicit og fortrolighed gælder også efter aftalens op- hør.

11. Overdragelse
Databehandleren må ikke overdrage sine rettigheder og forpligtelser i henhold til denne databehandleraftale uden den Dataansvarliges forudgående samtykke.

12. Misligholdelse
Det betragtes som en væsentlig misligholdelse af Hovedaftalen som anført på side 1, såfremt Databehandler ikke overholder forpligtelserne i Databehandleraftalen, de til enhver tid gældende lovgevningensmæssige krav og kravene i de dokumenter, der fremgår af Databehandleraftalens blag. Den Dataansvarlige er i så fald berettiget til uden varsel at opsige samtlige gældende aftaler om databehandling, som udføres for denne.

Uanset ophevelse/opsigelser af aftalen er Databehandleren dog forpligtet til at levere databehandling i henhold til Hovedaftalen og denne Databehandleraftale indtil databehandling er sikret hos anden databehandler.

Databehandleren skal levere relevant ophærsassistance til den Dataansvarlige. Dette inkluderer, men er ikke begrænset til, Hovedaftalen, som nævnt på side 1, og samtlige andre aftaler indgået med samme Databehandler og/eller Underdatabehandler vedrørende behandling af samme data.

Databehandleren forpligter sig til at friholde og forsvare den Dataansvarlige imod alle krav, retskrav og ethvert ansvar, tab, bøder, omkostninger og udgifter forbundet dermed som følge af Databehandlerens overtrædelse af databehandleraftalen eller gældende ret, begået af Data-

Vedrørende "PROM integreret i opfølgningen af patienter med hæmatologiske kræftformer"
behandleren, Databehandlerens ansatte, Underdatabehandlerere eller repræsentanter i forbindelse med levering af persondatabehandlingen, gennemførelse af aftalen eller som i øvrigt aftalt mellem parterne. Databehandleren kan ved misligholdelse af Databehandleraftalen ifalde bod, såfremt der i Hovedaftalen er fastsat vilkår herom. Henvisning til vilkår om bod kan fremgå nærmere af punkt 15.

13. Lovvalg og værnemling
Denne Databehandleraftale inklusiv et hvort spørgsmål om Databehandleraftalens gyldighed er undergivet dansk ret.

**Forhandling**
Såfremt der opstår en uoverensstemmelse mellem Parterne i forbindelse med Databehandleraftalen, skal Parterne med en positiv, samarbejdende og ansvarlig holdning søge at indlede forhandlinger med henblik på at løse tvisten.

Såfremt en løsning ikke kan opnås ved forhandling, må tvisten løses i det valgte konfliktløsningsorgan, jf. nedenfor.

**Eventuelt:**
**Mediation**
Enhver tvist, som måtte opstå i forbindelse med denne Databehandleraftale, skal søges løst ved mediation i overensstemmelse med Danske IT-advokater (DITA)'s mediationsprocedure (www.danske-it-advokater.dk). En Part er uberettiget til at søge tvisten løst ved voldgift, før Parterne har søgt tvisten løst ved mediation. Som minimum har en Part pligt til at deltage i det første møde, som mediator indkaldes til. En Part er dog berettiget til at indlede voldgiftssag, såfremt en udsættelse deraf kan fare til retsfordømelse f.eks. på grund af forældelse.

**Eventuelt:**
**Vejledende ekspertuddalelse**
En Part er indtil eventuel indledning af voldgiftssag berettiget til at få en juridisk/tekniisk uddannelse om den pågældende tvist udarbejdet efter de gældende regler herfor vedtaget af bestyrelsen for Danske IT-Advokater, Dansk ITs fagudvalg, IT-Branchens juridiske udvalg og Voldgiftsinstituttets bestyrelse.

**Enten:**
**Voldgift**
Hvis enhed ikke kan opnås via forhandling eller på anden vis, skal tvisten løses ved voldgift. Tvisten skal løses ved Voldgiftsinstituttet - The Danish Institute of Arbitration efter de af instituttet vedtagne regler herom, som er gældende ved indledningen af voldgiftssagen.

**Eller:**
**Domstolsbehandling**
Hvis enhed ikke kan opnås via forhandling eller på anden vis, skal tvisten løses ved de danske domstole.

Vedrørende “PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer”
14. Genforhandling
Datobehandleraftalen kan af hver af parterne kræves genforhandlet i anledning af ændret lov- og forordning herunder ikrafttrædelsen af EU-forordning om persondatabeskyttelse.

15. Ændringer til punkterne 3-12
Hvis det er tvingende nødvendigt at ændre punkterne 3-12, skal ændringerne beskrives her.

Det vil med aftalens indgåelse altid være op til den projektansvarlige på vegne af dataansvarlig at informere datobehandler om evt. ændringer – både i fht. projektet og i fht. Region Sjællands retningslinjer. Dette betyder, at det er op til den projektansvarlige at holde datobehandleren aujour mht. eventuelle ændringer og at ansvaret for dette dermed ikke påhviler datobehandleren.

Hvis der skulle opstå et krav om tilpasning i nuværende regler for dataopbevaring, så må datobehandler på et sådant tidspunkt vurdere, om en evt. udgift hertil vil kunne dækkes af omtalte salær, og hvis ikke indgå en aftale om yderligere økonomisk dækning med den projektansvarlige. Såfremt der ikke kan opnås enighed herom, er det muligt at opgive datobehandleraftalen, såfremt datobehandler ikke mener, at datobehandler er i stand til at leve op til de i aftalen listede krav.

16. Bilag

Bilag 1: Kontrakt mellem hæmatologisk afdeling, Sjællands Universitetshospital og Dansk Telemedicin A/S underskrevet
Bilag 2: Databehandlerinstruktør underskrevet
Bilag 3: Dataansvarliges informationssikkerhedsPolitik underskrevet

17. Øvrige henvisninger

- Lov nr. 429 af 31. maj 2000 om behandling af personoplysninger med senere ændringer
- Bekendtgørelse nr. 528 af 15. juni 2000 vedrørende sikkerhedsforanstaltninger til beskyttelse af personoplysninger, som behandles for den offentlige forvaltning
- Vejledning til sikkerhedsbekendtgørelsen
- Datalysynets it-sikkerhedsstekst ST3
- ISO 27001, ISMS - Ledelsessystem for informationssikkerhed

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3 Forslag til Europaparlamentets og Rådets forordning om beskyttelse af fysiske personer i forbindelse med behandling af personoplysninger og om fri udveksling af sådanne oplysninger (generel forordning om databeskyttelse).

Vedrørende "PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer"
18. Underskrifter

På vegne af den Dataansvarlige:
Navn: Dia Giarbini Lund
Underskrift: Lia Gabriella Giarbini Lund

Den Dataansvarliges projektansvarlig/systemejers kontaktperson:
Navn: Hans Hasselbalch
Stilling: Professor, Dr Med

Dato: 12-9-2016
Underskrift:

På vegne af Databehandleren:
Navn: Kristoffer Karlsen
Stilling: CEO
Adresse: Robert Jacobsensvej 68, 2300 Kbh S

Dato: 12-9-2016
Underskrift:

Vedrørende "PROM integreret i opfølgningen af patienter med hæmatologiske kæftformer"
Appendix 13: Approval from National Committee on Health Research Ethics

Vedr. det aktuelle forskningsprojekt:

Sekretariatet for Den Videnskabsetiske Komité for Region Sjælland bekræfter modtagelsen af det fremsendte forskningsprojekt "PROM integreret i opfølgningen af patienter med hæmatologiske kræftformer" ved mail af 29. maj 2016.

Spørgeskemaundersøgelser og sundhedsvidenskabelige registerforskningsprojekter skal kun anmeldelses til det videnskabsetiske komitésystem, såfremt projektet omfatter menneskeligt biologisk materiale, jf. komitélovens § 14, stk. 2.

Idet projektet er beskrevet som et rent spørgeskema- og registerforskningsprojekt uden brug af biologisk materiale, skal projektet ikke anmeldes til komitésystemet.

Den Videnskabsetiske Komité for Region Sjælland foretager sig således ikke videre vedr. denne anmeldelse.

Med venlig hilsen
Tanja Schwartzbach Frederiksen
Sekretariatet for Den Videnskabsetiske Komité Region Sjælland
PFI - Produktion, Forskning og Innovation
Alleen 15
4180 Sorø
Forsøgsdeltagerinformation

Du har nyligt fået at vide, at du har en sygdom i blodet og knoglemarven eller i lymfesystemet.

Der foregår en undersøgelse af, hvordan patienter med din sygdom, og patienter med andre sygdomme i blodet og knoglemarven eller i lymfesystemet, tilknyttet hæmatologisk ambulatorium, Sjællands Universitetshospital, har det. Desuden undersøges, hvordan kontrolbesøg i ambulatoriet og telefonkonsultation med lægen opleves, og hvordan udbyttet vurderes. For hvert planlagt kontrolbesøg i afdelingen eller telefonkonsultation med lægen stilles nogle spørgsmål.

Vi bruger spørgeskemaer i undersøgelsen. I det ene spørgeskema er der spørgsmål til, hvordan du oplever dine eventuelle symptomer, din funktionsevne og din livskvalitet. I det andet spørgeskema er der spørgsmål til din oplevelse af dit sidste kontrolbesøg i ambulatoriet eller telefonkonsultation og din oplevelse af udbyttet.

Det er muligt at besvare spørgeskemaerne enten sikkert på internettet eller på papir alt efter dit eget ønske. Inden undersøgelsen starter, vil du blive informeret om, hvordan spørgeskemaerne helt konkret udfyldes.

Du bedes i ugen op til hvert planlagt besøg i hæmatologisk ambulatorium eller planlagt telefonkonsultation med lægen besvare de to spørgeskemaer. Dog højst 1 gang om måneden. Vi giver dig besked, når det er tid til at besvare spørgeskemaerne. Besked om, at spørgeskemaerne bedes udfyldt kan ske via sms, e-mail eller begge dele afhængigt af dit ønske. Der vil blive sendt en påmindelse, hvis spørgeskemaerne ikke er blevet udfyldt i løbet af de første 2 dage. Besvarelsen af de to spørgeskemaer vil typisk tage 10-15 minutter. Efter 2 år vil du ikke længere blive bedt om at besvare spørgeskemaerne. Hvis det skulle ske, at spørgeskemaerne ikke udfyldes gentagne gange i løbet af forsøgsperioden, så tager vi det som et tegn på, at du ikke længere ønsker at deltage i undersøgelsen.

Bortset fra besvarelse af spørgeskemaerne vil din behandling og kontrol være fuldstændig som foreskrevet i de nationale vejledninger for behandling og kontrol.

Nogle deltagere i undersøgelsen vil ikke blive bedt om at besvare spørgeskemaer. Formålet med deltagelse uden besvarelse af spørgeskemaer er, at vi undersøger, om der er en forskel på, hvilke tiltag hæmatologisk afdeling gør for at optimere patienters velbefindende, hvis der afleveres spørgeskemaer sammenlignet med, hvis der ikke afleveres spørgeskemaer.

Som forsøgsdeltager bidrager du til, at vi som sundhedspersonale får indblik i, hvordan patienter tilknyttet hæmatologisk ambulatorium har det og oplever besøgene i ambulatoriet samt telefonkonsultationer, og om det at du regelmæssigt giver os informationer om, hvordan du har det og oplever besøgene i hæmatologisk ambulatorium forbedrer vores mulighed for at hjælpe dig relevant. Vi vil som sundhedspersonale følge dig og gøre tiltag for at optimere dit velbefindende, hvis der er behov for det.

En forsøgsdeltager har rettigheder. Vi vil bede dig læse informationen "Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt", inden du tager stilling til, om du ønsker at deltage i undersøgelsen. Ved den mundtlige information om undersøgelsen har du ret til at
have en bisidder med. Du har ret til betænkningstid inden, du beslutter dig for, om du ønsker at deltage i undersøgelsen. Du har ligeledes ret til aktindsigt i forsøgsprotokollen. Det vil sige, at du til enhver tid har ret til at se papirer, der vedrører din deltagelse i forsøget. Det vil på et hvilket som helst tidspunkt i undersøgelsesforløbet være muligt som forsøgsdeltager at udgå af undersøgelsen efter eget ønske uden at miste rettigheder som patient. En forsøgsdeltagers oplysninger og resultater af de undersøgelser, som vi foretager på hospitalet, er fortrolige. De vil blive anonymiseret, analyseret og udelukkende brugt i videnskabelig sammenhæng. Det vil ikke fremgå, hvem der har givet oplysningerne.

Udgifter forbundet med undersøgelsen vil blive finansieret ved fondstøtte. Forsøgspersoner deltager vederlagsfrit.

Hvis du har spørgsmål til undersøgelsen før -, under - og efter evt. deltagelse, så er du velkommen til at kontakte

Læge Sarah Friis Christensen
Sygeplejerske Stine Thestrup Hansen
Hæmatologisk ambulatorium,
Sjællands Universitetshospital
Træffes mandag – fredag kl. 11-13
på tlf nr 47324894
eller ved personlig henvendelse i hæmatologisk ambulatorium.
Forsøgspersonaers rettigheder i et sundhedsvidenskabeligt forskningsprojekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide at:

- Din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.

- Du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.

- Du har ret til at tage et familiediemed, en ven eller en bekendt med til informationssamtalen.

- Du har ret til betænkningstid, før du underskriver samtykkeerklæringen.

- Oplysninger om dine helbredssforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tværsmedspillet.

- Opbevaring af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i lov om behandling af personoplysninger og sundhedsloven.

- Der er mulighed for at få aktindsigt i forøgspunktokkeller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende din deltagelse i forsøget, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.

- Der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk.

Dette tillæg er udarbejdet af det videnskabelig komite system og kan vedlægges den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersonaers rettigheder kan rettes til den komité, som har godkendt projektet.

Revideret august 2014
Tilsagn om deltagelse i undersøgelsen

Erklæring fra forsøgsdeltager:
Undertegnede har læst patientinformationen og er mundtligt informeret om undersøgelsen af symptomer, funktionsniveau og livskvalitet samt oplevelser fra besøg i hæmatologisk ambulatorium og telefonkonsultationer hos patienter med sygdomme i blod og lymfesystem og har læst informationshæftet "Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt". Informationen fremstår klar og tydelig for mig. Jeg ved tilstrækkeligt om formål, metode, fordele og ulemper til, at jeg kan tage stilling til deltagelse i forsøget.
Jeg ønsker at deltage i forsøget.
Jeg ved, at det er frivilligt at deltage, og jeg er informeret om, at jeg til enhver tid kan vælge at afbryde min deltagelse i forsøget uden at miste rettigheder som patient.

…………………..
fulde navn skrevet med blokbogstaver

…………………..
dato underskrift

Erklæring fra den, der afgiver informationen:
Jeg har mundtligt og skriftligt informeret forsøgsdeltageren om undersøgelsen af symptomer, funktionsniveau og livskvalitet samt oplevelser fra besøg i hæmatologisk ambulatorium og telefonkonsultationer hos patienter med sygdomme i blod og lymfesystem. Jeg vurderer, at der er givet tilstrækkelig information til, at der kan tages stilling til deltagelse i forsøget.

…………………..
fulde navn

…………………..
dato underskrift

© Stine Thstrup Hansen, Hämatologisk afdeling, Sjællands Universitetshospital
Emnefelt: Vedr. spørgeskemaundersøgelse

Eks mailtekst til patient, der er randomiseret til at besvare spørgeskemaer, og hvor sundhedspersonale har adgang til svarene

Kære

Mange tak for dit samtykke til deltagelse i forskningsprojekt i hæmatologisk afdeling.

Vi kan fortælle dig, at du er blevet udvalgt til i forskningsprojektet at høre til den gruppe, som besvarer spørgeskemaer i ugen op til en planlagt samtale med en læge i hæmatologisk ambulatorium, samt i ugen op til en planlagt telefonkonsultation med en læge, og hvor lægen og det øvrige sundhedspersonale har adgang til svarene på spørgsmålene via din journal.

Din læge i hæmatologisk ambulatorium får at vide, at du besvarer spørgsmålene. Du er meget velkommen til at tale med lægen og det øvrige sundhedspersonale om de problemstillinger, som spørgsmålne måtte minde dig om, at du ønsker at tale med dem om.

Formålet med deltagelse på ovenstående betingelser er at undersøge, om det at besvare spørgsmålne bidrager til, at du og sundhedspersonalet i ambulatoriet taler sammen om flere problemstillinger, så der iværksættes flere understøttende tiltag for at højne dit fysiske - og psykiske helbred, end det er tilfældet, hvis vi ikke stiller dig spørgsmålne.

En uge inden du møder i hæmatologisk ambulatorium eller har en telefonkonsultation med lægen, vil du modtage en sms og e-mail med besked om, at det er tid til at besvare spørgeskemaer. Der trykkes på link/internetadresse i e-mailen for at komme til internetsiden med spørgeskemaer, og i det øjeblik, du trykker på internetadressen, vil der komme en kode i en sms, som anvendes til at logge ind til spørgeskemaerne. Du vil modtage dit første spørgeskema d. dato

Du bedes udfylde de 2 spørgeskemaer senest 2 dage inden planlagt ambulatoriebesøg/telefonkonsultation.

Vi er taknemmelige for, at du bidrager til forskningsprojektet.

Du er velkommen til at ringe, hvis du har spørgsmål til ovenstående eller til projektet i øvrigt.

Med venlig hilsen

Sygeplejerske Stine Thestrup Hansen og læge Sarah Friis Christensen
Hæmatologisk afdeling
Projekt tlf nr 47324894 mandag-fredag kl. 11-13
sttha@regionsjaelland.dk / safc@regionsjaelland.dk

© Stine Thestrup Hansen, Hæmatologisk afdeling, Sjællands Universitetshospital
Eks mailtekst til patient, der er randomiseret til at besvare spørgeskemaer, men hvor sundhedspersonale ikke har adgang til svarene

Kære

Mange tak for dit samtykke til at deltagte i forskningsprojekt i hæmatologisk afdeling.

Vi kan fortælle dig, at du er blevet udvalgt til i forskningsprojektet at høre til den gruppe, som besvarer spørgeskemaer i ugen op til en samtale med/vurdering ved en læge i hæmatologisk ambulatorium enten ved fremmøde i ambulatoriet eller telefonkonsultation, men hvor sundhedspersonale inkl. lægen ikke har adgang til svarene på spørgsmålene. Din kontaktlæge i hæmatologisk ambulatorium får at vide, at du besvarer spørgsmålene. Du er meget velkommen til at tale med sundhedspersonalet om de problemstillinger, som spørgsmålene måtte minde dig om, at du ønsker at tale med dem om. Så det er altså kun adgangen til dine skriftlige svar på dine spørgsmål, sundhedspersonalet ikke har.

Formålet med deltagelse på ovenstående betingelser er at undersøge, om det at læse og besvare spørgsmålene bidrager til, at I som patienter præsenterer lægen og andet sundhedspersonale i ambulatoriet for flere helbredsproblemer hos jer, end det er tilfældet, hvis vi ikke stiler jer spørgsmålene.

Du modtager en sms og e-mail, når det er tid til at besvare spørgeskemaer i undersøgelsen, og beskeden kommer én uge før ambulant kontrol eller telefonkonsultation i hæmatologisk ambulatorium. I e-mailen er et link/en internetadresse, som du bedes trykke på for at komme frem til spørgeskemaerne. I en sms kommer kode til at logge ind med. Første gang du modtager en mail vil være d.datum

Vi vil gerne bede dig om at udfylde de 2 spørgeskemaer senest 2 dage inden planlagt ambulatoriebesøg/telefonkonsultation.

Vi er taknemmelige for, at du bidrager til forskningsprojektet. Du er meget velkommen til at ringe, hvis du har spørgsmål til ovenstående eller til projektet i øvrigt.

Med venlig hilsen

Sygeplejerske Stine Thstrup Hansen og læge Sarah Friis Christensen
Hæmatologisk afdeling
Projekt tlf nr 47324894 mandag-fredag kl. 11-13
sttha@regionsjaelland.dk / safc@regionsjaelland.dk
Eks på mailtekst til patient, der er randomiseret til kontrolgruppe

Kære

Mange tak for dit samtykke til at deltage i forskningsprojekt i hæmatologisk afdeling.

Vi kan fortælle dig, at du ved lodtrækning er blevet udvalgt til i forskningsprojektet at høre til den gruppe, som ikke besvarer spørgeskemaer til helbredet eller oplevelser af det, hæmatologisk afdeling sætter igang for dig. Således beder vi dig ikke foretage dig noget. Formålet med deltagelse på ovenstående betingelse er, at vi bruger oplysninger fra din journal om dit sygdomsforløb til sammenligning med sygdomsforløb hos patienter, som besvarer spørgeskemaer i undersøgelsen.

Vi er meget taknemmelige for, at du bidrager til forskningsprojektet ved, at vi må anvende dine journaloplysninger.

Du er velkommen til at ringe, hvis du har spørgsmål til ovenstående eller til projektet i øvrigt.

Med venlig hilsen

Sygeplejerske Stine Thestrup Hansen og læge Sarah Friis Christensen

Hæmatologisk afdeling
Projekt tlf nr 47324894 mandag-fredag kl. 11-13
sttha@regionsjaelland.dk/safc@regionsjaelland.dk
Kære Sygeplejersker i Hæmatologisk Ambulatorium,

Som I ved har jeg gennem det sidste års tid gennemført feltstudier i ambulatoriet som led i mit Ph.d. projekt om PRO. Jeg har nu afsluttet feltstudiene og takker for jeres bidrag til projektet. Et af projekets forskningsspørgsmål er:

_Hvilke faktorer har betydning for om sygeplejersker integrerer PRO i opfølgningsforløbet?

For at besvare spørgsmålet ønsker jeg, at gennemføre et fokusgruppeinterview med jer. Formålet med gruppeinterviewet er, at få jeres perspektiver på anvendelse at PRO, at uddybe jeres oplevelser med PRO og hvordan tilgangen passer ind i jeres kliniske hverdag i hæmatologisk ambulatorium. Det er vigtigt for hele projektet at få jeres perspektiv på anvendelsen af PRO og de faktorer i jeres kliniske praksis der har indflydelse på jeres anvendelse af PRO.

Fokusgruppeinterviewet vil foregå som en arrangeret samtale blandt en gruppe (gerne 4-6 stk.) af jeres sygeplejersker og forventes at vare ca. 1-2 timer. Mette Kjerholt og undertegnede afholder interviewet og vil lægge op til spørgsmål og emner som i bedes drøfte undervejs. I første omgang skal jeg anmode om tilkendegivelser fra interesserede som vil deltag i et fokusgruppeinterview, derefter følger planlægningen i forhold til tid og sted. Interviewet er fortroligt, så alt hvad der fortælles under interviewet vil efterfølgende blive anonymiseret. I får naturligvis timebetaling for jeres medvirken.

Tilmelding kan ske ved svar på denne mail eller pr. telefon 60604601. Svar udbedes senest d. senest d. 20 juli 2018.

Jeg ser frem til at høre fra jer.

De bedste hilsener

_Stine Thstrup Hansen_
Ph.d. Studerende, sygeplejerske, Cand.cur.
Sjællands Universitetshospital, Roskilde
Hæmatologisk afdeling
Personlig e-post: sttha@regionsjaelland.dk
www.regionsjaelland.dk
Kære (navn på læge),

Som du ved har jeg gennem det sidste års tid gennemført feltstudier i ambulatoriet som led i mit PhD projekt om PRO. Jeg har nu afsluttet feltstuderne og takker for dit bidrag til projektet i form af min tilstedeværelse under en af dine konsultationer med en PRO patient.

Et af projektets forskningsspørgsmål er:

**Hvilke faktorer har betydning for om læger integrerer PRO i opfølgningsforløbet?**

For at besvare spørgsmålet ønsker jeg at gennemføre et dybdeinterview med 3 til 4 læger som jeg har fulgt i konsultationer. Formålet er, at få dine perspektiver på anvendelse af PRO, at uddybe dine oplevelser med PRO samt hvordan tilgangen passer ind i den kliniske hverdag i hæmatologisk ambulatorium. Det er vigtigt for hele projektet at få det lægefaglige perspektiv på anvendelsen af PRO og de faktorer i jeres kliniske praksis der har indflydelse på anvendelse af PRO.

I første omgang anmoder jeg om tilkendegivelser fra interesserede som vil deltaga til interview af ca. 20-30 minutters varighed. Vi planlægger interview sammen så tid og sted passer dig. Interviewet er fortroligt, så alt hvad der fortælles under interviewet vil efterfølgende blive anonymiseret. Tilmelding kan ske ved svar på denne mail eller telefonisk på 60604601 senest d. 20 juli 2018.

Jeg ser frem til at høre fra interesserede deltagere.

De bedste hilsener

Stine Thstrup Hansen

Ph.d. Studerende, sygeplejerske, Cand.cur.
Sjællands Universitetshospital, Roskilde
Hæmatologisk afdeling

Personlig e-post: sttha@regionsjaelland.dk
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© Stine Thstrup Hansen, Hæmatologisk afdeling, Sjællands Universitetshospital
Mailtekst til læge om, at en patient er randomiseret til at besvare spørgeskemaer, hvor svarene er tilgængelige for sundhedspersonalet

Kære
Din patient, (CPR) er blevet inkluderet i projektet "Patient-reported outcomes integreret i opfølgningen af patienter med hæmatologisk cancer". Hun er randomiseret til armen, hvor hun besvarer to spørgeskemaer med spørgsmål til, hvordan hun har det, og hvordan hun oplever det, der gøres for hende i afdelingen, og hvor svarene er tilgængelige for dig i et resumé i journalen. Hensigten er at undersøge, om det at patienter besvarer spørgsmålene samt at sundhedspersonale ser svarene gør, at der identificeres flere problemstillinge, som resulterer i iværksættelse af flere supportive care tiltag og for patienter og sundhedspersonale opleves som relevant inddragelse af patienterne.

Vi har meddelt patienten, hvilken randomiseringsarm hun er i, at du ser svarene på spørgsmålene, hun har svaret på, og at hun er velkommen til at drøfte de problemstillinge med dig, hun eventuelt kommer til at tænke på, når hun besvarer spørgsmålene.

Vi håber, at patienten og du vil opleve, at projektet bidrager positivt til sygdomsforløbet. Du er meget velkommen til at stille os spørgsmål til projektet.

Med venlig hilsen
Stine Thstrup Hansen og Sarah Friis Christensen

Mailtekst til læge om, at patient er randomiseret til at besvare spørgeskemaer, men svarene er ikke tilgængelige for sundhedspersonalet

Kære
Din patient, ……… (CPR) er blevet inkluderet i projektet "Patient-reported outcomes integreret i opfølgningen af patienter med hæmatologisk cancer". Hun er randomiseret til armen, hvor hun besvarer to spørgeskemaer med spørgsmål til, hvordan hun har det, og hvordan hun oplever det, der gøres for hende i afdelingen, men hvor svarene ikke er tilgængelige for dig. Hensigten er at undersøge, om det at patienter læser og besvarer spørgsmålene gør, at de informerer sundhedspersonalet om flere problemstillinge, som så resulterer i iværksættelse af flere supportive care tiltag, samt om det opleves som relevant inddragelse af patienterne.

Vi har meddelt patienten, hvilken randomiseringsarm hun er i, at du ikke ser svarene på spørgsmålene, hun har svaret på, men at hun er velkommen til at drøfte de problemstillinge med dig, hun eventuelt kommer til at tænke på, når hun besvarer spørgsmålene.

Vi håber, at patienten og du vil opleve, at projektet bidrager positivt til sygdomsforløbet.

Med venlig hilsen
Stine Thstrup Hansen og Sarah Friis Christensen
Mailtekt til læge om, at en patient er randomiseret til kontrolgruppen

Kære

Din patient, … (CPR) er blevet inkluderet i projektet "Patient-Reported Outcomes integreret i opfølgningen af patienter med hæmatologisk cancer". Hun er randomiseret til kontrolgruppen.

Vi informerer dig om det i tilfælde af, at hun på et tidspunkt under samtale med dig vil komme ind på deltagelsen i projektet. Patienten er informeret om, at hun er i kontrolgruppen.

Med venlig hilsen
Stine Thestrup Hansen og Sarah Friis Christensen

Vedr. inklusion af patient i PROM-protokollen (Mand)

Mailtekt til læge om, at en patient er randomiseret til at besvare spørgeskemaer, hvor svarene er tilgængelige for sundhedspersonalet

Kære

Din patient, (CPR) er blevet inkluderet i projektet "Patient-reported outcomes integreret i opfølgningen af patienter med hæmatologisk cancer". Han er randomiseret til armen, hvor han besvarer to spørgeskemaer med spørgsmål til, hvordan han har det, og hvordan han oplever det, der gøres for ham i afdelingen, og hvor svarene er tilgængelige for dig i et resumé i journalen. Hensigten er at undersøge, om det at patienter besvarer spørgsmålene samt at sundhedspersonale ser svarene gør, at der identificeres flere problemstillinger, som resulterer i iværksættelse af flere supportive care tiltag og for patienter og sundhedspersonale opleves som relevant inddragelse af patienterne.

Vi har meddelt patienten, hvilken randomiseringsarm han er i, at du ser svarene på spørgsmålene, han har svaret på, og at han er velkommen til at drøfte de problemstillinger med dig, han eventuelt kommer til at tænke på, når han besvarer spørgsmålene.

Vi håber, at patienten og du vil opleve, at projektet bidrager positivt til sygdomsforløbet. Du er meget velkommen til at stille os spørgsmål til projektet.

Med venlig hilsen
Stine Thestrup Hansen og Sarah Friis Christensen

© Stine Thestrup Hansen, Hæmatologisk afdeling, Sjællands Universitetshospital
Mailtekst til læge om, at patient er randomiseret til at besvare spørgeskemaer, men svarene er ikke tilgængelige for sundhedspersonalet

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Vi har meddelt patienten, hvilken randomiseringsarm han er i, at du ikke ser svarene på spørgsmålene, han har svaret på, men at han er velkommen til at drøfte de problemstillinger med dig, han eventuelt kommer til at tænke på, når han besvarer spørgsmålene.

Vi håber, at patienten og du vil opleve, at projektet bidrager positivt til sygdomsforløbet.

Med venlig hilsen
Stine Thstrup Hansen og Sarah Friis Christensen

Mailtekst til læge om, at en patient er randomiseret til kontrolgruppen

Kære

Din patient, (CPR) er blevet inkluderet i projektet "Patient-Reported Outcomes integreret i opfølgningen af patienter med hæmatologisk cancer". Han er randomiseret til **kontrolgruppen**.

Vi informerer dig om det i tilfælde af, at han på et tidspunkt under samtale med dig vil komme ind på deltagelsen i projektet. Patienten er informeret om, at han er i kontrolgruppen.

Med venlig hilsen
Stine Thstrup Hansen og Sarah Friis Christensen
Afsluttende mail til patienter i spørgeskemagrupperne

Kære

Du har deltaget i forskningsprojektet "Helhedsorienteret Opfølgning Hos Patienter med Kronisk Hæmatologisk Kræft" i den 2-årige planlagte studieperiode, og du vil således ikke modtage flere spørgeskemaer fremadrettet.

Såfremt du har feedback til studiet, hvad enten det handler om indholdet af spørgeskemaerne, sundhedspersonalets anvendelse af spørgeskemaerne eller IT-systemet du brugte til besvarelse af spørgeskemaerne modtager vi meget gerne din feedback ved at du besvarer denne mail.

Du er velkommen til at kontakte os, hvis du har spørgsmål til projektet.

Tusind tak for din deltagelse i studiet.

Med venlig hilsen

Læge Sarah Friis Christensen
Sygeplejerske Stine Thesstrup Hansen
Hæmatologisk afdeling, Sjællands Universitetshospital
Tlf. nr. 47324894 mandag-fredag kl. 11-13

Afsluttende brev til patienter randomiseret til kontrolgruppen

Kære

Tak for din deltagelse i forskningsprojektet "Helhedsorienteret Opfølgning Hos Patienter med Kronisk Hæmatologisk Kræft" på hæmatologisk afdeling, Roskilde.

Du har deltaget som patient i kontrolgruppen og har således fulgt det vanlige kontrolprogram i hæmatologisk ambulatorium i den 2-årige studieperiode.

Som afslutning på din deltagelse i forskningsprojektet vil vi gerne bede dig om at udfylde de 2 vedlagte spørgeskemaer. Det ene spørgeskema handler om hvordan du har det, mens det andet spørgeskema handler om hvordan du oplevede dit sidste besøg i hæmatologisk ambulatorium.

Vi vil være meget taknemmelige om du ville sende de udfylde spørgeskemaer til hæmatologisk ambulatorium i den vedlagte frankerede svarkuvert. Adressen er skrevet på svarkuverten.

Du er altid velkommen til at kontakte os, hvis du har spørgsmål til forskningsprojektet.
Endnu en gang tak for din deltagelse i studiet.

Med venlig hilsen

Læge Sarah Friis Christensen
Sygeplejerske Stine Thestrup Hansen
Hæmatologisk afdeling, Sjællands Universitetshospital
Tlf. nr. 47324894 mandag-fredag kl. 11-13

**Afsluttende brev til patienter randomiseret til kontrolgruppen**

Kære

Du har nu deltaget i forskningsprojektet "Helhedsorienteret Opfølgning Hos Patienter med Kronisk Hæmatologisk Kræft" i den 2-årige studieperiode, og du skal således ikke indsende flere spørgeskemaer.

Såfremt du har feedback til studiet, hvad enten det handler om indholdet af spørgeskemaerne, sundhedspersonalets anvendelse af spørgeskemaerne eller udfordringer med at aflevere/indsende spørgeskemaer modtager vi meget gerne din feedback på det vedlagte feedback-ark. Modtager-adressen er skrevet på den frankerede svarkuvert.

Du er velkommen til at kontakte os, hvis du har spørgsmål til projektet.

Tusind tak for din deltagelse i studiet.

Med venlig hilsen

Læge Sarah Friis Christensen
Sygeplejerske Stine Thestrup Hansen
Hæmatologisk afdeling, Sjællands Universitetshospital
Tlf. nr. 47324894 mandag-fredag kl. 11-13
Feedback vedrørende forskningsprojektet:

Helhedsorienteret Opfølgning Hos Patienter med Kronisk Hæmatologisk Kræft

Navn (valgfri):

Feedback:

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Appendix 21: Co-authorship declarations

Declaration of co-authorship (PhD thesis)

Under Section 12 (4) of the PhD order*, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfil the requirements of the Vancouver rules**

1. General information

<table>
<thead>
<tr>
<th>Candidate’s name</th>
<th>Stine Thstrup Hansen</th>
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<td>Patient-reported Outcome Measures (PROMs) Integrated in the Follow-up of Patients Diagnosed with Haematological Cancers: A Qualitative Study of Patients' and Healthcare professionals' experiences</td>
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</table>

2. This co-author’s declaration applies to the following article/manuscript No. I

“I Am Sure That They Use My PROM Data for Something Important.” A Qualitative Study about Patients' Experiences From a Hematologic Outpatient Clinic

The extent of the candidate’s contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. Declaration on the individual elements

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*The Danish Ministerial Order on the PhD Programme at the Universities (PhD order), no. 18 of 14 January 2008*

**Vancouver rules:** "All persons named as authors must satisfy the authorship requirement. The order of names must be a joint decision taken by all the authors. The individual author must have participated in the work to a sufficient extent to be able to accept public liability for the content of the scientific work. Authorship can only be based on substantial contribution with regard to: 1) conception and design or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published. Involvement based only on obtaining funding for the work or collecting data does not qualify for authorship. Neither does general supervision of the research group in itself qualify as authorship. If the authorship is collective, key persons who are responsible for the article must be identified. The editors of the scientific periodical may ask authors to account for their part in the authorship."
Declaration of co-authorship (PhD thesis)

Under Section 12 (4) of the PhD order*, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfil the requirements of the Vancouver rules**

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<th>2. This co-author’s declaration applies to the following article/manuscript No. II</th>
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<td>Nurses’ Experiences When Introducing Patient Reported Outcome Measures (PROMs) in an Outpatient Clinic: An Interpretive Description Study</td>
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The extent of the candidate’s contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
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4. Co-authors’ signatures

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<tr>
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<td>Stine Thestrup Hansen</td>
<td>PhD student, RN, MScN</td>
<td></td>
</tr>
<tr>
<td>16/12/2019</td>
<td>Mette Kjerholt</td>
<td>PhD, RN, MScN, MLP</td>
<td></td>
</tr>
<tr>
<td>16/12/2019</td>
<td>Sarah Friis Christensen</td>
<td>PhD student, MD</td>
<td></td>
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<tr>
<td>31/1/2019</td>
<td>John Brodersen</td>
<td>Professor, MD</td>
<td></td>
</tr>
<tr>
<td>3/1/2020</td>
<td>Bibi Holge-Hazelton</td>
<td>Professor, RN, MScN</td>
<td></td>
</tr>
</tbody>
</table>

5. Candidate’s signature

*The Danish Ministerial Order on the PhD Programme at the Universities (PhD order), no. 18 of 14 January 2008

**Vancouver rules:** "All persons named as authors must satisfy the authorship requirement. The order of names must be a joint decision taken by all the authors. The individual author must have participated in the work to a sufficient extent to be able to accept public liability for the content of the scientific work. Authorship can only be based on substantial contribution with regard to: 1) conception and design or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published. Involvement based only on obtaining funding for the work or collecting data does not qualify for authorship. Neither does general supervision of the research group in itself qualify as authorship. If the authorship is collective, key persons who are responsible for the article must be identified. The editors of the scientific periodical may ask authors to account for their part in the authorship."
Declaration of co-authorship (PhD thesis)

Under Section 12 (4) of the PhD order*, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfil the requirements of the Vancouver rules**

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2. This co-author’s declaration applies to the following article/manuscript No. III

Haematologists’ Experiences Implementing Patient Reported Outcome Measures (PROMs) in an Outpatient Clinic: A qualitative study for applied practice

The extent of the candidate’s contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

3. Declaration on the individual elements

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<td>Bibi Helge-Hazelton</td>
<td>Professor, RN, MScN</td>
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<td>3/1/2020</td>
<td>John Brodersen</td>
<td>Professor, MD</td>
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## 5. Candidate’s signature

*The Danish Ministerial Order on the PhD Programme at the Universities (PhD order), no. 18 of 14 January 2008

**Vancouver rules:** "All persons named as authors must satisfy the authorship requirement. The order of names must be a joint decision taken by all the authors. The individual author must have participated in the work to a sufficient extent to be able to accept public liability for the content of the scientific work. Authorship can only be based on substantial contribution with regard to: 1) conception and design or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content, and 3) final approval of the version to be published. Involvement based only on obtaining funding for the work or collecting data does not qualify for authorship. Neither does general supervision of the research group in itself qualify as authorship. If the authorship is collective, key persons who are responsible for the article must be identified. The editors of the scientific periodical may ask authors to account for their part in the authorship.”
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Under Section 12(4) of the PhD order*, a declaration on the extent and nature of the relative contributions, signed by the collaborators and the author, must accompany the PhD thesis if the dissertation or parts of it are the result of collaboration.

Co-authors should fulfill the requirements of the Vancouver rules**

<table>
<thead>
<tr>
<th>1. General information</th>
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<tr>
<td>Candidate’s name</td>
<td>Stine Thstrup Hansen</td>
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<tr>
<td>Title of PhD thesis</td>
<td>Patient-Reported Outcome Measures (PROMs) Integrated in the Follow-up of Patients Diagnosed with Haematological Cancers: A Qualitative Study of Patients and Healthcare Professionals’ Experiences</td>
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| 2. This co-author’s declaration applies to the following article/manuscript No. IV |
|-----------------|--------|
| Patients, Nurses and Haematologists Experiences when Patient Reported Outcome Measures are Implemented in a Haematological Outpatient Clinic: A Qualitative Study |

The extent of the candidate’s contribution to the article is assessed on the following scale

A. has contributed to the work (0-33%)
B. has made a substantial contribution (34-66%)
C. did the majority of the work (67-100%)

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<th>3. Declaration on the individual elements</th>
<th>Extent (A, B, C)</th>
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<td>1. Formulation in the concept phase of the basic scientific problem on the basis of theoretical questions which require clarification, including a summary of the general questions which it is assumed will be answered via analyses or concrete experiments/investigations.</td>
<td>B</td>
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<td>2. Planning of experiments/analyses and formulation of investigative methodology in such a way that the questions asked under (1) can be expected to be answered, including choice of method and independent methodological development.</td>
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<td>3. Involvement in the analysis or the concrete experiments/investigation.</td>
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<tr>
<td>4. Presentation, interpretation and discussion of the results obtained in the form of an article or manuscript.</td>
<td>C</td>
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### 4. Co-authors' signatures

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<tr>
<th>Date</th>
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