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Ellen Anna Andreassen Jaatun

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Digital assessment of pain distribution in patients with advanced cancer

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Thesis for the Degree of
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Il semble que la perfection soit atteinte non quand il n`y a plus rien à ajouter, mais quand il n`y a plus rien à retrencher

(Terre des Homme, 1939, Antoine de Saint-Exupery)

Summary

Pain is among the most feared symptoms of cancer, and in order to provide adequate pain management, pain assessment and communication are of paramount importance. Changes in pain location and intensity may be important signs indicating disease progression or treatment response. Thus, pain assessment and keeping track of changes yield important information for decision making in clinical practice.

Pain body maps (PBMs) have been in use for decades in different patient populations, but despite recent technological advances, paper is still the most common platform for these tools. The few projects presenting computerized pain body maps (CPBMs) in the scientific literature provide limited evidence on reliability and validity of CPBMs for patients with advanced cancer. Visualization of pain is perceived to simplify recognition of pain syndromes such as neuropathic pain.

Reduced cognitive and physical performance places restrictions on the tools that patients with advanced cancer are expected to use. This thesis presents the development and testing of a new CPBM specifically designed to be usable by the sickest and frailest patients with advanced cancer. The CPBM has been developed in an iterative manner, following the identification of several usability issues in the first version of the CPBM. The project highlights the importance of continuous involvement of both patients and healthcare providers in the development of new ICT-based healthcare solutions.

The concrete results of this project are a tablet-based CPBM for use by patients, and a companion web application for healthcare providers; the latter collects filled-in body maps from the former, and allows healthcare providers to retrieve and study longitudinal pain data from patients to assist in evaluating disease progression and treatment response. In total, the development of the CPBM system has been guided by the involvement of 639 patients and 55 healthcare providers.

Although the current version of the CPBM does not offer many fundamentally new features compared to a paper PBM, the computerized system represents a necessary first step that opens up a wealth of possibilities for pain management in palliative care in the future.

Sammendrag

Brukersentrert utvikling av et digitalt smertekart - Elektronisk kartlegging av smerteutbredelse hos pasienter med utbredt kreftsykdom

I denne avhandlingen har vi utviklet et digitalt smertekart spesielt beregnet på pasienter med utbredt kreftsykdom. Målet med studien var å utvikle en programvare på en plattform som selv de sykeste pasientene klarte å bruke. Det håndfaste resultatet av prosjektet er et nettbrettbasert smertekart for pasienter kombinert med en database for helsepersonalet. Databasen katalogiserer og visualiserer utfylte smertekart slik at endringer over tid kan fremstilles. Dette gir leger, sykepleiere og andre helsearbeidere et redskap for å følge behandlingsrespons og/eller sykdomsprogresjon over tid.

Smerte er et fryktet symptom for kreftpasienter og det å bruke en systematisk tilnærming til problemet kan bidra til god kvalitet i håndteringen. Grundig kartlegging og en felles forståelse av smerteproblemet mellom pasienten og legen er forutsetninger for å få til god smertebehandling. Endringer i smertelokalisasjon og/eller -intensitet kan være tegn på utvikling av sykdommen eller respons på behandling. Data fra tidligere kartlegginger for sammenligning vil derfor kunne ha stor verdi. Det er også slik at ulike årsaksforhold og patofysiologiske mekanismer kan gi ulike typer smerte og smertesyndromer, og visualisering av smertens mønster og utbredelse kan være en metode for å kjenne igjen visse typer smerte og smertemekanismer.

I mange tiår har smertekart vært i utstrakt bruk for kartlegging av smerter. Til tross for teknologisk utvikling og bruk av digitale verktøy innen medisinsk diagnostikk brukes informasjons- og kommunikasjonsteknologi (IKT) lite i samhandlingen mellom lege og pasient. Det er tidligere bare publisert noen få rapporter om digitale smertekart. Ingen av disse verktøyene har dokumentert pålitelighet og gyldighet for bruk hos pasienter med utbredt kreftsykdom. Hos denne pasientgruppen kan redusert kognitiv og fysisk funksjon begrense pasientenes evne til å bruke kartleggingsverktøy.

Utviklingsarbeidet i prosjektet har vært trinnvis. Smertekartet har i flere omganger vært testet av pasienter fra den aktuelle målgruppen. Underveis har vi identifisert flere utfordringer hos pasientene som påvirker deres evne til å bruke verktøyet, spesielt i første utgave av programvaren. Valget av plattform og utviklingen av programvare har vært styrt etter kartlegging og uttesting hos i alt 639 pasienter og 55 helsearbeidere. Vårt prosjekt fremhever viktigheten av å ha kontinuerlig involvering av både pasienter og klinikere under utvikling av IKT-verktøy i helsesektoren.

Den nåværende versjonen av det digitale smertekartet presenterer ikke nye, grunnleggende funksjonaliteter sammenlignet med smertekart på papir. Overgangen fra papirversjonen til et digitalt verktøy gir likevel nye muligheter for å effektivisere samhandlingen som kreves for å følge opp god smertebehandling, samt utnytte potensialet som ligger i et visuelt kartleggingsverktøy.

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torsdag 8. september 2016 kl 12:15

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This thesis has been assessed and found worthy of public defence for the degree Philosophiae Doctor in Palliative Care. The public defence takes place in the Medical Technical Research Centre Thursday 08.09 at 12:15

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I have spent much time during the last few years focusing on something I find much pleasure in. It has been fun, but sometimes frustrating and challenging, as well as competitive and rewarding.

Firstly, I would like to express my sincere gratitude to all four professors who have been my supervisors. Stein Kaasa, thank you for your trust in me by giving me this project.

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During this project, all four of my supervisors have experienced career advancements, which I most likely have not contributed to. Nevertheless, their success has shown the way.

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During my time in Scotland I was also included in the Social Informatics Cluster at the University of Edinburgh, where digital health was one of the main interests. One thing led to another, and I am mostly grateful for the introduction to the Digital Health and Care Institute by the Dean of Glasgow School of Art, Professor Irene McAra McWillams. The DHI has opened up new doors, and invited me to learn about design methods and qualitative research, and I have been introduced to so many talented and interesting people. Especially thanks to Elizabeth Brooks, Tara French and Professor Grant Cumming. I hope we can have many projects together in the future.

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From early childhood I have been made aware of my strengths and learned that the possible limitations to my capacity have to be tested and challenged. This has probably also been my parents' motto. My parents have been, and still are, the number one role models who practise what they preach. This lesson has been and still is valuable. Thank you.

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To my family and friends: I am not sorry for the way I have prioritised, but I hope that someday I will be able to repay and provide the same support you have given me through this project, thank you all. Should I ever forget, please remind me.

Contents

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List of abbreviations

BPI	Brief Pain Inventory
CPBM	Computerized Pain Body map
CIPN	Chemotherapy Induced Peripheral Neuropathy
EAPC	European Association for Palliative Care
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EORTC	European Organisation for Research and Treatment of Cancer
EORTC QLQ-C30	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30
EPCRC	European Palliative Care Research Collaborative
EPCRC-CSA	European Palliative Care Research Collaborative-Computerized Symptom Assessment
ESAS	Edmonton Symptom Assessment System
GP	General Practitioner
ICT	Information and Communication Technology
IASP	International Association for the Study of Pain
KPS	Karnofsky Performance Scale
LANSS	Leeds Assessment of Neuropathic Symptoms and Signs
NLM	National Library of Medicine
NRS	Numerical Rating Scale
PBM	Pain Body Map
PRC	European Palliative Care Research Centre
SUS	System Usability Scale
TAM	Technology Acceptance Model

TNM	Tumor Node and Metastasis
VAS	Visual Analog Scale
VRS	Visual Rating Scale

Definitions and terms

Adjuvant therapy: in cancer often referred to as additional treatment for possible microscopic disease to lower the risk of recurrence.

Advanced cancer: defined by disseminated disease (and often indicating more severe disease)

Assessment: the act of making a judgment of something (Merriam-Webster). In relation to pain it is defined as an ongoing and dynamic process, including evaluation of presenting problems, elucidation of pain syndromes and pathophysiology, and formulation of a comprehensive plan for continuing care (Oxford Textbook of Palliative Medicine)

Bitmap: an image which is stored as an arrangement of bits that represent each of the small dots that form the image (Merriam-Webster)

Chronic pain: defined as pain lasting longer than the tissue healing process (defined as 3 months)

Co-design: a design method involving users and experts to collectively create something in a process.

Cognitive functioning: an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It involves all aspects of perception, thinking, reasoning and remembering; (Free Dictionary)

Cognitive impairment: a measurable declined ability to process intellectually. Can be measured by different cognitive tests.

Comorbidity: independent co-existing disease

Computerized decision support tools: computer systems that collect, organize and analyze individual patient data to provide the clinician with patient-specific guidance for decision making [1]

eHealth: the use of information and communication technologies for health such as treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health (WHO)

Exacerbation: attack of more severe pain (in the context of pain)

Expressionism: A school of art which depicts the subjective emotions of the artists

Graphical User Interface (GUI): a way to make computer programs easier to use by using icons and a pointing device to make selections from a menu. A GUI is offered to navigate in the program instead of using commands such as F9 for update or Ctrl-C for copy.

Healthcare information system: a system underpinning decision-making with four key functions: data generation, compilation, analysis and synthesis, and communication and use. The health information system collects data from the health sector and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts data into information for health-related decision-making (WHO 2008).

Hypersensitivity: increased sensitivity threshold, where non painful stimuli such as a touch of wind to the face feel painful

Hyposensitivity: decreased sensitivity threshold, sometimes described as numbness

Incidence: the number of events in a given period of time. It is often referred to as new occurrence of disease in a population in a defined period.

Incremental iteration: a gradual implementation of functionalities in the software program. Often performed as a part of a participatory design process

Iteration: repetition of sequences of a process

Meronomy: a hierarchy that defines a constituent as "part of" something and describes an order

Mixed methods: a research approach utilizing a combination of qualitative and quantitative research methods, dependent on need and purpose. Often used in co-design and translational research

Mock-up: a model of something to demonstrate its features, used for studying

Neoadjuvant therapy: defined as the treatment given as the first step before the main treatment. The treatment intention can be to reduce the tumor size to make treatment options more accessible

Neuropathic pain: pain caused by a lesion or disease of the somatosensory nervous system (IASP)

Nociceptive pain: pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors (IASP)

Osteoradionecrosis: damage to bone structure, often as side-effect of radiation

Pain domain: the higher-order classification in the pain taxonomy

Pain item: in this thesis used as a sub-division of the pain domain, such as the NRS represents the sub-division of pain intensity, or QoL could represent a sub-division of pain interference

Paresthesia: an abnormal sensation such as burning, prickling. The sensation can be perceived around scar tissue after surgery, as side effects from other treatment options or related to diseases affecting the nervous system

Participatory design: a method related to the co-design method for development of a software system or service system. The method is based on user involvement in all phases of the project. The method consists of a stepwise process of (re)evaluation and (re)design until the needs and the requirements of the involved parties are acceptably met.

Physical functioning: defined as the individual's ability to perform different defined actions and activities considered as normal for age, gender, height, or weight

Physical impairment: loss of capacities to perform different defined actions and activities

Pixel: the smallest element in a digital image (from Picture Element)

Prevalence: in the context of cancer, the number or proportion of people living with cancer at a given time

Renaissance: refers to the revival of art, literature and learning in Europe between the 14^{th} and the 17^{th} century. This period constituted the transition from medieval to modern culture

Stakeholder: person, group or organization with a special interest in something such as a project or an organization

T2 type research: the evidence-based process of influencing health-related outcomes. Could be related to changing people's behavior or implementing a service into clinical practice

TNM classification: T_x defines the primary tumor size from $T_{1\text{-}4}$, N_x defines lymph nodes $N_{0\text{-}3}$, defined as regional=1 or distal=3, M_1 defines the distant metastasis

Taxonomy: the process or system of describing the way in which different living things are related by putting them in groups (Merriam-Webster)

Tissue mediator: agent from tissue that can transmit information in the tissue and create a specific response

Usability: the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use (International Standards Organization)

User: the one interacting with a system

Waterfall model: a method of software design following a sequence of steps toward a product. Each step in the process should be finished before the next step is started. The product is tested toward the end, right before production or implementation.

1 Introduction

The healthcare industry currently faces significant opportunities as well as challenges regarding the use of digital information and health information systems [2]. Tools and equipment for diagnostics and treatment have had tremendous impact, e.g., Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scan, and robotic surgery [3, 4]. These tools represent the forefront of today's technology regarding diagnosis and treatment, whereas information systems to acquire, search, process, display and store patient information are lagging behind in the sense that they have yet to reach their true potential [5, 6]. Both diagnostic tools and information systems are based on modern technology, but it seems easier to find arguments for the need to invest in new diagnostic equipment than in systems that can collect and organize objective and subjective data to improve care.

Most people in the Western world are accustomed to communicating through digital texts, audio, video or a combination of these. This means that there is a continuous update and flow of information 24 hours a day. Within Norwegian healthcare organizations, the platforms and software programs that provide the same functionalities (support for audio/visual and written communication) are based on hardware and software developed for the healthcare profession. The functionalities are often limited, and the programs' ability to integrate and communicate with related systems is either restricted or non-existing. The reason for this may be hard to justify, but the conservative attitude toward digital communication has restricted the interaction for a long time. The means for electronic communication between healthcare providers or with patients have been limited related to how (short message service (SMS) or e-mail through secure web site), what (restricted by way of communication), and with whom to communicate. Today this represents a big challenge in the healthcare field.

In Norway, health information systems were implemented in hospitals around the millennium and in general practitioner (GP) offices a bit earlier [7]. However, one general criticism of health information systems in many countries, and in Norway as well, is that they provide limited clinical benefits [5]. This reproach stands out compared to the great benefits that are evident in terms of medical technology such as MRI and PET [3, 4].

The cancer incidence[1] is rising [8], first of all due to people living longer and cancer being mostly a disease of old age, but also because of improved ability to detect the disease. Better treatment options have led to more people being cured from cancer, but also to a high number of people living with

[1] The number of events in a given period of time. It is often referred to as new occurrence of disease in a population in a defined period.

cancer [8] and suffering from cancer-related or treatment-related symptoms [8]. Pain is probably the most feared cancer symptom. Depending on study designs and patient populations, the reported prevalence rates of cancer pain vary from 62 to 86 percent [9].

Treatment of pain is an important part of clinical practice, and one of the core responsibilities of every physician. However, good pain management relies on a systematic pain assessment. Treatment choice for pain management is based on the cause, severity and duration of the pain, its interference with daily activities, as well as comorbidities and the individual response to and tolerance for the treatment. Pain severity can be assessed in a relatively standardized way with different assessment tools, most of which have been developed for patient self-report. In addition, standardized tools can also provide clues to the etiology of the pain, and aid in the clinical examination [10, 11]. However, quality management of complex pain requires significant resources from the healthcare organization.

Currently, healthcare provision is facing new challenges in many parts of the world due to a different composition of the population with an increasing proportion of elderly, and consequently a higher incidence and prevalence of chronic conditions. The current ways in which healthcare is organized require large resources. It is foreseen that healthcare provision to match the expected demographic changes will require a substantial scaling up of human resources [12]. One of the challenges when planning for future healthcare provision is the need for effective and feasible methods for symptom assessment to provide better quality of life for a larger population with chronic diseases.

The research project in this thesis is neither purely technological nor purely medical, but defined by tailoring a technological solution to a medical challenge. The research has been performed at the intersection of healthcare and information technology. This thesis has the structure of a traditional medical thesis, because my point of view is basically medical. At the same time, the evidence from this research project is relevant for both the medical and the information technology fields. Thus, professionals from both fields should be able to comprehend the contents and find relevant evidence to support the results.

1.1 Objectives

The PhD project in this thesis started as an integrated part of a large, EU funded project, the European Palliative Care Research Collaborative (EPCRC) project [13]. One of the project's main objectives was to develop a computerized tool for the assessment and classification of cancer pain. The development of a Computerized Pain Body Map (CPBM) for patient self-report of pain location and intensity was part of this work. A CPBM is a computer program displaying images of a human body on which patients can mark the location of their pain. A pain body map is a widely used assessment tool in many different medical disciplines such as rheumatology, rehabilitation and cancer care. My

involvement in this project started with the international, multicenter EPCRC-CSA study, presented in Paper 1, while the further work was carried out independently of the EPCRC.

The overall scope of this thesis was to develop a CPBM for patients with advanced cancer and to investigate how the CPBM can facilitate pain communication between patients and healthcare providers.

The aim was to develop an information and communication tool that was:

- flexible enough to be used by the most frail and sick patients and,
- robust enough to be reliable and useful in clinical practice for pain management in patients with advanced cancer

1.2 Thesis structure

The remainder of this thesis is structured as follows:

The essential background and domain knowledge from medicine and information technology upon which the thesis is founded, is presented in Chapter 2. The aims of the study and the research questions are given in Chapter 3. The development process of each version of the CPBM is described in Chapter 4. Chapter 5 presents the material and methods used. Chapter 6 contains a summary of the results presented in the three papers included in the thesis, and Chapter 7 presents a discussion of the methods and results. The final chapter contains the conclusions from the work, the contributions made, and suggestions for future work.

2 Background

This chapter is an introduction presenting the background knowledge for the context, contents and research methods in the present project. This chapter starts by presenting the medical aspects through an introduction to cancer and cancer pain. The next section contains the background for the work process involving pain assessment and pain communication. The last section introduces the health information technology field and related issues.

2.1 Medical aspects of cancer

2.1.1 Cancer incidence, prevalence and mortality

In Norway, incidence, prevalence and mortality rates for each cancer type are registered and published each year by the Cancer Registry of Norway [8]. Cancer incidence is a measure of occurrence of new cancer cases in a population within a specified period of time [8]. The cancer incidence in Norway was 31,651 in 2014 [8]. An estimate of the worldwide cancer incidence was 14.1 million in 2012 [14]. Among the most frequently occurring cancers worldwide are lung, female breast, bowel and prostate [14, 15]. The statistical reports from the Cancer Registry of Norway [8] show a gradual increase in most cancer types through the last couple of decades. This is partly related to early screening tests, and increased incidence of certain types of cancer, but mostly to increased life expectancy, as cancer predominantly is a disease of the elderly [8].

Cancer prevalence is the number or proportion of people living with cancer at a given time. The cancer prevalence in Norway was 242,000 in 2014 [8]. The prevalence of cancer is increasing, due to several causes. Earlier detection of the cancer disease and continuous improvement of cancer treatment are two factors contributing to a higher prevalence of cancer. Screening programs and media campaigns may have had an impact on people's awareness of cancer, but there is limited evidence on how successful such campaigns are in terms of earlier diagnosis [16, 17].

The mortality of cancer is defined as the number of people who died from cancer within a given time. The mortality of cancer in Norway in 2014 was 10,971.

2.1.2 Cancer, advanced cancer and palliative care

Cancer is a cluster of diseases defined by changes in the regulation that controls the life cycle of the cells and the connection to the mother tissue [18]. Cancer tissue has potential for invasive growth and may also spread by blood or lymphatic vessels to other organs of the body. Changes in the genetic code can occur at several stages of the disease development. Cancer may affect any cell and any type of tissue, but is most common in epithelial tissues, i.e., tissues covering a body surface or lining a body cavity [18]. The different cancer types have predilection to certain age groups, but cancer is mostly a disease of old age.

The stage (dissemination) of the cancer disease is one of the crucial factors for decisions on treatment, evaluation of prognosis and comparison of treatment results. The international TNM system is based on classification of the primary Tumor, regional Node(s) and distant Metastasis [19]. Advanced cancer is classified with an index for tumor, $T_{n,}$ indicating size, $N_{1\text{-}3,}$ indicating number of lymph nodes with tumor infiltration, and $M_{1,}$ indicating distant metastases [19].

In addition to the type of cancer and disease stage, the choice of treatment is influenced by the patient's age, physical performance status and comorbidities. Treatment protocols for the specific cancer diagnoses have been developed, and are continuously updated based on the most recent evidence [20, 21]. The treatment intention can be cure, life prolonging, or limiting the impact of the disease. The treatment intention is revised during the disease trajectory, based on the treatment response and/or the clinical condition of the patient. The treatment response is influenced by the same factors as mentioned above, as well as the patient's genetic make-up, and several other individual factors such as tumor genetics. The main cancer treatment options are surgery, chemotherapy and radiation, or a combination of two or all three treatment modalities. Surgical removal of the tumor may be followed by chemotherapy or radiotherapy as adjuvant therapy, which refers to additional treatment for possible microscopic disease to lower the risk of recurrence. Additional treatment can also be given to reduce the tumor size before the main treatment. This is referred to as neoadjuvant therapy, often given as radiation or chemotherapy before surgery. When treatment modalities are combined, they can increase the potential for cure, but also potentiate the side effects.

Disseminated disease needs systemic treatment in the form of chemotherapy, which in this respect also includes hormonal therapy, immunotherapy and other new, targeted therapies. The different treatment modalities may affect the patient in different ways. The location and size of the tumor and the degree of invasion of the surrounding tissues affect the extent of the treatment and consequently the side effects and treatment-related complications. To give some examples, radiation for cerebral metastases may affect cognitive functioning [22], and radiotherapy for lung cancer might lead to fibrosis of remaining lung tissue. As for chemotherapy, the toxicity is dose dependent, but may be potentiated when combined with radiotherapy.

Advanced cancer

The term advanced cancer is not universally defined but is frequently used. It denotes severe cancer disease in which the primary tumor has infiltrated the surrounding tissues locally or regionally (locally advanced cancer) or spread to another place in the body (metastatic disease) For most cancer diagnoses, advanced cancer is beyond cure, but life expectancy will vary depending on the tumor type and available life-prolonging treatment options. For instance, about one third of patients with metastatic breast cancer live more than five years [8], while almost all patients with advanced lung cancer die within one year of diagnosis [8]. Disease-related complications and symptoms also vary,

with bone metastases often causing pain and morbidity. Additionally, treatment-related side effects such as changed threshold of smell or nausea can increase the effect of the disease. Patients with advanced cancer often receive palliative care, focusing on symptom relief and better quality of life.

Palliative care

From the mid-20th century advances in medicine made cure the main goal of treatment, and non-cure was often considered a failure. At the same time, it became clear that patients without prospects of cure were in need of quality treatment and care to preserve a good quality of life. This awareness gradually led to the organization of palliative care services in medical practice around the world. The strategy was to consider palliative care a public health issue [23], with pain control as a particularly important issue.

Palliative care services as well as research in this area are quite recent advances. The first palliative care services in Norway were organized at the beginning of the 1990s [24]. This means that in Norway as well as other European countries, the body of research evidence in palliative medicine has been limited. However, in the last decade, the quantity and quality of palliative care research have increased substantially [25].

The prevailing definition of palliative care was presented by the WHO in 2002 (see Figure 1).

"Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Palliative care:

- *provides relief from pain and other distressing symptoms;*
- *affirms life and regards dying as a normal process;*
- *intends neither to hasten nor postpone death;*
- *integrates the psychological and spiritual aspects of patient care;*
- *offers a support system to help patients live as actively as possible until death;*
- *offers a support system to help the family cope during the patients illness and in their own bereavement;*
- *uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated;*
- *will enhance quality of life, and may also positively influence the course of illness;*
- *is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications."*

Figure 1: WHO definition of palliative care [26]

According to the WHO definition, providing palliative care also includes dissemination of knowledge and skills to people involved, supporting patient autonomy, providing spiritual support, and forming

networks of those affected and involved in the management, including the closest family [27]. This makes the team of professionals and the work description much wider than in many other fields of healthcare. The boundaries related to where and to whom palliative care should be provided are decided by the needs of the patient and family [26].

The WHO definition recommends early detection of pain and other symptoms, implying that the symptom burden determines when palliative care is needed [26]. Even if palliative care often is associated with advanced cancer, there is no restriction as to type of disease. Gradually, extending palliative care to non-cancer diseases is getting more common [28, 29]. Increased life expectancy and better treatment modalities enable elderly people to live longer with their chronic diseases. It is therefore predicted that many more patients will have palliative care needs in the foreseeable future [30].

2.1.3 Characteristics and common symptoms of patients with advanced cancer

A recent study reported that patient characteristics in this population are inconsistently described and reported, which makes comparisons of study results challenging [31]. The most commonly used descriptors for patients with advanced cancer were age, gender, performance status and survival [31]. The study concluded that there was a need to standardize the description and reporting of patient characteristics, both in research and clinical work. This resulted in the development of the European Association for Palliative Care (EAPC) Basic Dataset to describe a palliative care cancer population. The dataset is a minimum set of socio-demographic and medical variables, developed through an international Delphi process, and is currently subject to international testing [32].

The EAPC Basic Dataset contains a list of symptom scores, as one common denominator of patients with advanced cancer is the presence of distressing symptoms. A cancer symptom[2] is defined as a subjective experience that can be measured by self-assessment, such as fatigue, pain or anxiety [33]. (One challenge is to discriminate symptoms from signs of cancer, as they are sometimes reported as one domain, as in the large study by Vandyk et al. [34]. A cancer sign refers to something that can be objectively measured, such as fever or fecal occult blood.) Frequent symptoms associated with advanced cancer are pain, fatigue, appetite loss, constipation, depression, anxiety, dry mouth, nausea and poor sleep [9, 35, 36]. However, it is challenging to find studies that cover the same patient population and assess the symptoms with comparable methods. A summary of the *most frequently* reported symptoms in different papers on cancer patients ranges pain, fatigue, depression and dyspnea highest [34, 37].

[2] subjective evidence of disease or physical disturbance; *broadly*: something that indicates the presence of a bodily disorder (Merriam-Webster)

All of these symptoms can have a great impact on the patient's quality of life [9, 35]. Symptoms are interrelated, and influence and potentiate each other. The perceived symptom burden is dependent on tumor type and site, stage of the disease, previous treatments and comorbidities, as well as important social and personal factors [38, 39]. However, with progressing disease, the symptom burden usually becomes more dominant and disturbing, although the intensity may fluctuate over time [40]. Not surprisingly, in-patients with advanced cancer generally experience much more symptoms than out-patients [40, 41].

A proper symptom assessment is the cornerstone of optimal symptom management. Although the comprehensive assessment should include objective signs of disease and tests of different functions, e.g., physical performance and cognitive functioning, patients' self-report is the gold standard for symptom assessment. Numerous assessment tools have been developed for symptom assessment. Different assessment tools have different focus. Some are generic such as the McGill Pain questionnaire (see 2.2.30), and intended for use in a general patient population; some are disease-specific such as the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)[42]; and some are symptom specific, such as the Hospital Anxiety and Depression Scale [43]. The Edmonton Symptom Assessment System (ESAS) [44] is probably the most widely used symptom inventory in palliative care all over the world [45]. It covers the most frequent cancer-related symptoms and is scored on a 0-10 Numerical Rating Scale (NRS).

2.1.4 Pain perspectives

Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [46].

It is claimed that the German psychologist and philosopher Nietzsche, who lived and worked at the end of the 18th century, considered pain and pleasure not as two different entities, but categorized pain as a *part* of pleasure. The two emotions are epiphenomena, outcomes or correlates of events, and interconnect with one another [47].

The Canadian psychologist Ronald Melzack proposed a similar theory. He hypothesized that pain should not be regarded as a separate sensory experience, but rather as a modification of the continuous ongoing sensory input to the brain. The sensations are perpetually processed in the brain in order to tell us about where we are and what we are doing, and whether or not we are feeling fine [48]. If we stand in one position for a long time, the status of feeling fine will be interrupted, and we might experience pain in our legs or back. In order to reach a new "state of equilibrium" we can change position and thus feel better. The processing of information of "feeling fine" might be seen as the steady state, where information from our sensory system is continuously processed. The same sensory

system will send signals to the brain which will be interpreted as pain [48]. Hence, perception of pain is an important sensory signal for survival.

The processing of the impulses is individual and based on different factors such as genetic make-up, previous experience, and emotions [48]. This pathway of sensory processing gives each individual a unique pain experience, like a "finger print".

As a compassionate human being or as medically trained personnel we are challenged every day to try to understand the pain in our fellow human beings or our patients. The linguist Elaine Scarry investigated the language of pain and concluded that

> "[…] *having pain may come to be thought of as the most vibrant example of what it is to "have certainty", while for the other person it is so elusive that "hearing about pain" may exist as the primary model of what it is "to have doubt"[49].*

Communication of pain was described by Virginia Woolf in *On Being Ill*:

> *"[…] but let a sufferer try to describe a pain in his head to a doctor and language at once runs dry. There is nothing ready made for him. He is forced to coin words himself, and, taking his pain in one hand, and a lump of pure sound in the other (as perhaps the people of Babel did in the beginning), so to crush them together that a brand new word in the end drops out. Probably it will be something laughable"*[50].

Studies on a standardized pain measure were conducted before World War 2 in the United States. Inducing pain and providing pain relief were reproducible in a laboratory setting, but could not be successfully replicated in "the wild" [51]. During World War 2 an American anesthetist observed the pain response from injured soldiers taken out of the war zone and compared their response with that of civilians in the war zone [52]. He observed that the pain experience was more severe among the civilians than the soldiers, even with the same type of injury. From this finding, he proposed that pain was a subjective experience that could be modified by different factors [52]. This is also the current view both in clinical practice and research.

2.1.5 Cancer pain

The present project is focused on one of the most important and most feared cancer symptoms: pain. Other common symptoms will not be discussed in detail in this thesis, but should always be considered when assessing pain due to their influence and impact on the pain experience.

Evidence shows that pain is a frequent problem among patients with advanced cancer [53, 54], it is a complex problem and challenging to understand [55-57].

Pain prevalence as well as pain intensity in advanced cancer are often closely related to the progression of the disease [10]. The high pain prevalence and pain intensity have a great impact on the individual patient's life, as well as on family and friends. Unrelieved pain has been found to be an important factor leading to emergency visits to the hospital [58]. Pain affects cognition, sleep, mood, and mobility, and increases distress [36]. Pain relief improves the situation for the individual and their close relatives and also potentially reduces the burden on the healthcare services.

Pain related to cancer can have different characteristics and etiologies. It can be caused by the disease itself or result from the cancer treatment [59]. Examples of pain caused by treatment side effects are chemotherapy induced peripheral neuropathy (CIPN), pain caused by osteoradionecrosis after radiotherapy, or pain after surgery [10, 60, 61]. In many cases, treatment related cancer pain can be hard to relate to one treatment modality, but is rather caused by synergistic effects.

Different types of pain have different pathophysiological features and temporal patterns [62-64]. A patient's pain experience is also influenced by comorbidities, presence of more than one pain type, previous experiences with pain and pain management, social status, and psychological state [54, 64].

IASP defines nociceptive pain as "pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors" [46]. The mechanism of cancer pain can be nociceptive, neuropathic, or mixed [62]. Nociceptive pain occurs as a response to an activation of a pain receptor (peripheral nerve) by tissue mediators (local tissue substance). These mediators are set free as a response to actual or threatening tissue damage. The tissue damage can be caused by inflammation, infection or injury [18].

Neuropathic pains arise from the nervous tissue itself, and are defined as "pain caused by a lesion or disease of the somatosensory nervous system" [46]. Perception of neuropathic pain is often quite different from nociceptive pain and characterized by a chronic background pain with acute exacerbations[3] several times a day [10, 62]. The skin in the area of the background pain has an altered sensibility and may be hyposensitive[4], hypersensitive[5], or both. The exacerbations of pain may be spontaneous or can be triggered, and are often described with words such as electric shock, throbbing, burning and aching. Related to cancer, neuropathic pain is often a treatment related problem, and has been reported in 19 to 90 % of patients treated with neurotoxic chemotherapy [62, 65, 66] (the wide variation in frequency may be related to different criteria for how neuropathic pain is diagnosed). However, neuropathic pain may also be related to the cancer itself [64]. To improve recognition of this challenging problem four criteria have been proposed [67]:

[3] Exacerbations defined as attacks of more severe pain
[4] Hyposensitivity; decreased sensitivity threshold, sometimes described as numbness
[5] Hypersensitivity: increased sensitivity threshold, where non painful stimuli such as a touch of the wind to the face feel painful.

1. *Pain with a distinct neuroanatomical plausible distribution*
2. *A history of a relevant lesion or disease affecting the somatosensory system*
3. *Confirmatory tests demonstrating presence of negative and positive sensory signs confined to innervation territory of the lesioned nervous structure*
4. *Further diagnostic tests confirming lesion or disease entity underlying the neuropathic pain*

The first two criteria are obligatory, and include visual identification of a neuroanatomical pain distribution on a body map, with a link to pain etiology in the patient's disease history. Criterion 3 includes examination of touch (cotton bud tip/brush), vibration (tuning fork), warm and cold sensations (warm and cold rollers) and pain sensitivity (using a toothpick) in the areas marked on the body map. Criterion 4 includes confirmatory tests such as Computer Tomography/ Magnetic Resonance Imaging, laboratory tests, or skin and nerve biopsy. In all four criteria, the visual distribution of pain is an important basis for further assessment.

2.2 Communication of pain

Pain is individually experienced and has multiple associated modulating factors. Communication of this experience is complicated due to the lack of a universal pain language [11, 49]. This means that it is challenging both to express and understand pain.

The subjective pain experience is constantly influenced by internal and external factors, as described above. In order to communicate the pain perception, we need a language that can be modified and adjusted and at the same time provide the necessary accuracy in a communication setting.

Early in the 16th century, the luminary German painter Albrecht Dürer made a self-portrait with a painful area marked on a body drawing (Figure 2). His self-portrait has been referred to as the Renaissance prototype of a pain body map (PBM) [68].

Figure 2: Der Kranke Dürer; ***Do der gelb fleck is und mit dem finger drawff, do is mir we*** **[69]**

Dürer visualized the exact pain location and emphasized the location by encircling the area with yellow color, a pointing finger and an annotation which said "where the finger points, I have pain". It is believed that Dürer made this drawing in connection with a visit to his doctor. His diary has provided us with more specific symptoms such as fever, weakness, nausea and headache, which have led to many speculations as to the cause of his illness. The drawing could also visualize Dürer's state of mind since the yellow spot is located above the spleen, which in those days was believed to be the location for melancholy [68].

Figure 3: Munch, E ; Skrik [70]

Half a millennium later, the Expressionist era started. Expressionism displays the artist's subjective representation of the world, and influenced writers, musicians and painters. The artist Edvard Munch has contributed to the concept of visualizing subjective emotions as one of the most famous Expressionists. The artists influenced by Expressionism used distortion and exaggeration for visualization of their emotions. Edvard Munch's famous picture "The scream" [70] is thought to express the intense emotions of the painter who was plagued by anxiety and neuroses throughout his life.

Munch and Dürer have visualized two important pain domains, location and intensity. However, intensity as presented in Munch's painting does not represent a universal scale, and cannot show subtle changes for the better or worse. Additionally, we do not know what Dürer pointed at or what he wanted to visualize with his drawing. This makes the visualization of pain location and intensity in both paintings inaccurate and unreliable. Thus, in clinical use we need to know which pain qualities can be communicated and how, in order to provide a universal visual language.

2.2.1 Cognitive and physical functioning

Communication of pain has some basic challenges in patients with advanced cancer. A patient with advanced disease may suffer from drowsiness, fatigue and tiredness, all symptoms that may affect the patient's ability to communicate. Also, a frequently recognized barrier to effective communication between patients with advanced cancer and their clinicians is cognitive impairment [71-73].

Cognitive impairment in patients with advanced cancer may be due to several factors, such as the cancer disease itself, comorbidities (e.g., dementia) or treatment, (e.g. radiation to the brain or neurotoxic chemotherapy) [62, 74, 75]. However, it might also be related to a natural aging process. The impairment can affect all areas of cognition, such as cognitive speed, attention, learning ability, orientation to time and place, and language and visual construct [75, 76]. Cognitive impairment may also be caused by delirium, an acute state of confusion and altered attention that may be provoked by any condition influencing brain functioning, such as infections, organ failure, sleep disturbances, drugs (e.g., opioids), or other stressors (e.g., surgery and pain). Frail, elderly patients are especially prone to this condition, which typically fluctuates [77]. Delirium as a type of cognitive impairment is characterized by delusion or misinterpretation of sensory stimuli as well as affection of tempo and attention [77, 78].

When addressing cognitive impairment, a systematic approach is necessary [79]. Evaluation of cognitive function for diagnostic purposes requires extensive testing. This testing is performed by specialist consultants in neurology, neuropsychology or geriatrics. In a palliative care setting, extensive assessment tools are challenging due to their content and length. Patients with advanced stage disease have additional physical challenges that can add to, or be intertwined with problems related to cognitive functioning, such as fatigue and/or depression [80]. This may present additional limitations to their ability to participate in extensive testing.

Cognitive impairment might have been present already before the treatment started or can gradually appear or be intermittently present during or after treatment. Dependent on purpose of testing, different cognitive tests can be chosen. The most commonly used tool to assess cognitive function in palliative care research and practice is the Mini Mental State Exam (MMSE) [81]. This is a global cognitive test initially developed to screen for Alzheimer disease, and widely used in clinical practice. Another option is the Trail Making Test (TMT). The TMT addresses less complex cognitive functions than the MMSE, but can give important clues as to mental flexibility, speed of processing visual search, scanning, and executive functions [82]. A more detailed description of these tools is given in Section 5.5.2.

Advanced cancer may affect physical functioning in a similar way as cognitive functioning. Evaluation of physical functioning is an important part of the assessment, it may be decisive for selection of treatment and may also give valuable prognostic information [83]. Studies have shown a

strong association between physical performance status, symptoms and survival [83]. The physical performance of the patient is often evaluated by the care team by use of a standardized scale. The most commonly used scales are the Karnofsky Performance Status (KPS) scale[84] and the Eastern Cooperative Oncology Group (ECOG) scale [85]. The KPS scale is scored from 100 (normal, no complaints) to 0 (dead). ECOG is scored from 0 (fully active) to 5 (dead).

2.2.2 Pain assessment

A review by Knudsen et al. identified six different classification systems for cancer pain. However, these systems have so far had very limited impact on practice [86]. Work is ongoing to develop a more clinically relevant classification system to predict pain management complexity. The features or factors included in such a system would obviously influence the pain assessment strategy as well as decisions on therapy.

The Oxford Textbook of Palliative Care describes assessment of pain as "an ongoing and dynamic process that includes evaluation of presenting problems, elucidation of pain syndromes and pathophysiology, and formulation of a comprehensive plan for continuing care" [33]. The process of pain assessment requires a holistic view that includes all factors related to pain perception. The primary source of information is the patient, and the purpose of pain assessment is to obtain a best possible understanding of the pain problem in order to provide optimal, individualized pain management. Pain is a multifaceted experience which has been conceptualized in pain domains (also referred to as dimensions). An expert panel has listed the different pain domains that need to be addressed when assessing pain in patients with advanced cancer [87]. The specific domains are intensity, temporal pattern, treatment and exacerbating/relieving factors, location, and interference with health-related quality of life [87]. In a patient interview study, patients listed sleep disturbances as an important factor which could be considered as a supplemental domain [88].

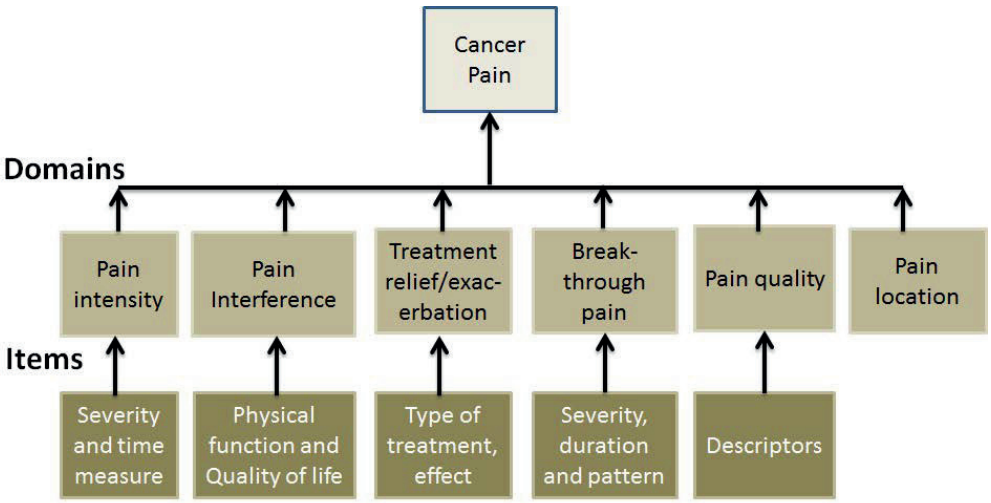

Figure 4: Cancer pain domains and items for self-assessment.

Pain items are the operationalization of the content within each domain, as illustrated in Figure 4. Figure 4 is based on a figure presented by Hjermstad et al. [89], visualizing different pain domains and pain items. The arrow indicates the expression of meronomy between cancer pain, pain domains and pain items.

Different conditions have different dominating pain domains and influencing agents which can alter the perception of pain [86, 90]. A challenge for pain assessment is the plethora of different assessment tools to choose from. Many of the available assessment tools cover only some of the acknowledged pain domains, while some tools cover all of them. When selecting a pain assessment tool, it is of great importance that the domains and items included in the questionnaire have relevance to practice and are perceived as important by patients and health care providers. Additionally, there has to be a balance between comprehensiveness and brevity of the assessment tool to avoid overburdening frail patients. Ideally, the choice of assessment tool should be based on guidelines founded on available evidence and international consensus [89]. The next revision of the EAPC guidelines for treatment of cancer pain, administered by the European Palliative Care Research Centre (PRC), is meant to include recommendations on assessment. The recommendations have not yet been released.

In order to standardize the measurement of pain intensity, universal scales have been developed. The different types of scales include Numerical Rating Scale (NRS), Visual Analogue Scale (VAS), Verbal Rating Scale (VRS) and Faces Scale [91-93]. For adult patients with palliative care needs, Hjermstad et al. concluded that there is no statistical evidence for preference of one rating scale over the other, as long as we are sure that the patient is able to understand and use it. However, in line with other recommendations, NRS was recommended as a standard measure for pain intensity [92]. Also, a

number of studies have shown that an NRS generally works best in a palliative care population [94, 95].

The usefulness of a systematic pain assessment is well documented [96, 97]. Still, it might cause consternation to some that in order for healthcare providers to understand the severity and fluctuation of the symptom, systematic pain assessments need to be performed. Breuer et al. documented in a large survey that from a medical oncologist perspective, poor pain assessment presented the most important barrier to cancer pain management [98]. However, especially in the last phase of a cancer disease trajectory, subjective assessment may be challenged by reduced patient compliance due to a high symptom burden and reduced physical and cognitive functioning [35, 71].

The ability of healthcare providers to evaluate the patient's pain has been investigated in several studies, showing that healthcare providers systematically underestimate the pain [55, 56, 99]. Evaluation of pain by proxy assessments has also been studied. The results show that the patient's close ones tend to overestimate the patient's pain [35, 57]. Consequently, the patients' self-report should be sought, whenever possible.

However, in cases where the patient is not capable of self-assessment, such as in severe dementia, proxy pain assessment represents a valuable contribution, preferably when performed by persons knowing the patient well. Some pain assessment tools based on observations have been developed [100, 101]. These tools require education and training to be used consistently.

2.2.3 Common pain assessment tools for patient self-report

A multitude of assessment tools exists, and there have been few recommendations as to which tool to use for a comprehensive pain assessment [102]. Additionally, most tools are presented in paper versions which impacts on their use, usefulness, functionalities and ability to display data.

The commonly used assessment tools for self-report of pain have different focus and scope, assess different domains, use different wordings and cover different time frames. Parts of the Brief Pain inventory (BPI) [103] and the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) [104] were used in the studies presented in this thesis.

Mc Gill Pain Questionnaire

The McGill Pain Questionnaire is one of the most frequently used assessment tools for pain and pain quality. The questionnaire was published by Melzack et al. for measuring any pain, and the questionnaire could be used in pain research [105]. The tool includes the following domains: sensory quality including temporal pattern and pain quality (verbal descriptors), affective qualities (verbal descriptors) and evaluative factors such as intensity and impact of pain on quality of life [105].

The original McGill Pain Questionnaire Short Form includes 20 categories of pain descriptors, such as flickering, quivering and throbbing pain, and accompanying symptoms such as nausea, headache and dizziness. Additionally, the present pain is to be identified and evaluated with a categorical scale for severity of present pain. The McGill Pain Questionnaire also includes a pain body map to assess pain location and is developed for global use.

Brief Pain Inventory (BPI)

The BPI was developed by a consensus group and tested mostly on cancer pain patients [103, 106]. This assessment tool is more commonly used in clinical practice, but can also be used for research. The tool assesses pain intensity as well as pain interference with daily activities and well-being. The BPI was developed with a higher focus on cancer pain than, e.g., the McGill Pain Questionnaire.

The BPI consists of nine categorical questions and the scoring method is a 0-10 NRS anchored with 0 (no pain) and 10 (pain as bad as you can imagine).The timeframe ranges from now to the last 24 hours. The BPI also includes a pain body map.

Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)

The LANSS was developed to screen patients for neuropathic pain irrespective of cause [104]. It is frequently used also for cancer-related neuropathic pain. LANSS consists of five questions which are dichotomously scored with yes or no. The time frame is the last week. A maximum of 30 points can be obtained, and a score equal to or above 12 indicates presence of neuropathic pain.

Edmonton Symptom Assessment System (ESAS)

ESAS is not a specific pain assessment tool, but mentioned here because it includes one question on pain severity together with other frequent cancer symptoms. It also has a pain body map for marking of pain location [44]. ESAS is a commonly used tool for assessment of nine symptoms frequently experienced by patients with advanced cancer. These symptoms are pain, nausea, tiredness, drowsiness, lack of appetite, shortness of breath, depression, anxiety, lack of well-being and a free row to add a problem of the patient's choice. The timeframe is now, and each symptom is scored on a 0-10 NRS anchored as 0 = no perceived symptom and 10 = worst possible perceived symptom. ESAS also includes a pain body map.

2.2.4 Validity and reliability evaluation

Assessment tools are mostly developed as questionnaires, and evaluation of their validity, reliability and usefulness should be reported systematically. In a review of pain measures, Jensen presented wide options for evaluation of reliability and validity, but no guidance for which method to choose [107]. Consequently, this field also seems to lack a consensus.

Among the most important factors for evaluating a questionnaire are the appropriateness, meaningfulness and usefulness of the content [107]. This is referred to as *validity*. *Face validity* is

defined as the degree to which the content and grading system are perceived as appropriate and understandable by both parties (patients and healthcare provider)[108]. As opposed to face validity, *construct validity* requires an evaluation of the underlying theoretical concepts to determine the degree to which a test measures what it claims, or purports, to be measuring. Use of an inappropriate tool will most likely affect information accuracy [109]. *Criterion validity* is related to whether the test is measuring what it claims to measure [108]. This could be the concordance between recollected pain attacks by a patient recorded in an assessment tool, compared to the actual number of pain attacks reported real time by the patient.

Reliability denotes the overall consistency of a measure. Reliability reports cover consistency, completeness and accuracy of data. This constructs the statistical evidence for how well patients are able to provide stable reports over time (consistency) and to what extent these reports, at the same time, are complete and accurate. A test-retest reliability study can provide information on the consistency of an instrument, provided that the issues being assessed are unchanged between assessments [108]. Accuracy and completeness depend on clear definitions of the requirements for each measure. For assessment of subjective symptoms, this is challenging, as it might be hard to provide an accurate definition or instruction for the measure. This can be illustrated by assessment of intensity and pain location. Evidence shows an accuracy of +/- 2 on a 0-10 NRS [110], indicating an inaccurate measure on individual level. For measurement of pain location, patients tend to mark the painful area by encircling, or marking with a dot, a cross, or shading the area [111]. Consequently, an accurate measure for these two variables might not be very precise.

To evaluate the reliability, the collected information has to be unambiguously interpreted. This can be measured by an inter-rater reliability test, which measures the clarity of the measure as reflected in the raters' ability to provide unanimous reports [108].

The evaluation of the assessment tool should also include data on responsiveness, i.e., how well the measure is able to detect important changes over time [108] (note that responsiveness in computer science refers to the timely performance of computer programs). For pain assessments this is important in view of fluctuating pain over time. Responsiveness gives information about the symptoms in a timely manner. The reliability and stability of the assessment can be hampered by practical issues related to the assessment itself as well as the burden it imposes on the patient. Consequently, practicality and patient burden are also two important issues that need to be considered when evaluating the qualities of an assessment tool.

2.2.5 Assessment of pain location, visualization of pain

Finding out where the patient hurts might give important clues to those providing care for the patient. The location of pain is thus one of the core domains to be included in any pain assessment, and provides important information in cancer [10, 87]. In patients with advanced cancer, pain in new

locations is a sign of disease progression until otherwise proven. It may indicate the occurrence of new metastases or local progression of disease. Also, the pain pattern can provide information about the cause of the pain, such as for bone lesions or neuropathic pain.

A pain body map is a drawing of the human body on which patients can mark their painful areas. As described above, the portrait of the sick Dürer published in the 16th century is referred to as a Renaissance prototype of a pain map [68]. However, as described in section 2.2, we do not know whether Dürer actually was trying to visualize his pain, or if he was referring more obliquely to his state of mind.

The most commonly available pain body maps are presented as images to be printed and marked with a pen. A single internet search for "pain body map" using a conventional search engine[6] returns a large number of such images that are easily available for use in clinical practice. Pain body maps are used for assessment of pain location as part of different assessment tools (questionnaires) such as the BPI [103, 106], McGill Pain Questionnaire [105] and ESAS [112], also in cancer care and palliative care. However, the available evidence for reliability, validity and accuracy of assessment of pain location in patients with advanced cancer is limited.

Verbally communicating pain poses strict requirements on the communicator's ability to give an accurate presentation, as well as on the other part's ability to listen and comprehend. However, one study has demonstrated how to reduce the complexity of a textual presentation of pain location by making a simple pain drawing [113]. The textual description of a pain experience presupposes precise anatomical knowledge and presentation skills, and leaves room for interpretation by the reader, whereas the pain drawing does this to a much lesser extent [113].

PBMs have been used in studies in different areas of medicine such as rheumatology, orthopedics and geriatric medicine [114-116]. Reliability has been evaluated by *test-retest studies for location*[7] in general chronic pain patients as well as in elderly patients [114, 117]. It is important that PBMs are reliable also for use by elderly and cognitively impaired persons [116, 118] due to the high pain prevalence among elderly patients [119]. The fact that reliability of PBMs has been shown in these patient groups also demonstrates the simplicity of the principle of the PBM tool.

Different studies have evaluated the marking of *pain patterns* on PBMs, and found that different methods for visualizing location and character of pain are feasible in different patient populations

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[6] A search in Google for "pain body map" returned this URL https://www.google.no/?gfe_rd=cr&ei=7qzJVsLyIqer8wfj6p_oDQ&gws_rd=ssl#q=pain+body+map. Due to the personalization feature of Google, most people will have slightly different results when searching for the same phrase.

[7] The reliability testing has mostly been performed as a test-retest validation to ensure that patients were able to mark the same area twice based on their subjectively perceived pain location.

[115, 120, 121]. *Extension of pain* is a relevant variable to identify as a component of the pain pattern. This has also been demonstrated as a reliable variable in patients with chronic low back or neck pain [122].

The unambiguity of PBMs has been shown by high inter-rater reliability in the evaluation of marked pain locations by non-clinical staff provided with proper training [123]. PBMs have also been evaluated for inter-rater reliability among clinicians [114, 117].

Keele and Palmer presented two studies on the importance of visualizing a log of changes in pain location and intensity by a graphical display as well as a PBM [124, 125] . This was a paper system which would have limited usefulness in a network of healthcare providers providing pain management to the same patient, unless everyone was given access to the same information. However, it could be very useful for a clinician providing care to the same patient over time, as changes could be rapidly recognized. Keele and Palmer focused on how assessment of pain, including pain location and intensity, could be used to provide better patient care.

Applying traditional test-retest reliability testing in a cancer pain setting may be challenging, since cancer pain can be fluctuating and complex. Cancer patients may also have different characteristics from other groups of patients [62, 64]. However, as demonstrated by Jang et al. [113], presenting pain location as a drawing is considered easier and more precise than a verbal description.

Despite extensive searches in Medline and Embase, limited evidence on reliability of the spatial annotation of pain on a pain body map for patients with advanced cancer has been uncovered. This corresponds with the reported results from Jensen [107] as well as Southerst [120]. One promising report on a tool for assessment of symptoms including pain location was retrieved, which assessed reliability and validity among three groups of cancer patients [126]. The assessment tool included a PBM with the body divided into predefined areas. In clinical practice and research, ESAS and BPI are frequently used. Both assessment tools include a PBM, but we have not been able to identify any study covering the validity and reliability of the PBM for cancer patients [44, 106]. In general, there is a lack of evidence on the cancer pain domain covering self-assessment of cancer pain location and distribution of cancer pain.

An expert consensus suggested neuropathic pain patterns to be one of two core diagnostic criteria to make neuropathic cancer pain a plausible hypothesis for further investigation [67]. This was supported by a recent Delphi study [127]. Additionally, a recent publication presenting an expert consensus on general neuropathic pain patterns specifically suggested assessment by use of a pain body map to visualize the pain pattern [128].

Bertilson et al. [129] have published a study in which patients were examined to verify that the clinician's interpretation of pain location from the PBM correlated with the painful area on the

patient’s body. This study reported a concordance of 90% between the patients' marked areas on a paper PBM and the clinical examination. However, the 10% concordance gap was related to additional painful areas being detected when patients underwent a clinical examination, described by the authors as patients withholding evidence [129].

The current evidence presented in this section demonstrates that a validation of the reliability and validity of PBM for patients with advanced cancer is still needed [107]. However, both Wilkie et al. [130] and Jud et al. [131] have demonstrated that visualization of pain location could be useful for assessment of cancer pain. Consequently, pain assessment on a paper PBM for patients with advanced cancer has great potential for improvement, possibly widening the scope for clinical use of the PBM. Pain location is also defined as a core cancer pain domain, as previously described [86, 87, 89].

As mentioned, most of the scientific evidence on assessment of pain location is based on the use of paper PBMs. A paper platform for the PBM limits the usefulness of the tool in many ways. Information and communication technology may grant rapid sharing of information and access to data when needed; two important factors for efficient care. A CPBM that includes relevant pain information for decision making could therefore contribute to better and more tailored pain management in patients with advanced cancer.

A number of web sites featuring PBMs for defined purposes can be found on the internet. The use of PBMs varies from interactive visualization of pain location for cataloging patient health information, to serving as an integrated part of an educational program on pain management from a pharmaceutical company [132, 133]. Both these examples of PBMs are integrated parts of commercial web sites without any scientific evidence for development and use.

Several searches in the databases Medline and Embase with a defined search string for PBMs gave us one hit for a CPBM. A snowballing method (defined as search starting from one key document) and search in different databases such as Medline, Engineering village, IEEE Xplore and Google scholar returned a few papers on digital PBM tools listed in Table 1 below.

Table 1: Review of published CPBMs

Author	Aim	Study design	Projection of the CPBM/ platform	Development method	Population	Outcome
Wilkie et al. 2003[130]	Improvement of efficiency of pain management	Feasibility testing, quantitative and qualitative data (field notes)	2-D PC	NA	Cancer patients and members of the public	Confirmed usability, but improvements were needed
Jang et al. 2014	Visual encoding of pain, efficacy assessment, validation of design decision	Exploratory design study	2-D PC	User-centered testing	Students and university employees, physicians, nurses, pharmacist	Supported natural drawing behavior, content perceived more detailed compared to text
Jud et al. 2014	Describe spatial distribution of paraesthesia	Exploratory study	2-D PC	NA	Breast cancer survivors	Defined distribution of sensory symptoms
Lalloo et al. 2011	Develop a tool for visual supplementation of information about location, intensity and quality of pain	Exploratory study	2-D Laptop	No information about the original development User-centered testing	Chronic pain patients from a support group	Confirmed usability and perceived usefulness
Jamison et al. 2011	Evaluate temporal reliability	Pilot testing, comparative study	3-D Laptop	NA	Stable chronic non-cancer pain	Temporal stable pain marking in x, y and z dimensions
[1]Serif et al. 2005 [2]Ghinea et al. 2008 [3]Spyridonis and Ghinea 2010 [4]Grønli et al. 2015	[1]Develop a system for monitoring low back pain [2]Refine the [1]3D pain drawing system [3]Compare subjective and objective measures for pain, pilot testing [4]Usability investigation of a PBM	[1,2,4]Exploratory study [3]Comparative study [4]Pilot testing	3-D Personal Digital Assistant (PDA) Android	[1]User centered design study [2]No user-involvement reported in development [3]NA [4]No user-involvement reported in development	Wheel-chair users and physicians	[1,2]Proof of concept, [1]Interaction problems [2]Need for scalability and higher discrimination of response [3]Association between pain marking and pressure point [4]Positive user experience

Table 1 lists different projects involving development and/or testing of CPBMs. A general observation is that most of the studies are qualitative exploratory studies (only one study used a quantitative study design [134]). From this we can conclude that the concept is not fully explored, and a consensus on design has not been established.

All the studies in Table 1 provided weak descriptions of their test participants in terms of how the disease affected their abilities to interact with the tool. Two studies included cancer patients [130, 131]. Only one study [135] explicitly reported involvement of patients in the development process. However, test results from the qualitative studies reported interaction problems related to patients' disabilities or design flaws. One study recommended natural drawing behavior based on the test results [113]. Natural drawing behavior means to be able to draw freely without using predefined squares, dots or circles for marking. This was also the implicit strategy of the other studies.

Implementation of pain dimensions other than location was considered in all but the study from Jud et al. [131]. The different pain dimensions implemented were location (distribution) and intensity, and additionally Jamison et al. included an option for annotating superficial or deep pain [134].

Both PC and mobile devices were used in the different studies. Hand-eye coordination difficulties were not reported for any of the mobile platforms. Most studies reported interaction problems, but there is limited evidence to the exact problems and when they occurred. None of the studies in Table 1 have reported to include patients with cognitive impairment, and there is limited evidence of efforts to customize the CPBM to patients severely burdened by disease.

Only one study reported on cancer patients, but the qualitative approach in this study provided limited data [130]. Only two studies reported information on the user interaction during development of the tool [113, 135]. The test participants were recruited from Amazon Mechanical Turk[8] in Jang et al. [113], whereas Serif et al. reported on wheelchair users' interaction with their tool. Both reports were based on interaction self-report by a survey, such as user response to "in which interface was your symptom description more detailed?" [113] or "I find the process of inputting pain data on a PDA/Pain diagram easy" [135]

All studies have reported results from different projections of the body, except the study reports from Serif et al.[135], Ghinea et al.[136], Spyridonis et al.[137, 138], and Grønli et al.[139], which are understood as reports on the same evolving product. The different projections in all the different study reports were results of the intention to provide more accurate pain drawings. Based on the current evidence, groups of people with special traits such as cognitively disabled or breast cancer patients

[8] Amazon Mechanical Turk (MTurk) is a crowd sourcing internet market place to recruit people for small jobs such as usability evaluation or other tasks that can be performed on a computer.

with axillar pain need more detailed anatomical PBMs, as described in the studies by Jud et al. [131] and Bromley et al. [118]. Enlargement of the body image was included in the study by Bromley et al. [118], probably intended to reduce requirements to impairments such as dexterity problems or poor vision. Jud et al. specifically displayed the axillar area on the body image, as an area where paresthesia[9] after breast cancer treatment was frequently noticed [131]. However, extensive searches have not yielded recommendations on the level of detailed anatomical drawings that provides most benefits to patients when marking their pain, and to clinicians when interpreting the drawings. Thus, there seems to be a lack of consensus on projections and the level of accuracy needed for a tool like this. This was also commented on in an editorial in Pain 36 years ago [140].

The accuracy of the spatial pain drawing has been given very limited focus in research. However, a more detailed pain drawing *might* be associated with a higher accuracy. One study reports on more detailed pain drawings by patients as a result of training and proper instructions [129]. Training and instructions seem to be beneficial also for clinicians evaluating the pain drawings [129].

Visualization of subjective pain information is an important concept in all the studies presented in Table 1. Especially, Lalloo et al. [141] and Jang et al. [113] promote the advantages of using a visual image to reduce the complexity of a pain description.

A common denominator among all CPBM papers was the inconsistencies in the presentations of the computerized tools and the descriptions of interaction with the tool, the study aims, and the choice of study method. Most studies aimed to explore usability of their computer program in different patient groups. However, this was performed without describing the characteristics of the users. One of the reports pointed at the specific usability needs of wheelchair users with more impaired function in their upper limbs, without further description [139] .

From the patients' self-report data in these studies, visual communication was preferred to verbal descriptions of pain [113, 142]. Additionally, patients perceived sharing of data as useful [141]. The reports from clinicians, although they were in a very limited number, were positive and enthusiastic with respect to using digital assessment and visual communication in the interaction with their patients [113, 138].

Most studies consider the use of CPBMs promising for future clinical practice and patient-clinician communication; however, the methods, reports, patient groups and tools are too fragmentary and inconsistently reported to provide satisfactory empirical data. Also, the research reports from the CPBM studies seem to demonstrate limited clinical collaboration in planning, development and

[9] Defined by IASP as an abnormal sensation, whether spontaneous or evoked

evaluation of results. Surprisingly, only one of these studies [113] seems to have considered the challenge of transferring the concept of a paper PBM to a computerized version.

The studies in Table 1 span from 2003 to 2015, but generally seem to cover the same ground, indicating that there has been little real progress in the past decade. Although the programs and platforms have evolved, there is no evidence elsewhere in the literature on how this evolution has influenced clinical practice.

The current evidence, both from the medical and the technological side, could potentially provide useful contributions to future pain management. The medical studies have mostly been performed as comparative studies providing evidence for a limited research question. How this evidence could be used to refine the concept of pain assessment with a PBM, has been given very little focus. In the information technology field, the studies can be characterized as exploratory, with a wide view on the concept of visualizing pain, and limited detailed evidence on development method, user groups, domains to assess, reliability and validity. This implies that joining forces between the clinical and the technological fields is necessary to move forward in this area.

2.2.6 Cancer pain management

Quality pain management is dependent on all aspects presented up to this point. Even though the severity of the cancer pain problem is recognized, studies have shown several barriers to good pain relief. On the clinicians' side, a lack of knowledge of adequate therapies has been pointed at [98]. One of the solutions to this problem is the development and implementation of treatment guidelines. The best known and most frequently used guideline for cancer pain management is the WHO pain ladder [143]. This guideline proposes a three step approach for treatment of mild, moderate and severe cancer pain with non-opioids (e.g., paracetamol) for mild pain, non-opioids combined with mild opioids (e.g., codeine) for moderate pain, and strong opioids (e.g., morphine) for severe cancer pain. On all three steps adjuvant medication to calm fear and other symptoms can be given. The guideline also suggests providing the medication by the clock, and not on demand.

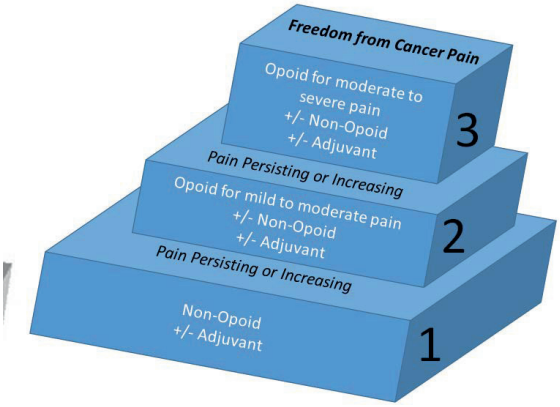

Figure 5: WHO pain ladder for adults

An international team of pain and palliative care experts of the EAPC presented in 2012 updated guidelines for the treatment of cancer pain with opioids, in the form of 16 evidence-based recommendations [144].

However, providing a guideline does not ensure that the recommendations are followed and interpreted the correct way. Implementation of guidelines requires substantial efforts. Fear of opioids, lack of knowledge and fear of addiction on the part of patients, relatives and healthcare providers have been identified as additional barriers to good pain management [98, 145]. Computerized decision support tools are defined as computer systems that collect, organize and analyze individual patient data to provide the clinician with patient-specific guidance for decision making [1]. These systems may have a potential to influence aspects of pain management. However, studies have shown that there is still a way to go before decision support systems can fulfill their potential [6, 146].

Organizational aspects of cancer pain management

Cancer pain management is most often provided by a multi-professional team. The medical care teams closest to the patients are located in hospitals, hospices, and care homes, or based in primary care in the local community [147]. The professional background can range from non-specialized medical professionals to highly specialized physicians, nurses, physiotherapists and occupational therapists as well as medical assistants or volunteers. The main focus of the team is the patients and their families, and their task is to prevent suffering and provide symptom relief [26, 148].

Organizational level

Delivery of healthcare to patients with advanced cancer should as much as possible be performed in the patient's home or immediate surroundings [147], under the responsibility of the primary care services. Support from a hospital-based specialist palliative care team may enable community services to handle complex situations in home care [149].

When more advanced procedures or complex evaluations are needed, this becomes the responsibility of secondary care [147]. This means that patients often are able to live at home early in the disease trajectory, but more often need in-patient care in the later phases [71].

The individual patient will be connected to a wide range of professionals at different levels of care. Transfer of responsibility occurs between primary and secondary care, as well as between professionals at the same care level, depending on the problem they need to solve [149].

The seamless passing of responsibility between professionals, and turn taking to respond to the patient's and the closest family's needs, require efficient and effective communication. This highlights the need for information and communication technology support.

2.3 Information and communication technology from a healthcare perspective

Hippocrates (460-377 BC) was the father of Western medicine. Traditional medical knowledge was mainly obtained from observation of human behavior from birth to death. Information transfer was based on oral lectures and personal notes. About 1,000 years after Hippocrates, important innovations contributed to great improvements in acquisition and dissemination of medical knowledge as well as improvement of diagnostics and treatment. After the 15th century, the printing press was invented, enabling a systematic collection and organization of medical knowledge; this also contributed to more efficient dissemination of medical findings. The medical professionals were often involved in different disciplines of science, and significant discoveries made in mathematics, physics or chemistry could frequently be directly implemented into medicine and used for solving medical problems.

2.3.1 Representations of the human body

Ability to make calculations of more exact body proportions was important for Albrecht Dürer. He was influenced by the Venetian mathematician Luca Pacioli, who inspired him to refine a mathematical calculation of the proportions of the body [150]. Dürer's work [10] also included calculation of spatial movements of the human body in order to make more accurate drawings [150]. Dürer's application of scientific mathematical knowledge for the purpose of more accurate body drawings could at the time be considered an advanced piece of information technology.

[10] This work was published in 1528, right after his death.

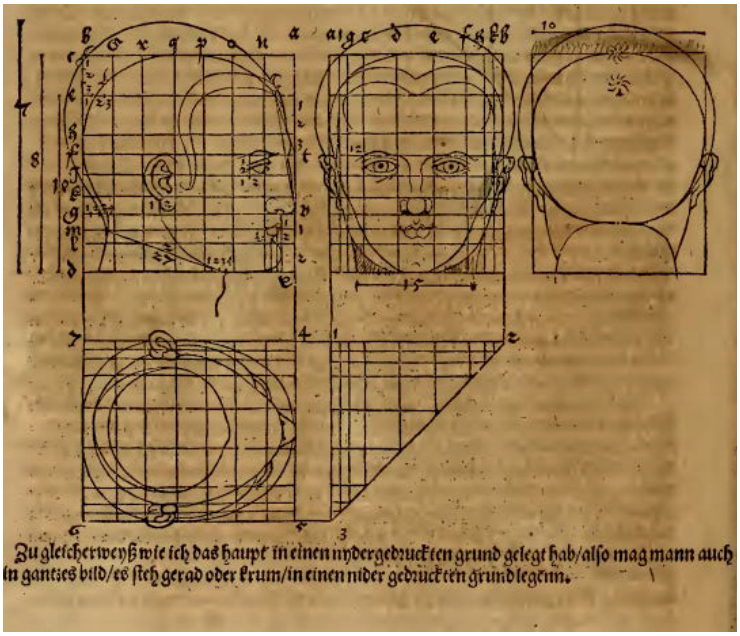

Figure 6: Dürer's calculations of the proportions of the head [150]

With a more accurate representation of the human body, more detailed information was obtained and shared among practicing medical professionals as well as researchers. Albrecht Dürer and Leonardo da Vinci were two multi-talents of the same era. It is likely that they have had knowledge of each other's work, but there is no evidence to show whether they actually met. Whereas Dürer was mostly interested in esthetics and the outer surface of the body, Leonardo da Vinci also took an interest in the inside of the body. In the days of Dürer and da Vinci, boundaries between scientific specialties were less clearly delineated, and scientists had limited means of supporting themselves. Some scientists were dependent on their affluent families or financial support from the church, but for others, teaching and practicing medicine were means of earning a living. Thus, many of the early scientists had a background from medicine, and medical students frequently had extensive knowledge of subjects like mathematics, physics, chemistry and biology. This background made many of them multi-talents.

2.3.2 Discoveries in science and medicine

The ability to have a comprehensive understanding of problems might be one of the important factors that led to the wide range of discoveries in science and medicine through the 15th, 16th and 17th centuries. One of these discoveries was made by Kepler, who in 1604 documented the image formation on the retina [151]. Through his theories on optics he discovered that the lens in our eyes inverts the images. Kepler also suggested that the upside down image would be corrected by the brain.

In the field of electrophysiology, Borelli (1608-1679) showed the mechanical movements of the heart, later visualized as an electrocardiogram (ECG) by Lippmann in 1887 [152]. In 1800 Volta (1745–

1827) invented batteries and showed how an electrical impulse could stimulate hearing for the first time [153]. This knowledge is refined and currently used to provide auditory stimuli to deaf people via a cochlea implant. All these examples show how researchers have used applied science to explore and treat medical problems. The definition of technology according to the Merriam-Webster Dictionary is "the application of scientific knowledge for a practical purpose". Consequently, the inventions described above represent the field of medical technology [154].

2.3.3 Dawning of the information age

In 1879 the National Library of Medicine (NLM) in Bethesda, Maryland was founded. The aim was to *index* all medical literature. This *index* was a substantial contribution to *medical information technology* in a similar way as the printing press 300 years earlier. In the last centuries, the body of medical knowledge has increased exponentially, supported by better and more precise tools for diagnostics as well as better methods for calculation. After 1950, medical libraries were challenged by the large amount of literature, and this applied especially to NLM. Up to this point computers were used for calculating mathematical problems. NLM was the first institution to make use of computers for retrieval of information, which ultimately led to the world wide accessible and systematically indexed Medline. From this database, searches for scientific evidence from fields related to medical science can be returned, which is particularly useful and reliable when conducting a review of medical evidence within a given area.

Currently, the most common association with information technology is linked to the use of computers. However, innovation in health technology and health information technology started long before the digital era and has been an interdisciplinary science.

The digital era continues to drive medicine towards better and more precise tools for diagnostics and treatment. At the same time the abundance of data from diagnostics and surveillance of disease is exponentially growing. These data and the digital systems are components of medical information technology systems and bridge healthcare and information technology. In order to keep these two fields connected, there is a continuous need to include both medical and information technological perspectives.

2.3.4 Information and communication technology development process

Digital support in healthcare is a rapidly developing field and currently a very fast growing market. The global value is believed to reach 233 billion dollars in 2020 [155]. This is believed to be particularly driven by the mobile health market [155]. The digital healthcare era has the potential to support powerful changes in interaction, information distribution and processing, as well as workflow.

The 1980ies heralded the beginning of the digital era in healthcare, and the development of advanced information technology and computerized tools for healthcare commenced. The development was stepwise and consisted of creating a design that reflected the client's requirements, followed by

implementation of the design, and the verification of flawless functioning and maintenance [156]. This process is called a waterfall model (Figure 7).

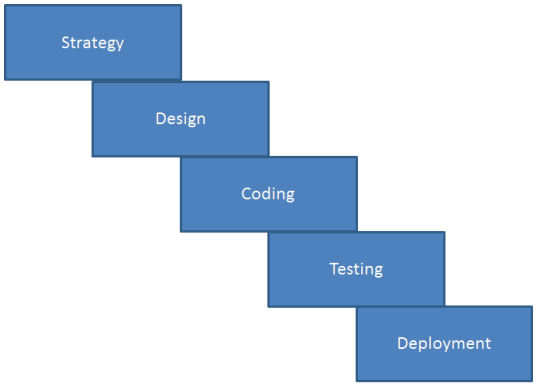

Figure 7: Waterfall model where sub-tasks are performed in a consecutive order

This development method has actually been very challenging for healthcare providers. To assign proper requirements in a process like this, the developer needs detailed knowledge on what the software program should do, how users would interact with the different design options, and how the tool may affect the work process. Furthermore, the developer must catch any emerging issues connected with practical use of the tool, which is usually obtained by testing the tool on actual users. Healthcare providers as clients have not been trained to anticipate how advances in information technology would change the healthcare services [157, 158].

Traditional medical research has investigated and attempted to solve medical questions. The research field has improved our knowledge, and consequently enabled us to define, characterize and treat diseases. From this knowledge, experiments have been performed to identify diseases, explore treatment options that can provide a cure, or improve survival rates or quality of life of the patient. Evidence of efficacy and efficiency in the medical field is traditionally gained through large quantitative studies, where strictly defined hypotheses are tested. Normally, knowledge in the medical field is built in small steps.

Research in the health information technology field investigates and solves medical problems using applied research. Scientific evidence in the health information technology field is based on experiments where the medical knowledge should be processed and presented to benefit the healthcare provider when identifying disease, providing a cure, or aiming to improve survival or quality of life of the patient. Evidence of efficacy and efficiency can be obtained from large quantitative studies. Additionally, adaptation of the technology to humans is an evolving and quite new field of research, which is built on behavioral science. Potentially, this field could also present a risk factor for introducing medical errors unless both medical professionals and technological developers have this in

mind. A technological device such as an ultrasound device or a Magnetic Resonance Image machine works because there are complex information systems telling the tool how to collect data and what to do with the data. The tools have an interface communicating with the healthcare provider who needs to understand how to make the tool work in order to be useful, and the clinicians must also be able to interpret the data correctly.

The waterfall method of development suffers from the fact that the actual interaction between users and software/platform comes too late in the development process. In healthcare, many digital tools have been developed using the waterfall method, and quite often interaction flaws have been demonstrated, i.e., that unfortunate user interface design causes tools to be used incorrectly. As an example, Kurshniruk et al. demonstrated how interaction flaws affected clinicians using a handheld device for medical prescriptions. The design of the tool made clinicians susceptible to prescribing incorrect medication to patients from the clinical interface [159]. This resulted in problems such as dispensing insufficient number of tablets, and inability to correct the error. Consequently, poor usability of a computer program can adversely affect the reliability and validity of a technical tool. A similar problem is illustrated in Figure 8, which shows a touch screen interaction problem, where the user is not able to hit the wanted option, and the device has (incorrectly) accepted an entry. Additionally, the device makes it possible to select an option that is not available. Without any possibilities to correct the error, the user is forced to abandon the operation and start the whole process from the beginning.

Figure 8: Example of poor interaction design

Introducing new types of programs and platforms for a new group of users should be treated as an unknown field, where evidence on all aspects (including usability) has to be built before the programs/platforms can be taken into practice. This principle is also recognized in the medical domain, where validity and reliability of tools in each particular patient population have to be demonstrated before the tools are taken into practice or research (see 2.2.4).

The waterfall method may be an efficient method to develop something that is already proven to be valid and reliable. However, it is not considered the method of choice in a new and unknown territory because feedback on possible problems is presented after the tool is defined. In Section 2.2.5, PBMs for different patient populations are presented. In each of the papers, very limited information on design issues is presented. Thus, it is fair to assume that new participatory design methods have not been a common approach for development of paper PBMs. Most likely the common approach for new PBMs in different patient populations has been a process equivalent to a waterfall model. However, the new PBMs and methods of use have not evolved substantially through the last five or six decades.

The need to establish a better approach for development of healthcare technology is evident.

Participatory development methods represent a team-based trial and error approach, where sharing of knowledge and aims as well as investigations of the interaction and the potential impact of the tool have emerged [160]. This approach incorporates the aspect of user interaction in the development process, ensuring that the solution is evaluated by users, and that their preferences are taken into account. In a medical context, the participatory design method should be a preventive measure to avoid introducing poor design that could reduce the potential validity and reliability of the tool.

The role of the healthcare providers as stakeholders has become more intertwined with the process of development, where qualities such as engagement, being a dependable participant and provider of knowledge and experience from the healthcare sector in the development process, and the ability to look for opportunities and new ways of providing service are important qualities. Unfortunately, evidence shows that healthcare professionals have a proclivity to pay too little attention to, and show limited engagement in, development and implementation of information and communication technology [161]. This lack of engagement may limit the adaptability as well as the contribution of new technology in the healthcare domain [162, 163].

Consequently, to include healthcare providers in the development may be an important contribution to increase the impact of future healthcare technology devices as well as health information systems.

This thesis presents an eHealth solution, defined by the WHO as "*the transfer of health resources and health care by electronic means. It encompasses three main areas:*

- *The delivery of health information, for health professionals and health consumers, through the Internet and telecommunications.*
- *Using the power of IT and e-commerce to improve public health services, e.g. through the education and training of health workers.*
- *The use of e-commerce and e-business practices in health systems management. "[164]*

My personal interest in this research field is related to how medical information technology can cross the barriers between healthcare silos and provide access to information as well as support for decision-making for better services to more people.

3 Motivation and research questions

This project was motivated by some intertwined healthcare and health and technology related challenges in the field of pain assessment in patients with advanced cancer. This chapter will present the project aims and the research questions addressed.

3.1 Aim and objectives

The overall aim of this project was to develop a CPBM to be used for self-assessment by most patients with advanced cancer. The following specific objectives had to be met:

- To define the clinicians' need for information related to pain location.
- To develop a CPBM with consideration to the interaction challenges presented by the frailest and sickest patients, without compromising the required content of the information provided to the clinicians.
- To develop a CPBM with pervasive and ubiquitous qualities for patients and clinicians to address individual pain management. This includes a CPBM that could deliver detailed information irrespective of geographical location or time, as well as possess the advantages of an information system, such as sharing of information, processing of data, and in particular, visualizing trends or changes in the patient's pain experience.

3.2 Research questions

This project aimed to answer the following research questions (RQ).

RQ1. What are the pain and palliative care specialists' wants and needs for a CPBM?

RQ2. Are patients able to use the CPBM in a way that provides the clinicians with the necessary information?

RQ3. What are the perceived mutual benefits of the CPBM for patients and healthcare providers in clinical practice?

The research project did not follow a linear process. It was multidisciplinary and required data collection from different stakeholders and by several different methods in order to answer the research questions.

Table 2: Research questions addressed in the different papers included in this thesis

Research question	Paper 1	Paper 2	Paper 3
1	X		X
2	X	X	X
3		X	X

4 Design of the computerized pain body map for assessment of pain location

This section describes the stepwise development of the CPBM for assessment of pain location in patients with advanced cancer. To give a presentation more focused on the digital tool, I have separated this section from the method and results sections.

Development of version 1 of the program was based on the waterfall method. In this method, programming of the tool is performed according to a set of requirements delivered by the customer. Versions 2 and 3 of the CPBM were developed through a team approach that represents a different design process, in which colligated knowledge obtained in stepwise development cycles enabled a gradual trial and error approach defined as an iterative incremental process. An overview of the development processes for the various versions is given in Figure 9.

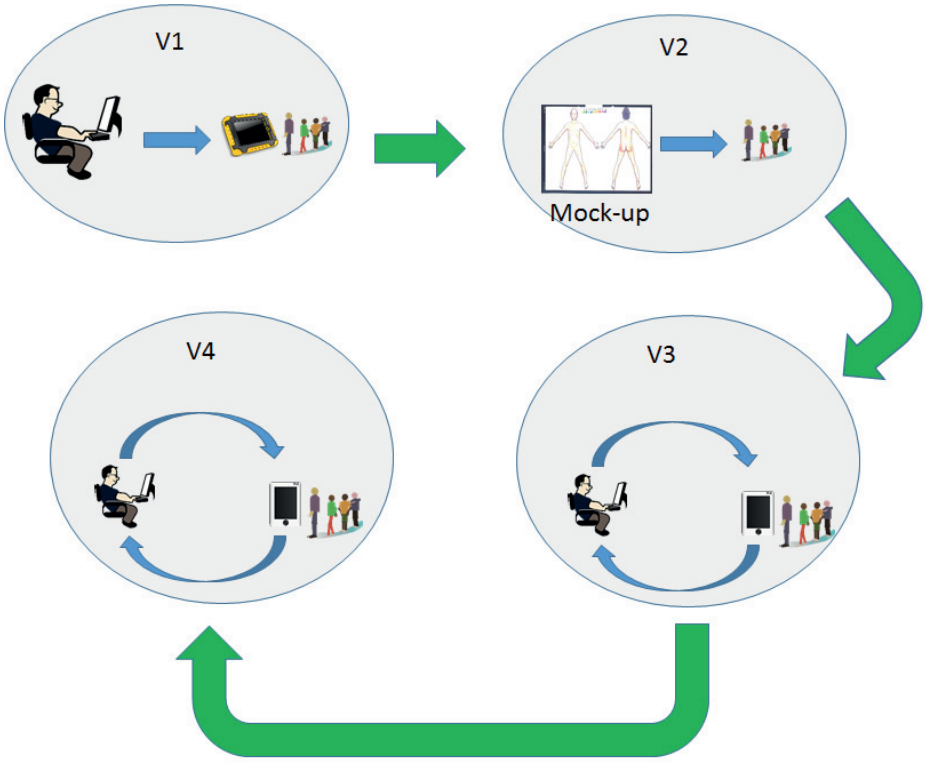

Figure 9: High-level overview of the development process of CPBM V1-4

4.1 CPBM Version 1

The aim when designing the CPBM V1 was to develop a tool that would meet the requirements from pain and palliative care specialists. We identified two sets of stakeholders based on their involvement in pain assessment and management in clinical practice. Stakeholders are presented in section 5.2.

4.1.1 Requirements

From surveying of 36 pain and palliative care experts (see Section 5.2.1), the following list of requirements was established for development of a CPBM for patients with advanced cancer.

- Content of the CPBM: pain location. Also, pain radiation and intensity should be part of the contents, although rated lower than pain location
- Projections: Whole body projections, 2 dimensional body, anterior (front)/ posterior (back) views
- Pain intensity rating should be compulsory for all patients
- For all levels of cognitive functioning, only one version of the CPBM should be made.

4.1.2 Prototype development CPBM V1

Based on the above requirements, the software vendor made three different software versions of a CPBM, which were presented to the patients. The platform was a laptop (HP Compaq TC 4200 L 1200 tablet PC) with a touch sensitive screen. Interaction with the program was made by pointing with a stylus on the screen. Patients were asked to test the three different prototype options of the CPBM. The best fit was decided by evaluating a patient survey (described further in Section 5.2.2).

The different prototype versions presented different layouts of the body (black and white, shaded gray, or shaded color versions), three options for the actual marking of painful areas, and two options for scoring pain intensity, with two different layouts/sizes of the NRS buttons.

The highest score from 28 patients was given to the shaded color version of the whole body images. The patients preferred the option for encircling and shading the marked painful area, and the larger radio buttons for selecting pain intensity.

The developer provided the CPBM V1 based on the requirements above (see Figure 10).

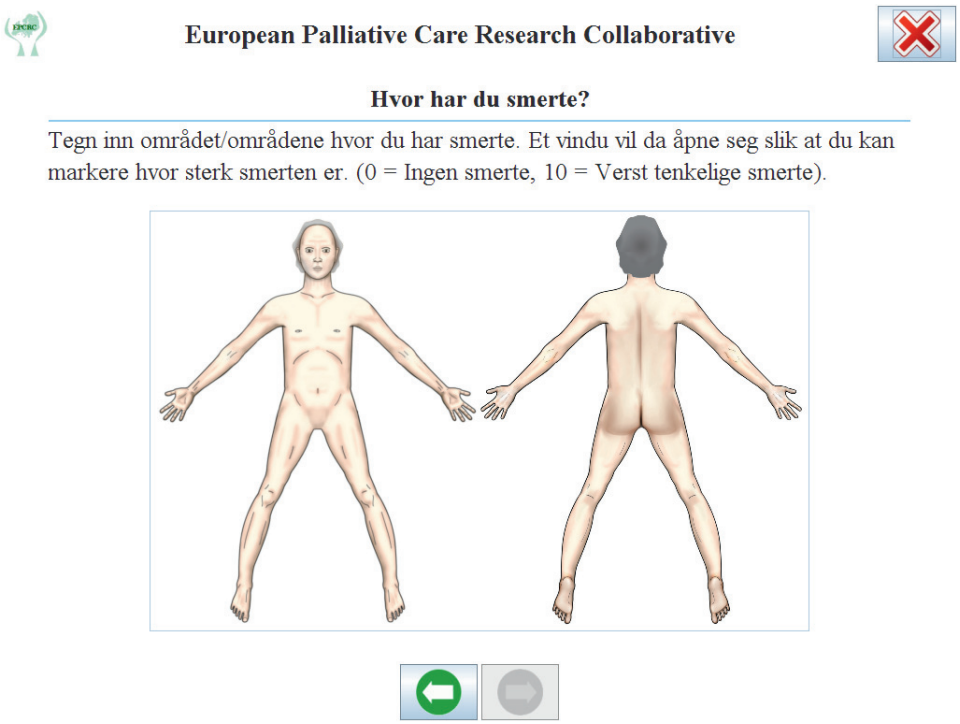

Figure 10: CPBM V1

4.2 Usability test of CPBM V1

The initial requirements for the CPBM included developing one version that most patients would be able to interact with. The CPBM V1 did not satisfy this requirement. In the following studies, the development team was reorganized, and people who were involved in the actual process of pain assessment were invited to participate as stakeholders (see Section 5.3).

New requirements to the next version of the CPBM emerged from the results of the usability studies described in Sections 5.3.1 and 5.3.2 (involving nine patients).

The following observations were made:

- Physical and cognitive impairment were the main barriers for interaction.
- The written instructions were too long for the frailest patients
- The frailest patients did not understand the content of the instructions
- Changes on the screen not made by the patients, confused them, such as the pop-up box, and the change of colors of the marked area after selecting the pain intensity
- Weight, size and quality of the laptop computer were very important for the most physically impaired

- Low responsiveness of the screen was challenging for the cognitively impaired.

Thus, the new requirements for the next version of the CPBM included the following:

- A new design framework
- Short, informative instructions
- No quick changes on the screen
- A lightweight computer platform with high quality screen and reliable responsiveness.

4.3 CPBM Version 2

The development of the next version of the CPBM was based on the requirements presented in Section 5.2 and the initial requirements from pain and palliative care specialists presented in Section 4.1.1. This version was a paper mock-up of the CPBM that eventually would become CPBM V3.

4.3.1 Patient stakeholders

For testing of the patient interface, we included 27 patients with advanced cancer. They were recruited from the Oncology Outpatient Clinic and the Palliative Medicine Unit at St. Olavs Hospital, Trondheim, Norway. The patients included were admitted to the hospital either because of intractable pain (in which case they were going to be discharged after better pain control had been achieved) or because their symptom burden was so high that they needed more surveillance and support than what was possible to achieve outside the hospital. This last group of patients was in the very last stages of life. The patient stakeholders described in this section contributed to the development of CPBM Versions 2 and 3.

4.3.2 Usability testing

The usability testing consisted of the three steps pre-test, test, and post-test (see Section 5.3.2).

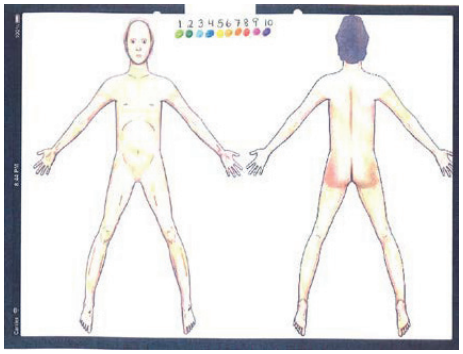

Figure 11: Mock-up for the new CPBM (V2)

Nine patients were recruited. Each patient was given oral instructions on the use of the mock-up. The instruction was to mark the mock-up PBM in a way that would make their physician understand where they had pain and its intensity.

The patients were presented with a paper containing a drawing of a human body (Figure 11). The upper part of the drawing also included a colored set of ‘‘buttons’’ with numbers from 1 to 10. Above the paper, ten coloring pencils were set up. Each pencil was numbered from 1 to 10 (the scale 1 = “mild pain” and 10 = “as bad as you can imagine” was explained to each participant), and colors and numbers corresponded with the colors of the buttons below the numbers on the paper mock-up. The paper was attached to a piece of cardboard with paper clips.

The following observations were made:

- Patients immediately understood the purpose and what they were supposed to do without further instructions, and navigated easily through the assessment
- In general, the patients interacted quite well with the mock-up
- The patients understood how to select pain intensity and pick the right coloring pencil
- The think aloud exercise did not reveal any insecurity or questions, and the system worked better in this group of patients compared to the CPBM on a laptop
- The problem correcting errors and the necessity of many components (box of coloring pencils put in the right place) made this system more awkward
- For healthcare workers, the area and location of the pain were more visible than on the commonly used paper PBM, but the lack of a good error correction system made paper as medium unreliable

From this iteration, we learned that providing an oral instruction was useful and including the purpose of making the pain drawing also seemed to be useful.

The patients easily understood that they were meant to select the pain intensity first, and then mark the location. However, we were not sure if the radio buttons meant anything to the patients.

4.4 CPBM Version 3

The development consisted of incremental iterative cycles of testing (described in Sections 5.3.3 and 5.3.4) that allowed us to tailor the CPBM program to the patients.

4.4.1 Initial version

The first iPad version of the CPBM was based on the paper mock-up. It consisted of a drawing of the human body (front and back) with a picture of coloring pencils numbered from 1 to 10. A description of pain levels (mild, moderate and severe) and a scale were presented below the pencils (Figure 12).

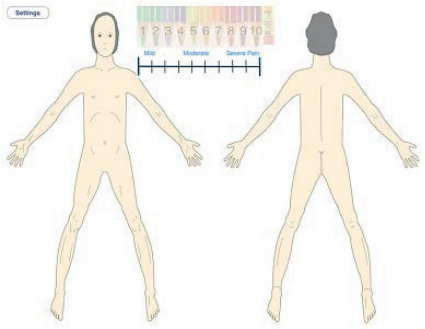

Figure 12: First iPad version, CPBM V3

Ten patients with advanced cancer were presented with the iPad CPBM V3 (initial version). The patients were instructed to mark the area where they had pain on the image of the human body so that the physician would understand where they had pain and the intensity of the pain.

Patients were instructed to select the intensity of the pain by touching the 1-10 NRS with a stylus. The NRS was implemented as an image of numbered coloring pencils (Figure 12). When selecting the numbered coloring pencil, the marking would be of the same color as the pencil.

The following observations were made:

- Three of the ten patients had no problem using the iPad and were able to figure out themselves how to pick the intensity first and then mark the painful area
- Five were able to mark intensity and area with some guidance. A common approach among these patients was that they said aloud that they intended to mark the painful areas and then started marking directly on the body without selecting intensity. When the program did not respond, they were confused. The patients were then asked to scan the content of the iPad screen, and when doing so, recognized the pain intensity scale within the image of the coloring pencils. The patients then suggested to select a number on the NRS to identify the pain intensity before marking on the body
- The patients did not understand what the scale below the NRS represented, and found it confusing. The scale was put there to aid the patients in selecting the correct pain intensity
- Two of the ten patients were not able to use the CPBM, even though both patients were considered by the clinical staff as eligible for inclusion. However, one of them was confused and was not able to follow instructions; the other was too frail to manage to give input. The reduced cognitive functioning made both understanding and navigating on the iPad impossible. The result of the cognitive test (see Section 5.5.2) for these two patients who were not able to provide input showed that they spent much more time filling in the TMT than the rest of the group

- Bedridden patients had more problems with the touch screen than the patients who were sitting at a table. These patients were tested in bed (in the following referred to as the "bed scenario") because they were too tired, frail, or in so much pain that sitting up was no option. The patients that had to be tested in bed had a lower KPS score (see Section 2.2.1) than the patients who were able to sit at a table (in the following referred to as the "table scenario").
- Patients in the "bed scenario" had no problems with the view of the screen and could identify all the contents on the screen. The iPad was light, and most patients were able to hold it while drawing. The problem arose when the patients were marking on the screen. Insufficient support for the arm made patients rest part of their hand on the iPad screen, which made further marking difficult or impossible. Providing a cover for the iPad where patients could rest their hand proved helpful
- A few tried to mark on the iPad with their finger but found the finger to cover too much of the area they wanted to mark
- We discovered that the eraser function was set too narrow, which required more precision and time when removing markings. Correction of errors was somewhat confusing, as some patients did not take the time to remove all they had marked, although it was obvious that there had been an attempt to do so, when inspecting the completed CPBMs afterwards. The trouble correcting errors was also observed during the test
- Some found the tip of the stylus to be too wide and round, and suggested we could use a more pointed stylus
- Interviews with the physicians showed that the output was clear and gave good information.

From this iteration, we learned that:

- The image of coloring pencils seemed to confuse patients and should be replaced
- It was necessary to limit the details on the CPBM screen and only include items with a clear purpose
- Evaluating the physical functioning of the patients was useful for considering possible challenges they could have when interacting with the tool
- Simple adaptations such as a cover around the iPad could improve frail patients' ability to use the tool
- Evaluating the patients' ability to use the CPBM in term of their cognitive functioning seemed to be challenging
- Patients were able to complete the TMT even if they were not able to interact with the CPBM. These patients were "outliers" in the test, and spent up to twice as long time to finish the test. This indicated poorer cognitive function
- The eraser function should be set wider to facilitate correction of errors

- The narrow line for marking represented a challenge regarding the dexterity of the patients included, and a blunt stylus tip increased this problem.

4.4.2 Final CPBM V3

Eight patients from the Palliative Medicine Unit at St. Olavs Hospital, were recruited (see Section 5.3). The final CPBM V3 iPad version consisted of the same body drawing as above (Figure 12), but the coloring pencils and scale were replaced with buttons numbered from 1 to 10 and an image of an eraser placed next to the buttons.

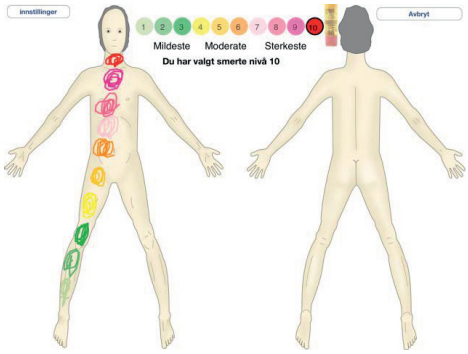

Figure 13: CPBM V3

We set the eraser function to erase in a wider line. The test setup was identical to the first iPad-based PBM test above. The patients were given the same oral instructions as before.

The following observations were made:

- From think-aloud we observed that when patients said that they intended to mark the painful area, they started by selecting the pain intensity by touching the numbered buttons. Then they went on to mark the location of their pain on the body image
- Two patients were not able to fill in anything at all due to drowsiness/sleepiness and having problems following instructions
- In both the "bed scenario" and the "table scenario", one or two of the patients wondered about the eraser function or tried to hit the button in order to see what happened. One asked for help to remove markings, and was shown to press the eraser button and use the stylus as an eraser.
- The results from the cognitive testing showed two patients who took a very long time to complete the TMT. These two patients showed limited abilities to follow the instructions on the CPBM. Additionally, these two patients had the lowest KPS scores in the study.

From this iteration, we learned that

- The change from coloring pencils to buttons worked well, as six of the nine patients had no problems related to choosing intensity of the pain and marking the painful area.
- The TMT and KPS seemed to be useful for identifying which patients were not able to use the tool.

4.5 CPBM Version 4

The aim for the new version was to tailor the CPBM program to patients with cancer related neuropathic pain. These patients often have a pain distribution that requires more detailed pain drawings, especially on hands and feet. We included 33 patients from the Oncology Outpatient Clinic at Edinburgh Cancer Centre as described in Section 5.4. All patients had advanced cancer and verified neuropathic cancer related pain.

The development consisted of incremental iterative cycles of testing (see Section 5.4.1). The process was designed as a field study with the benefit of development and testing in a realistic environment and close communication with the pain specialist stakeholders. However, this methodology provided a maximum time restraint and challenged coordination and timing.

Each iteration of testing an updated CPBM version consisted of the three steps pre-test, test, and post-test (see Section 5.3.2). The oral instruction was slightly changed to: Please *mark the painful area in a way that would make the physician understand where you have pain and the extension of your pain*.

Before marking the area, the patients were instructed to choose the correct pain intensity, displayed as a triage system of a 1-10 NRS [165]. The triage of three colors was presented as a traffic light system (NRS 1-2 green, NRS 3-4 amber, and NRS 5-10 red). Triage systems are frequently used for prioritizing between patient urgencies in emergency departments [166].

4.5.1 Iteration 1

The first iteration exposed a mock-up consisting of a menu for selection of enlarged body parts for marking of cancer related neuropathic pain, and the corresponding images for marking the pain. It consisted of a laminated paper representing a tablet and 3 markers (green, amber and red) representing the stylus. The mock-up was used to test if the patients were able to navigate through the menu and if they found the enlarged body parts to have sufficient size and details for marking their painful areas.

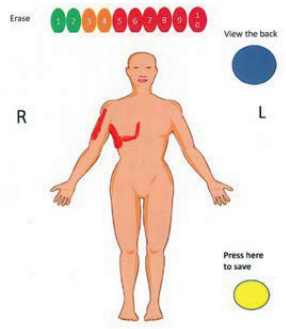

Figure 14: Mock-up of CPBM V4

Four patients were presented with the mock-up of the program. We observed in this iteration that all four found the navigation easy and that the mock-up gave sufficient area for marking their pain.

From this iteration we learned that the layout was useful, and exactly the same features were transferred from the paper mock up to the iPad for further testing. The oral instructions seemed to be understood and made the patients provide detailed pain drawings.

4.5.2 Iteration 2

The second platform was an iPad application of the CPBM, consisting of the same features as the paper mock-up (Figure 14). The iPad application was set up to transfer data through the wireless network to a server where each PBM from the individual patients was stored in separate folders.

We observed in this iteration that

- All the patients understood and were able to follow the instructions on the iPad
- Some tried to use a finger instead of the stylus for marking on the screen. This did not work well, since the finger covered the area the patient intended to mark and consequently made the marking more complicated and inaccurate
- Marking pain on the head and neck, trunk and legs presented no problem. We had chosen not to use a zoom function to present enlarged body parts, but rather present a menu of oversized images of body parts for patients to choose from
- The image of two arms unattached to the upper body presented some problems related to locating the intended side (left or right) for the patients
- The patients considered the NRS scale easy to use.

From this iteration, we learned that

- The stylus gave patients more control over where to mark. This was particularly important when marking small areas like fingers and toes for neuropathic pain

- The NRS scale seemed to work better together with the triage system and patients commented that it was easier to select an intensity with the help of the three colors.

4.5.3 Iteration 3

During this development iteration, we included patients with pain in different regions of the body. We investigated their ability to make accurate pain drawings as well as the responsiveness of the program. The final product of the program worked smoothly and we did not observe any patients with difficulties identifying what they perceived as the correct area for marking their pain. This observation was from the think-aloud and the observation of the patients' interaction with the program on the iPad.

During development iterations 2 and 3, the iPad application was set up to transfer the data to a web server. The data was intended to be used by the healthcare provider. The server program should process and present the patient data as well as include an archive for the data, which enabled display of series of registrations. During the development of this function, we did not actually do longitudinal testing with patients since the study was performed in an out-patient clinic, and longitudinal testing would have required the patients to be frequent visitors. The web application could be accessed on any computer, provided it had network connectivity. The patient data from the iPad is transferred as bitmaps[11] to the server where the data is processed to calculate extension, cartographic location and radiation based on dermatomes. The data was displayed as graphical annotations on identical body images as on the iPad, and also in a table. The web application displayed patient drawings from a series of registrations either as a layered presentation showing the composite changes in pain registrations over time (Figure 16), or as a side-by-side presentation of the individual body maps (Figure 15). The system allowed the physician to trace the pain location and to identify changes in intensity from a table, or listed on the screen above the CPBM, as well as offering the option to annotate the patient drawings. The visualization of the patient data was designed to include changes in pain intensity calculated from the highest pain score on the previous assessment, extension of the marked area in percent of available surface, as well as the exact location of the marked area in relation to body dermatomes.

[11] Bitmap is a representation of an image in computer science. The components of a bitmap are pixels, which can be classified as each dot in an image. The pixels represent a predefined number of different colors.

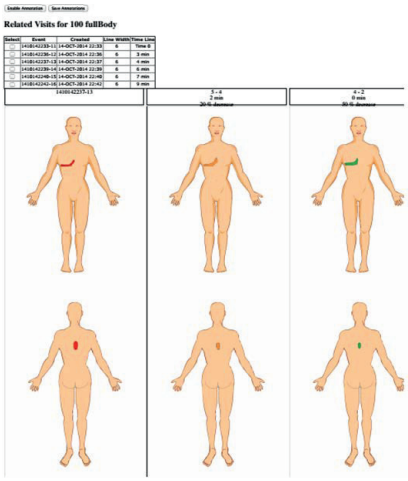

Figure 15: Side by side presentation on the clinician's web page

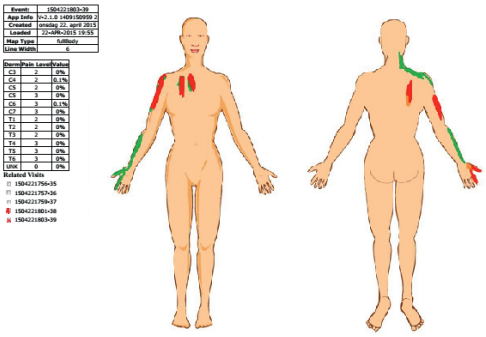

Figure 16: Layered presentation from the clinician's web page

5 Material and methods

In this chapter I will present the material and methods used to collect empirical data to respond to the research questions. The content of this chapter is organized according to the three included papers. The different study methods are categorized and justified, and data analysis is described. The last section in this chapter presents the specific research tools, and ethical considerations.

This research can be described as a translational research project, often referred to as a T2 type project. T2 type research is defined as research translating the findings from clinical trials into everyday practice for improvement of health [167]. The translational research design implies a mixed methods approach [167]. This is defined as the combination of qualitative and quantitative methods that focus on different aspects of the project's outcomes. Qualitative methods can be used to explore a new area such as how patients with advanced cancer interact with a computer and a software program for assessment of symptoms. Quantitative methods can be used to investigate if variables identified and tested in a clinical study are representative and valid.

At the inception of this project, there was limited evidence available on how patients with advanced cancer interact with a computerized assessment tool. Consequently, qualitative methods have been important in this work.

The following empirical studies are included in the present project:

One pilot study (Paper 1) - RQ 1

Two feasibility studies (Papers 1 and 3) - RQs 1, 2 and 3

One comparative study (Paper 1) - RQ 2

Two exploratory studies (Papers 2 and 3) - RQs 1, 2 and 3

Table 3: Overview of the included studies in this thesis.

Paper	Study design	Population	Method	Outcomes
Paper 1	Pilot study Feasibility study Comparative study	Clinical experts Patients with advanced cancer having pain ≥ 1 on an NRS* National and international patient populations	Hands-on testing Survey Statistical evaluation Test-retest reliability test Inter-rater reliability test	Feasibility Reliability
Paper 2	Exploratory field study	Patients with advanced cancer having pain ≥ 1 on an NRS. From a palliative care unit, Norway	Usability testing. Incremental iterative design study Survey	CPBM*** version 3 Requirements related to ergonomics and cognitive and physical functioning Usability Reliability
Paper 3	Exploratory field study Feasibility study	Patients with advanced cancer, LANSS** score ≥ 12 and verified NP**** in a clinical examination From outpatient cancer clinic, Scotland Healthcare providers from Norway and Scotland	Incremental iterative design study Usability testing Survey Focus group interviews	CPBM version 4 Support for pain communication for patients with NP**** Characterization of a work process supported by the CPBM system

*NRS Numerical Rating Scale
** LANSS Leeds Assessment of Neuropathic Symptoms and Signs
***CPBM Computerized Pain Body map
****NP neuropathic pain

5.1 Research methods

The European Palliative Care Research Collaborative (EPCRC) [13] was a translational research project funded by the European Commission 2006-2010. One of the project's main objectives was to develop a computerized tool for assessment and classification of cancer pain, including a CPBM. The EPCRC Computerized Symptom Assessment (CSA) study was the main empirical data collection of the EPCRC project. This was an international multicenter study with eight participating countries; Norway, United Kingdom, Germany, Italy, Canada, Austria, Australia and Switzerland. The patient population consisted of patients who were ≥ 18 years old and had a verified diagnosis of cancer in the advanced stage. Patient inclusion started in 2008, and was closed in 2009. The main focus of the EPCRC-CSA study was to gain knowledge on assessment and classification of cancer pain, by use of an extensive set of questions related to pain, depression, nutritional intake, need for assistance, and

cognitive functioning; i.e., symptoms and conditions that are commonly experienced by patients with advanced cancer [168]. In addition, demographic data and data on physical functioning, medication, cancer diagnosis and treatment was provided by the care team [168].

The three studies in Paper 1 were partly conducted as an integrated part of the EPCRC-CSA study (the survey and feasibility study), and partly as an add-on study (the comparative study).

5.2 Paper 1

The patients in the pilot testing study were recruited from the Oncology department at St. Olavs Hospital, Trondheim, Norway. It was a convenience sample of patients from the in- and outpatient clinic.

Patients included in the feasibility study in Paper 1 were patients with advanced cancer who reported pain ≥1 on a 0-10 NRS. They were included from palliative care programs in Norway, UK, Germany, Switzerland, Austria, Italy, Canada and Australia.

The comparative study was an add-on to the EPCRC-CSA study (the feasibility study), where data for the Norwegian patients included in the latter was re-used in addition to new data. However, the sample was supplemented by nine patients who were too frail to complete the main study. The comparative study included patients from the Palliative Medicine Unit at St. Olavs Hospital, Trondheim Norway. The inclusion criteria were the same as for the feasibility study.

All patients were only included once.

5.2.1 Survey

The first methodological approach in this thesis was a survey. This type of data collection is inexpensive, efficient and systematic, and well suited to collect data both nationally and internationally. Respondents were recruited by email from national and international networks of pain and palliative care specialists. They were approached because of their long clinical and research experience in the field.

The first survey was an expert survey to guide the development of a CPBM. A web-based questionnaire was used, containing targeted questions on the contents of a CPBM (importance of including pain location, extension, radiation, intensity and character) and necessary projections of the body (anterior, posterior, lateral views, sole of foot, palm of hand, oral cavity or 3 D body) for use in the graphical user interface. The survey also contained questions about the functionalities of the program, e.g., if each pain location should include a measure of pain intensity. The questions were developed in understanding with an expert panel within the EPCRC, and consisted partly of open questions for the participants to elaborate on, and partly questions with categorical answers (yes or no). In addition, the experts were asked to rate their level of agreement with a series of statements, scored on a 0-10 NRS

(0 = lowest agreement and 10 = highest agreement). The survey method was selected because it allowed us to reach a wide group of experts in a short period of time.

5.2.2 Pilot testing

A pilot testing study was conducted as a part of the software development for the first prototype of the CPBM. Patients included in the pilot study in Paper 1 were patients with incurable metastatic or loco-regional cancer disease and tumor-related pain. Patients did hands-on testing of three different prototypes of a CPBM based on the requirements concluded from the expert survey described above. The different prototypes were colored or black and white images of a gender-neutral human, with different options for marking of pain intensity. The patients were presented with the different CPBM prototype versions followed by a questionnaire assessing their preferences. The questionnaire covered the patients' preference for different graphical user interfaces related to projections of the human body, and the size of the NRS buttons for selecting pain intensity. The response options were partly to select between alternatives A, B and C, and partly free text to comment on the choices.

5.2.3 Data collection in the comparative and feasibility studies

Patients in the EPCRC-CSA study responded to the questions directly on a computer touch screen by tapping with a stylus to select the answer. To be included in any of the two PBM studies (feasibility and comparative studies), patients were asked a question about their worst pain the last 24 hours. Patients entering pain ≥ 1 were directly routed to the CPBM version 1 (V1).

The first question was "*where do you feel pain*", followed by a request to mark the painful area(s) on the CPBM. During the marking on the screen, the program would shade the marked area in gray on the CPBM V1. After having marked the painful area and lifted the stylus from the screen, a pop-up box would appear (Figure 17), instructing the patient to select the correct pain intensity for the marked area.

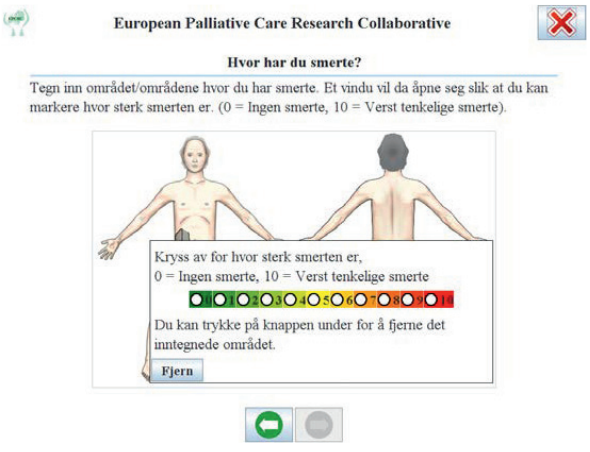

Figure 17: Pop-up box for pain intensity on CPBM V1

Pain intensity was selected on a 1-10 NRS. Each button representing a number on the NRS was programmed with a color that automatically shaded the marked area with the corresponding color when the patient was done. Then the pop-up window disappeared and the patient could proceed to the next page by pressing the arrow at the bottom of the screen. Each patient could mark an unlimited number of areas.

The study was conducted to assess the feasibility of the first prototype of the CPBM. The software program was intended to be used by the patients as a self-report assessment tool for pain location and intensity. Feasibility of the CPBM V1 was defined as the patients' ability to provide unequivocal information to the physician. Additionally, we wanted to examine if the patients' ability to use the tool was associated with any specific sociodemographic variables.

Feasibility was assessed in relation to age, performance status, cognitive functioning, educational level and computer experience. The completed CPBMs V1 were evaluated by two physicians. The CPBM from each patient was given a specific code for identification. Both physicians examined all CPBMs and made separate lists with anatomical descriptions of all areas that were marked on each body map. The lists with the anatomical descriptions were compared, and each CPBM classified as acceptable, based on whether the markings gave meaning to the physicians. In case of discrepancies between the interpretations of the anatomical location made by the physicians, the original pain drawing was consulted.

Differences across the patient groups in the feasibility study and the comparative study were investigated using Pearson's Chi-square as well as t-tests for the categorical and continuous variables. Data on descriptive variables was presented as means and standard deviations. All statistical calculations in Paper 1 were performed using the PASW 18 statistical package (SPSS Inc., Chicago, IL).

The aim of the comparative study was to compare the information on pain location on the CPBM and a routinely used paper PBM filled in by each patient. The method described is a test-retest and inter-rater reliability evaluation of the tool. This has been a frequently used method to evaluate reliability of paper PBMs in different populations [117, 123]. In similar research projects, such as described by Margolis et al. [117]. and Lacey et al. [123], this method is normally the method of choice. Using the same method makes it possible to compare the results in this study with evidence in the literature.

Patients were presented with either the paper PBM or the CPBM in a pre-assigned random order, and filled in the second map (paper or CPBM) after a break of 20-30 minutes.

The assessments of all patients in the main EPCRC-CSA study included the MMSE [81] (described below in Section 5.5.2). For the additional nine patients not participating in the full EPCRC-CSA study, the MMSE was performed between the two pain drawings.

Two physician specialists examined the two pain body maps in the same way as in the feasibility study above. However, in this study the aim was to compare the CPBM V1 and the paper PBM. Each patient's pain drawings were identified with a code, and separate lists identifying the anatomical site(s) for each of the pain body maps was made. We defined the CPBM and the paper PBM as alike if the location and number of areas corresponded. The assessment of whether or not the two maps could be considered identical was made at the same time as the inter-rater reliability test was performed. Test-retest evaluation of CPBM / paper PBM: Each patient was identified with a unique code for paper PBM/ CPBM. Each specialist created two lists per patient code, one list detailing anatomical descriptions from the paper PBM, and one with descriptions from the CPBM. The two lists from each specialist containing the code and the anatomical descriptions were compared. The descriptions had to be the same for location and number of pain sites.

Inter-rater evaluation: The same method as above was used, describing each anatomical location independently by two specialists. Location and number of sites on both paper PBM and CPBM were compared to verify whether the two specialists arrived at the same interpretation.

5.3 Paper 2

The studies in Paper 2 included 36 patients from the Palliative Medicine Unit at St. Olavs Hospital, Trondheim, Norway. The inclusion criteria were advanced cancer, pain ≥ 1 on an NRS, and ability to provide informed consent for participation.

5.3.1 Usability study of CPBM V1

The usability test method was chosen because the previous studies had made it clear that the selected variables for patient interaction and software functionalities did not provide statistical evidence for association, and the evidence showed a need for closer evaluation of the variables. We suspected that other variables might be more relevant for the feasibility of the tool. Additionally, we needed more knowledge on the software program and the platform. Consequently, the focus of our methods changed from a more quantitative to a more qualitative approach.

Usability testing is a method to evaluate the user-friendliness of a product [169]. It should be performed with representative users and in a standardized way. Data collection from several sources is highly advantageous (observation, audio-video recording, and survey). A usability test can be performed as a standardized laboratory test where the test environment and the procedure are standardized for each participant. Alternatively, testing software and a mobile platform solution in a realistic environment as a field study is also recommended [169].

Some of the test participants in our study were too frail and burdened by disease to be transported to a laboratory. In addition, many of them had symptoms such as shooting pain, fatigue, or problems sitting or lying down. These symptoms could be constant or intermittent. For these reasons, we were

not able to provide a "standardized" test situation. To minimize the burden on the patients we visited them in a place of their choice, and performed the testing where they felt comfortable. This was either in their hospital room or at the out-patient clinic; sitting up at a table (the "table scenario") or lying in bed (the "bed scenario"). Thus, we have defined our test as a field study.

The object for testing was the CPBM V1 that ran on a touch screen laptop computer (HP Compaq TC 4200 L 1200 tablet PC). For audiovisual recording, we used a version of Camtasia studio installed on the same laptop.

5.3.2 Procedure for usability testing of CPBM V1-V3

The usability testing of the CPBM performed in Paper 2 comprised three steps. First, we conducted a pretest interview, collecting demographic information about the patient. The next step was the actual testing of the CPBM, which included a think aloud test (described in Section 5.3.5) with audio recording, as well as video recording from a screen capture device showing the patient interaction with the screen. The last step was a posttest interview and a cognitive test. This procedure was used for the usability test of CPBM V1 as described above, and for the subsequent versions described in the following.

The test persons were well instructed and aware of their role in the process of testing "something". During the test session, the test person was instructed that the observer would not provide assistance, but any problems could be discussed after the test. In order to follow the test persons' reasoning, the "think aloud method" [169] was used during the test session. The think-aloud method is based on verbalizing all thoughts during the test session (see Section 5.3.5).

The posttest interview was intended to discuss any problems that were observed, or answer any questions from the test subjects. Additionally, we asked the test person about any thoughts or ideas for improvement. An integrated part of the test was a cognitive test procedure, the Mini Mental State Exam (MMSE) [81] for the usability test of CPBM V1, and the Trail Making Test (TMT) [82] for the following versions. Both tests are described in Section 5.5.2

None of our tests included time measures. This was because the patients' conditions affected them in various ways and led to interruptions during the test sessions. Some had to take a break due to shooting pain, others were drowsy from opioids or the disease itself, and had to rest. Consequently, we decided that time measurement would not be a valid measure.

Evaluation of the process was made by analyzing the audiovisual data (including the think aloud test) together with the final results of the interaction on the screen. The audiovisual data was consulted in case the interaction was not understood, or as visualization to the rest of the research/ development team.

5.3.3 Procedure for incremental iterative design

The usability testing of CPBM V1 (Section 5.3.1) provided some evidence of "what does not work" in a patient population such as ours. Consequently, it was necessary to re-design the CPBM to improve interaction with the patients in our population. We aimed to develop a CPBM based on the requirements from the international pain specialists and with focus on bridging the challenging situation of our patient population with a design and platform that were better adapted to the patients' needs.

5.3.4 Incremental iterative design study

Incremental iterative design is a common method of software development based on involving users in the development using a trial and error approach. The trial and error approach is applied in a usability test (described in Section 5.3.2 above), where prototype testing and gradual implementation of the intended functionalities are performed. This is a collaborative approach that requires close communication between all participants. In our case, domain knowledge on patients, disease and, symptoms as well as requirements for the assessment tool were needed. Furthermore, knowledge of the process of assessing patients was vital. We also needed someone to make design proposals that could be used in our patient population based on all the domain knowledge described. All this domain knowledge should be communicated within a development team in order to come to a common understanding. The reason for this was that we all needed to create a vision of how this tool could be used in a healthcare organization with patient-centered service in the future. The development process is a learning process for a well-structured team, where everyone is responsible, as described by Kensing and Munk-Madsen [170] and Steen [171].

Figure 9 illustrates the overall process through which the various versions of the CPBM were developed and tested. The initial mock-up prototype of the CPBM (V2 in Figure 11) was made on paper. The tool was tested on a group of users in a usability test as described above, collecting the same data as described in section 5.3.1 (usability test including think aloud). The interaction with the prototype was evaluated through observation, interview, survey, and audiovisual recording, supplemented by cognitive testing and evaluation of physical performance. During the first iteration we developed and tested the paper mock-up (CPBM V2). The same features were transferred to the tablet computer (V3 in Figure 9), and the graphical user interface was refined through two iterations of the CPBM V3 development cycle. As a part of the usability test, the functionalities and patient interaction were evaluated. The functionalities and/or the graphical user interface were changed if needed, and re-tested in a new iteration of the cycle until the patients were able to use the tool, and the errors in the program were identified and removed. The first iPad version of the CPBM presented in this paper was V3. The same data was collected and evaluated in each iteration of the development cycle.

We made one change in the usability test procedure between the usability test of the laptop version and the development of the new iPad version of the CPBM. This was to exchange the MMSE with the

TMT. Both cognitive tests are described below in section 5.5.2. The reason for this change was that the information provided by the MMSE did not help us to define patients with cognitive problems without overburdening the frailest patients. This was related to observation of interaction with the CPBM V1 and impressions from communicating with the patients, indicating that some patients had cognitive problems, although the results of the MMSE were within the normal range. Additionally, the frailest patients had difficulties completing the MMSE, but were able to use the CPBM. The MMSE test is a global cognitive test providing basic information about several cognitive functions. This was not required knowledge in our study. However, we needed a simple test measuring attention and speed of the participant as well as putting less burden on the patients. Thus, the TMT part A was selected (see Section 5.5.2).

The data from the interviews was compared and categorically grouped into the specific interaction problems. In paper 2, the observational data was first evaluated for each cycle. Then the overall results from each cycle were compared.

The qualitative data was used as evidence for the need to improve the software in each cycle or as evidence for a well-functioning software with sufficient usability for patients. We also used the data to characterize the patients.

5.3.5 Think aloud

During the usability test, patients were instructed to think aloud [172] [160]. The test participants were encouraged to speak all thoughts aloud to let the observer understand their reasoning, what they intended to do, and how. They were instructed that any questions that might come up during the test would be answered after the test. The audiovisual recording would capture their "monologue" for use in the evaluation of the interaction. The think aloud test was an important part of all usability tests performed in this study.

Audio and user interface interaction during the test was recorded using screen capturing software in Paper 2. The audio recording could be played from the screen capture device in Paper 2 in case of uncertainties of patient interaction with the CPBM.

5.4 Paper 3

5.4.1 Incremental iterative design study

The aim of this study was to adapt the CPBM V3 to meet the needs of patients with cancer related neuropathic pain.

The patients in this study were included from the Oncology Outpatient Clinic at Edinburgh Cancer Centre, UK. The main inclusion criterion was cancer related neuropathic pain, which was defined by

screening for neuropathic pain using the LANSS questionnaire [104]. The neuropathic pain was verified through a standard clinical examination.

In Paper 3, the CPBM developed in Paper 2 was modified to fit the needs of patients with neuropathic pain. This was done by enlargement of the body map images. During the iterative testing, the application was set up to identify and measure the marked area (as projected onto the body surface, as usual), but also to define its neuroanatomical location based on the defined segmental cranial and spinal nerve innervation of the skin. Additionally, the CPBM V4 program was extended to submit data to a server. The method was incremental iterative design as described above.

Through each iteration almost the same three step data collection method as described in Paper 2 above was followed, but two adjustments were made. Due to time restraints and because the outpatient sample was perceived to have better cognitive functioning, cognitive testing was not performed. Audiovisual recording was not feasible because the screen capture device used in the previous testing was not updated and a new application was not available. Also, a camera for audiovisual recording was not permitted in the out-patient clinic for confidentiality reasons. Thus, the observer had to make written notes from the think aloud test during the testing. These notes were consulted if any information was not clear.

5.4.2 Survey

The exploratory study described above provided information about the patients' interaction with the tool. Additionally, data was collected from two standardized surveys, the System Usability Scale (SUS) [173] and the Technology Acceptance Model (TAM) [174]. These surveys collect data on usability of the tool (SUS) and the perceived usefulness of the tool (TAM). TAM was filled in by both patients and healthcare providers. The data collection was based on patients' perceived usefulness of the CPBM and the healthcare providers' perceived usefulness of the CPBM system (consisting of the tablet-based CPBM and a web-based healthcare provider interface). Both interfaces are described in Section 4.5.

Descriptive data was processed using SPSS version 21 (IBM Corp. IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY).

5.4.3 Feasibility study

The aim of this study was to elicit the opinions of different specialist physicians about the CPBM system. This included what information they perceived to get from the system and their thoughts on how to use a system like this. Additionally, we wanted information about the requirements for a software system to support pain assessment in patients with advanced cancer.

The feasibility study in Paper 3 included specialist physicians working in palliative care or oncology, or GPs serving patients with advanced cancer. The included healthcare providers were recruited from

three different geographical regions in Norway and two regions in Scotland. The recruitment was based on inviting one from each site and asking them to recruit minimum two other healthcare providers from the same field of service.

The focus group interview is a method for qualitative research used in a small group of people. The group discussion allows for a wider reflection than in individual interviews, and can be useful when wanting to explore an idea or a topic [175]. A focus group interview can provide more extensive and in-depth information than a questionnaire. The method is preferred when the research topic is not well known and reflections in the group can trigger further discussion and interaction that can lead to a deeper understanding of the topic [175]. In order to obtain relevant data the group must be purposefully selected and facilitated in a good way. In our study, the focus group interviews were planned and facilitated by one of the researchers[12] who was experienced in this method [175]. The interviews were guided by a semi-structured interview guide, and aimed to elicit the perceived usefulness of the CPBM, both in terms of facilitating pain communication and supporting clinical decision-making. The participants were asked to discuss aspects of a patient scenario and the CPBM system based on their own professional experience.

In this study, focus group interview was the method of choice because of the novelty of the CPBM concept. We expected that the composite experience of a group with regard to important aspects of pain assessment would exceed the experience of the individuals, and thus provide a better and more critical evaluation of the CPBM system. The brainstorming of ideas, discussion between colleagues on pros and cons, and the resulting critical evaluation would probably make the group able to cover more topics than the sum of individual contributions.

Each group interview was verbatim transcribed by a professional transcriber. After re-reading the contents, the transcribed data was organized in categorical themes. The categorical themes were further analysed and grouped into main themes in an iterative process between two researchers [175].

5.5 Software, tools and analysis

5.5.1 Program platform and software

In Paper 1, we used a touch screen laptop computer (HP Compaq TC 4200 L 1200 tablet PC).

The CPBM V1 was a Java application developed using the Eclipse integrated development environment, compiled to run on a Windows XP operating system.

In Papers 2 and 3 we used an iPad 2 and an iPad 3 (Apple Inc). The CPBM versions 3 and 4 were developed using x-Code, and were successively updated to run on iOS versions 5-9.

[12] Kristin Halvorsen PhD

To record audiovisual data, we used a laptop-installed version of Camtasia studio in the first usability test in Paper 2. For usability testing of the iPad versions of the CPBM in Paper 2, we used a beta version of a screen capture application for iPad.

The clinician web interface was implemented as an Oracle database using PL/SQL.

5.5.2 Assessments

In this project, we have used a range of different assessment tools and different ways to describe and classify the patients, quantify usability, and quantify the perceived usefulness of the CPBM. The employed questionnaires have been developed for use in clinical practice and clinical research or for software development. The different assessment tools are presented in the following sections in categorical order.

The first two physical performance indexes, KPS and ECOG, are described in Section 2.2. Both scores are normally based on a clinical evaluation by a healthcare provider.

Cognitive functioning

The **Mini Mental State Exam (MMSE)** [81] is a global cognitive screening test originally used to screen cognitive function in psychiatric patients, but is now used in other medical disciplines as well. The test assesses different cognitive functions such as orientation, registration, attention and calculation, recall and language [81]. The test consists of seven different categories and a total of 20 questions, with a maximum score of 30 points. Normally, it takes between 10 and 15 minutes to answer the questions; however, this depends on the cognitive functioning of the patient. The patient completes the test as a combined self-assessment/ oral response, and to verbal questions as well as copy of two geometrical figures. The score is calculated by the clinician. A score below 25 points may be indicative of cognitive impairment.

The **Trail Making Test (TMT)** [82] is a cognitive test measuring cognitive functions such as visual search speed, scanning, and speed of processing, mental flexibility, and executive functioning. The test consists of two parts, A and B [176]. Test A consists of the numbers 1-24 randomly spread on a page (either a piece of paper or the electronic equivalent). The test person is instructed to link the numbers in consecutive order. Performance is measured in how many seconds it takes to finish the task. Test B consists of numbers and letters on one page. The test person is asked to draw lines alternating between numbers and letters in consecutive order.

In our research, TMT part A was used in a patient sample in Paper 2. The TMT part B was not used in our studies because it was considered too complicated for the frailest patients.

Assessment of pain

The **Leeds Assessment of Neuropathic Symptoms and Signs scale (LANSS)** is a questionnaire designed to screen patients for neuropathic pain [104]. The questionnaire consists of seven questions, and assesses 12 characteristics of neuropathy, which patients respond to with yes / no, or by selecting the most appropriate statement out of two. The time frame under consideration is the preceding week. Maximum score is 24; a score equal to or above 12 suggests pain is believed to be predominantly of neuropathic origin.

In Paper 1, a subsample of patients included in the EPCRC study was included. The inclusion was based on their response to a screening question about pain taken from the BPI questionnaire [103, 106] (see Section 2.2.2). The question was "Please rate your pain by marking the number that best describes your pain at its worst in the past 24 hours". The patients were presented with a 0-10 NRS anchored with 0 = "no pain" and 10 = "pain as bad as you can imagine". Entries ≥1 were directly routed to the CPBM V1.

In Paper 2, we included patients who were screened by the station nurses based on a 0-10 NRS assessment for pain right now. On the CPBM, patients were given a 1-10 NRS without any written anchors. The 0 for "no pain" was not included, since "no pain" would not require an entry on the CPBM. The NRS was provided with a color code ranging from shades of green between 1 and 3, shades of orange between 4 and 6, and shades of red above NRS 7.

In CPBM V4, pain severity was denoted in two different "modes". The default setting was highlighted by a triage of green, amber and red color, marking the levels of pain (mild, moderate and severe). NRS values 1-2 were marked green, NRS values 3 and 4 were highlighted amber, and NRS values 5-10 were highlighted in red color. The second "mode" had the same color code as CPBM V3.

Usability assessment

The **System Usability Scale (SUS)** is a 10 question long self-report questionnaire developed for software engineering, assessing how well the user finds the application/service to be adapted to his/her needs and abilities [173]. The main aspects are effectiveness (whether the user can use the application for the intended purpose), efficiency (whether it is easy to use, or the user needs help filling it in), and satisfaction [173]. Patients rated their agreement to the statements from 1 (strongly disagree) to 5 (strongly agree).

The **Technology Acceptance Model (TAM))** is a questionnaire assessing perceived ease of use and perceived usefulness of a product [174]. TAM was originally developed to assess social/psychological behavior, and adapted to understand information technology (IT) use and behavior [177]. In Papers 2 and 3 questions about perceived usability were taken from the TAM questionnaire and used to assess the healthcare providers' views on the whole system (the CPBM and the clinicians' interface). In paper 3, the TAM questionnaire was also used to assess the patients' perceived usefulness of the

CPBM V4. Answers were scored on a 1-5 NRS (1 = strongly disagree; 5 =strongly agree). Originally, TAM was intended to provide a prediction of the users' intention to use a product. This requires use of the whole questionnaire, which we did not. This was mainly because we presented a prototype where the clinicians were not allowed to test the system in their own patient population. Thus, to do calculations of true values of perceived usefulness did not seem appropriate. Instead, we calculated the mean score for each item. In the questionnaires for both patients and healthcare providers, we included one additional question about using the CPBM for sharing of information. These questions were developed within the research group.

Demographic information and computer literacy

As a part of all three studies (Papers 1-3) we collected demographic data such as years in school, highest academic, and age and gender. In Paper 1, we also asked the participants to self-assess computer experience in the range [none, a little, some, a lot]. In Papers 2 and 3, we asked the participants about actual use of digital tools as well as assessed frequency of use. The response options were limited to four choices on a scale between "never used a smart phone" to "daily use of smart phone". We also asked about level of education on a scale between "less than 12 years of schooling" to "university degree".

Ethical considerations

The studies conducted in Papers 1, 2 and 3 were all subject to ethical evaluation. Approval from the Regional Committee for Medical and Health Research Ethics, Central Norway, was obtained for the studies included in Papers 1 and 2. The patient study in Paper 3 was approval by South East Scotland Research Ethics Committee 01.

All patients were given oral and written information about the study, and gave written informed consent. They were informed that withdrawal of consent was possible at any time.

6 Study results and conclusions

In this chapter, I will present a short summary of the results and conclusions of each of the three papers included in this thesis.

6.1 Paper 1

Development and Testing of a Computerized Pain Body Map in Patients with Advanced Cancer

Ellen Anna Andreassen Jaatun, Marianne Jensen Hjermstad, Odd Erik Gundersen, Line Oldervoll, Stein Kaasa, and Dagny Faksvåg Haugen

Introduction

This study was performed as a part of the EPCRC-CSA study, a large international, multicenter study that aimed to continue previous work on development of a computerized pain assessment tool by developing a tool for assessment of pain location for clinical work and research. The first aim of Study 1 was to develop a CPBM in which the content should be guided by international pain and palliative care experts, and the graphical user interface selected by the patients.

The second aim was to evaluate the feasibility and reliability of the tool in an international population (feasibility study) and a national population (reliability in a comparative study) of patients with advanced cancer.

Results

International pain and palliative care specialists (n= 36) agreed on the required content of a CPBM for assessment of pain location, radiation and intensity. The highest score was given to full body anterior and posterior views for projections on the screen (as the graphical user interface).

The graphical user interface was tested and evaluated by patients from the Oncology department at St. Olav Hospital in Norway (n= 28). The CPBM V1 was developed based on the results from this pilot testing.

The feasibility of the CPBM V1 was evaluated in an international group of patients with advanced cancer (n=533). The majority of patients provided acceptable CPBMs (85%). We were not able to detect any statistically significant differences when comparing the groups with acceptable and non-acceptable maps with regard to gender, age, and physical or cognitive functioning. However, in this study we were not able to get positive confirmation from the responsible study managers at each site

that the patients actually had completed the CPBM themselves, and from the survey data of the main study, there seemed to be a large number of patients who were provided help from family and friends.

Identical paper PBMs and CPBMs were provided by 65 out of 92 patients (71%). However, on many of the CPBMs, patients had made markings that were difficult to interpret, such as markings that were made outside the body outline, on top of other markings or with a color that did not correspond to any number on the NRS. Consequently, these markings had to be errors, reducing the validity of the test results.

The patients' evaluation of the computerized tool was positive.

Conclusion

Patients had a positive attitude toward using the CPBM, but we had too limited information about the patients' interaction with the CPBM and the program. Thus, a different approach to investigate the usefulness of the tool was needed.

6.2 Paper 2

Designing a reliable pain drawing tool: avoiding interaction flaws by better tailoring to patients' impairments

Ellen Anna Andreassen Jaatun, Dagny Faksvåg Haugen, Yngve Dahl and Anders Kofod-Petersen

Introduction

The previous paper left many questions unanswered and we needed to find a new approach to evaluate the CPBM presented in the previous paper. The results gave doubts as to the usability of the CPBM, and questions about the need to re-design the tool. This study was an exploratory study aiming to investigate the usability of the CPBM from Paper 1 and to use the results to re-design the tool. Additionally, we aimed to test the new version of the CPBM also in patients in the last phase of the cancer disease trajectory, in order to tailor the tool to their needs.

Results

We included 36 patients and eight physician specialists in this study. The usability test uncovered difficulties related to interaction with the first version of the CPBM. These were ergonomic problems with the platform, malfunctions of the program, as well as poor function of the touch screen. Based on these findings we created a list of requirements for the next version of the program.

The MMSE test did not seem helpful in classifying patients who had difficulties using the tool, as several patients classified as having "no cognitive impairment", still had difficulties using the

program. The range of the MMSE scores did not vary although the ability to use the CPBM V1 showed large differences in the test population.

Re-design of the CPBM was performed through three incremental iterations, testing three different versions of the product: Mock-up, iPad minor version 1 and iPad minor version 2 (CPBM V3).

We changed the method for measuring cognitive function to TMT. From this test, we were able to see how time to finish the TMT test corresponded with the patients' ability to use the tool. We were also able to identify some patients who were not able to use the tool. These patients were confused and had great difficulties following any instructions.

The ergonomic problems of the previous platform (laptop) were reduced by using a tablet computer. We put a cover around the iPad to improve support for the hand when needed. With the iPad, the weight of the tool and the responsiveness of the screen were not a problem. The program was designed to resemble drawing with a pen on paper. This worked well in our patient population.

The last survey evaluated clinicians' views on the CPBM system. Their views were very positive in terms of perceived usefulness.

Conclusion

The CPBM V1 had limited reliability, especially for patients burdened by advanced disease**.** Both the platform and the software program showed substantial limitations especially for the patients who were cognitively impaired. Additionally, the physical restraints made the laptop too bulky and the quality of the touch screen required patients to be able to sit upright in order to see the screen.

An incremental iterative approach based on real users' evaluation of the CPBM enabled us to re-design a CPBM V3 that could be used by representative patients with advanced cancer. The indexing of KPS and cognitive testing with TMT were very useful parts of the process. The product was perceived useful by clinicians.

6.3 Paper 3

Pilot testing of a Computerized Pain Body Map – facilitating coordinated management of neuropathic cancer pain

Ellen Anna Andreassen Jaatun, Marie Fallon, Anders Kofod-Petersen, Kristin Halvorsen and Dagny Faksvåg Haugen

Introduction

Cancer pain is often a mixed pain type that includes neuropathic pain. This type of pain is often under-recognized and thus under-treated. One of the criteria for the diagnosis of neuropathic pain is recognition of a typical neuropathic pain pattern. Neuropathic pain patterns often include hands, feet and distinct sites, which could challenge the patients' dexterity. Thus, specific focus on projections and size of the body image to draw on was needed.

We also wanted to create a separate interface for healthcare providers where data from each patient could be stored, displayed, processed according to the healthcare providers' need. This study was an exploratory and feasibility study and an extension of the work presented in Paper 2. The aims were to adapt the CPBM V3 from Paper 2 to patients with cancer-related neuropathic pain. We also wanted to create a clinical interface for healthcare providers offering care for patients with neuropathic cancer pain.

Results

The study resulted in the CPBM V4 as described in Chapter 4, last section. The functionalities of this version were well received by the patients. Patients (n= 33) as well as healthcare providers (n=19) perceived that using the system could improve and give better control over the pain communication. The CPBM tool could also be helpful for patients in visualizing their pain to family and friends to create a better understanding of their problem.

The surveys (SUS and TAM) in the patient study showed high usability and high perceived usefulness of the CPBM V4. The TAM results in the healthcare providers study showed a high perceived usefulness of the whole CPBM system.

The focus group interviews showed that the physicians were positive to the use of an information system that could connect healthcare providers involved in the treatment of a specific patient. The historical data was perceived to provide important insight, and visualization of the pain was considered to be useful for rapid recognition of pain syndromes.

Conclusion

Patients confirmed the usability of the CPBM and found the tool to be a useful contribution to making them a more active part in the pain communication with their healthcare providers. The healthcare providers found that the CPBM system provided important functionalities for improvement of pain management, functionalities that were not available in their current practice. These functionalities included an archive of the patient's pain history available to all healthcare providers involved in the treatment, as well as support for communication when discussing the patients' pain problem between colleagues. Additionally, the visualization of the pain with the traffic light system made it hard to ignore. Also, they believed that the CPBM system had potential to change the way they worked by supporting collaboration across professional boundaries or the levels of healthcare provision.

7 Discussion

Through three consecutive studies, we have developed a clinical application for visualizing pain location and intensity especially designed for patients with advanced cancer. The tool can be used by most patients within the target population. The patients in our test population found convincing representation of their pain when using the CPBM. This applied to most patients regardless of gender and age, but was to some extent dependent on physical and cognitive performance.

The tool is developed in a clinical setting with patients and healthcare providers as stakeholders. The evaluation of the performance of the tool and the user interaction was conducted by the same stakeholders. Both patients and healthcare providers considered the tool useful in terms of improving the quality of pain communication, making it more efficient and focused. The CPBM was considered to provide important information in handover situations, and in presenting the pain information from the patient's perspective. Additionally, healthcare providers perceived the visual content of the patient pain drawing to improve their ability to recognize critical information. Consequently, the patients and healthcare providers perceived the CPBM system to be a useful tool for clinical practice.

7.1 Practical application of cancer pain visualization for clinical purposes

In this project, the purpose was to develop a tool that could help the patient to present important information for making decisions about pain management. This information should ideally be evidence–based, which means we should know the validity of the patient's pain information and the reliability of the patient's pain drawings. In that case the information from the patient could be scientifically evaluated, helping the clinician to classify and make decisions to manage the patient's pain problem.

Based on the results from previous studies [178], it was initially assumed that elderly people with limited computer experience would have more problems using a digital tool than, e.g., paper. However, we did not find any evidence to support this from our studies, although in the international multicenter study presented in Paper 1 we were not able to confirm that all the patients actually did fill in the CPBM themselves. On the other hand, in Paper 2 we found that poor design challenged all the test participants. Patients who were frequent computer users had the benefit of prior experience to make inferences on how the program was intended to work, and thus had a higher ability to interact with it. After re-programming the CPBM with a better and easier design, self-reported previous experience with computers did not substantially influence the ability to use the CBPM. Consequently, limited experience with using computers can (and should) be compensated with a better design.

Our task was to take important aspects of medical domain knowledge on cancer pain and delivery of care, add the perspective of patients with advanced cancer, and combine these with knowledge and

skills from the design and computer programming domain. The challenge was to understand how the human factor affected this process, and then how to adapt the digital program and platform to give support to patients providing us with the pain information we wanted. This was an evolving process in which solving unanticipated problems required an interdisciplinary approach. Various frameworks for collaboration and knowledge exchange, such as participatory design or user-centered design [160], have been proposed for similar projects. Still, the collaborative work process challenges eHealth and health information technology developers. A common criticism in this field has been limited involvement of the healthcare professionals. The limited involvement of clinicians may be caused by many factors. One problem has been lack of engagement [161], or it could also be that healthcare providers have simply not been invited to join the team [179]. One way to avoid this problem could be to reverse the roles. In this project, the main responsibility has been on the medical researchers. Setting a common goal and coordinating the team efforts might be easier when the medical professionals have a special interest in the project.

The focus of this thesis lies in the information that can be visualized on a pain drawing. A visual representation of pain location has been used for clinical communication for many years and in many different patient groups [116, 118, 180]. The usefulness of visualization of information such as extension, radiation and quality of pain has also been evaluated in several studies [129, 131, 142]. However, a review on available evidence on reliability and validity of the different cancer pain domains in pain assessment tools concluded with a lack of evidence on documentation of cancer pain location [107]. In the same paper, the author concluded that documentation of pain location might be especially useful to evaluate treatment response in cancer pain management.

In the first part of the study presented in Paper 1, the development of a program for patient interaction was outsourced to a commercial vendor. The development process had limited involvement of stakeholders who would make use of the product, and the final results showed limited usefulness for clinical practice. In hindsight, it is clear that the organization of the project reduced the development team's ability to see the problems with other eyes or combine domain knowledge. The frequently cited communication model from Kensing and Munk-Madsen [170] in Table 4 can help us understand which fundamental challenges were not well supported. In Paper 1, the medical researchers had knowledge based on the use of paper PBMs that gave patients limited problems with interaction, representing the concrete experience in Table 4. The knowledge of available technological options with their pros and cons was clearly limited (technological options), and the observation of user interaction during testing of the first prototype missed the critical information (new system). The same applied to the vendor, who had no knowledge of advanced cancer patients' limitations, or of how signs of disease could affect their ability to interact with an interface. These points were all part of the specific domain knowledge that should have been communicated before and during the development process.

Table 4: Domain knowledge in user-developer communication, by Kensing and Munk-Madsen [170]

	Users' Present work	Technological options	New system
Concrete experience	Concrete experience with users' present work	Concrete experience with technological options	Concrete experience with the new system
Abstract knowledge	Relevant structures on users' present work	Overview of technological options	Vision and design proposals

In the next two papers, the stakeholders and the collaborative process were more clearly defined. Papers 2 and 3 describe a new design approach using an incremental iterative development process. Upfront, the stakeholders were identified as

- The European Palliative Care Research Centre (PRC)
- Patients with advanced cancer
- Clinicians
- Development team

The European Palliative Care Research Centre (PRC) represents an international network of pain and palliative care researchers. The requirements to the tool were as before anchored in this organization, and they provided a source of extensive domain knowledge for the development process. The patients were defined as stakeholders for the period when they were seeking help for better pain management. Through the two studies we defined two subgroups of patients with specific characteristics (the frailest patients with advanced cancer, and patients with neuropathic cancer-related pain) to be our main target stakeholders. Clinicians who were going to use the system for communication with patients were also identified as stakeholders. The delivery of the product was the responsibility of the development team, the last stakeholder in this process.

The core development team consisted of the programmer team (computer programmer and a clinical oncology nurse) and a medical doctor specialist. The location of the team was in Maine, USA (programmer team) and Norway/Scotland (clinical specialist).

Communication and information transfer in the development team were supported by different audiovisual communication tools such as Skype and join.me, modelling with mock-ups, storyboard and simulation programs for computers. The communication method supported transfer of concrete information in the team. Additionally, communication and information of more abstract character were often dependent on visualization methods in the core development team, especially since we were challenged by the lack of physical proximity and needed to work efficiently. The process of making mock-ups, and the use of storyboards, simulator or paper drawings during conversations, provided a much more tangible and realistic setting where information transfer found good support. The process of visualization and presenting information in a team where each participant represented different

domain specific knowledge, made it necessary to put effort into building good visual models. The gain in this process was effective learning within our own knowledge domain as well as in other domains within the team. This visualization method is a way of learning from experiences as presented by the American philosopher John Dewey, and the process has been described in relation to co-design as an effective and useful way for innovation [171].

7.2 Creation of a mental image of pain perception

Visualization is defined as a method to form a mental image[13] from more complex information. In medical practice, visualization is frequently used to present numerical data in a way that makes it easier to understand. The data can be displayed as information on a process, such as changes over time in a table or a graph or compare measured results to standard values in a table. The main goal of our task is to allow patients to use visualization to display complex pain information to clinicians. The rationale behind this process is to reduce the complexity of communication for patients by using a combined verbal and visual cognitive route [181]. The theory is a multimedia way of learning of abstract information, where combined audio and visual information can be used to reduce the complexity. In our case, we use Mnguni's model to explain the presentation of abstract pain information from the patient by providing visual support by using the CPBM [181]. The verbal communication allows patients and HCP to present additional information or ask questions that can help them to reach a common understanding of the problem. The communication model is defined as an expert-patient communication setting, where the healthcare providers are offered information about the patient's pain (Figure 18), and use the information to learn from the patient.

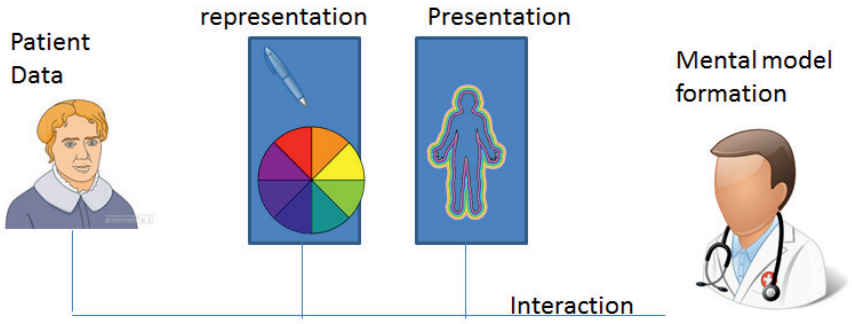

Figure 18: From the patient's perception to forming a mental image for the clinician, created in a communication setting

The concept of learning in a multimedia setting can be considered a stepwise process, as illustrated in Figure 18. The medical doctor can see the abstract information from the patients about pain, and

[13] Visualization defined by Merriam-Webster as formation of mental visual images

internalize the pain information. Figure 18 illustrates how pain currently is communicated using a paper PBM. This is also the way a CPBM as described in Papers 1 and 2 could have been used.

One of the potential benefits of a computerized tool is the ability to process data. In our case, the raw data was a collection of different shaped graphical annotations defined as bitmap (see Section 4.5.3). Each bitmap was defined by the continuous marking made by the same NRS value. In order to be able to process these annotations in a clinically meaningful way, we transferred the data to a computer program on a web server (the web application). To process the data, we had to define a structure that defined the annotation(s). The web application running on the web server would then use the defined structure to rebuild the data and present it in a way that made sense to the healthcare providers.

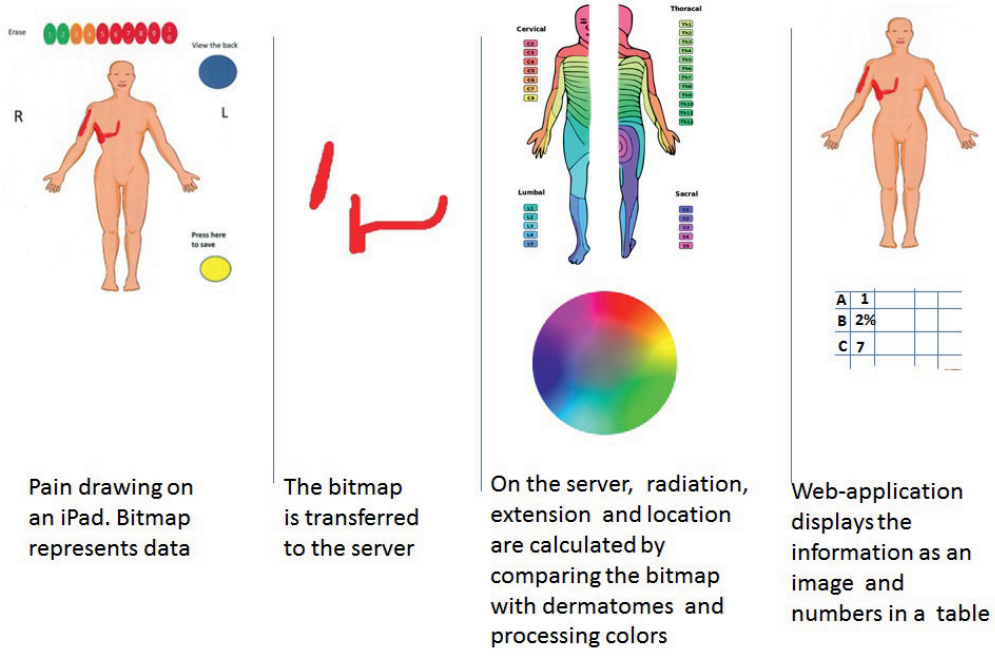

Figure 19: From the iPad pain drawing to bitmap and representation as an image and table of data

Figure 19 illustrates how the data from the iPad was transferred and stored on the web server. In order to decide on the final options for presentation of the data on the web application, we had to find a useful way of processing it to display information that could be of clinical value. The requirements from the clinical experts in Section 5.2.1 stated that radiation of pain should be presented on the CPBM. Thus, a program was developed to compute and present the radiation of pain as described by the sequential nerve innervation of the skin (dermatomes). The same process also described the location of the pain, defined by the same variable. The final calculation set up by the program was to detect the extension of the pain by counting the pixels organized in the same defined bitmap.

Additionally, the last set of data was the pain intensity represented by a NRS value associated with each bitmap (Figure 19).

The subset of data defining the entire primary source was a combination of radiation and location defined by number of pixels in a defined dermatome. The location was also visualized as an image. Extension was presented as the total number of pixels in a defined bitmap. In addition, pain intensity in each pain marking was detected in each individual bitmap.

This setup enabled us to provide two interfaces, one for patients and a separate interface for healthcare providers (Figure 20) that could store, compute and present the patient data.

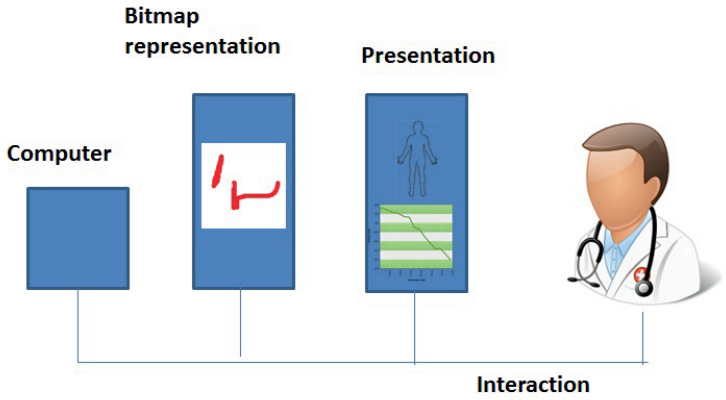

Figure 20: Modified visualization model presented by Spencer (2014)

The information from the patient is calculated as shown in Figure 19 and displayed on the screen of the computer in Figure 20. The clinician will interact with the screen and conceptualize the information and compare it to what is already known, as described by Mnguni [181] .

Categorization of the different levels of pain between the anchors 0 = "no pain", and 10 = "pain as bad as you can imagine" should ensure that the severity of the problem is understood, and that decisions for adequate pain management are made. A consensus meeting suggested a categorization of NRS levels for pain with mild pain, NRS value ≤ 3; moderate pain, NRS value $< 3 - 7 >$; and severe pain, NRS value ≥ 7 [182]. However, a large study on pain in breast cancer patients showed a higher predictive value for worse outcome for pain already at an NRS level of 5 [183]. In Paper 3, we adapted the NRS scale to fit these recommendations. The scale used in this study suggested moving the cut-off point for severe pain from NRS value 7 to NRS value 5. The reason for this is to prompt earlier intervention [183]. The mild and moderate pain has consequently also been moved to a lower level on the NRS scale on the CPBM V4 as described in Paper 3. Consequently, we presented the pain levels as a triage system using green (range 1-2), amber (range 3-4) and red color (range 5-10). Triage systems

have been used for many years in emergency departments to improve efficiency and safety in prioritizing between patients according to urgency for treatment [166]. This was considered useful by most patients, as it was perceived to reduce complexity when deciding on a pain level. The usability test showed that the patients had good interaction and high satisfaction when assessed using observations, think aloud and SUS survey. Presenting a 3-point scale instead of a 10-point NRS has earlier been suggested as an adaptation for patients with cognitive impairment [73].

However, in hindsight it was most likely not necessary to change the scale on both the patient and healthcare provider interfaces, since our intention primarily was prompting healthcare providers. The clinicians thought that the coloring of pain levels made the pain "*hard to ignore*". This was also the effect we were after, and most likely an attribute of the triage system [166].

7.3 The cognitive and medical rationale for the design of the application

Cognitive and physical decline is a common sign of different advanced diseases together with the symptom of pain [184, 185], and this also applied to our patient population. Consequently, we had to consider how patients perceive pain, and how cognitive and physical impairment could affect the patient in a pain communication situation.

In Papers 1 and 2, we categorized patients using cognitive tests (MMSE and TMT), the think-aloud-method, and physical performance (KPS) evaluation. Our purpose was not diagnostic, but to tailor the tool to patients with some degree of cognitive and physical impairment.

Through different approaches, we were able to detect how cognitive impairment (such as reduced ability to read and comprehend) and physical impairment (such as weakness in arms that should hold the computer) played an important role in the interaction with the CPBM. Consequently, Paper 2 was mainly focused on solving the actual problems encountered when we tried to adapt a pain drawing program to the patients' ability to interact. The physical problems were rather easy to handle, since the new tablet platform was better suited to the needs of the patients. However, the cognitive problems were more challenging.

In order to try to understand how and why the patients had difficulties providing information on the pain distribution, we had to investigate closer the theoretical concept of perception and interpretation of peripheral pain [48]. The basis for pain perception is sensory stimuli that present the primary "data" to start off the cognitive process of perceiving pain. The next level is the pain perception, a cognitive process of making sense of the primary pain data. The cognitive process increases the substance of the pain data to become pain information. Consequently, the assessment of pain distribution as performed on the CPBM is the patient's current pain perception. This constructs the patient's perception of pain as described by Melzack [48].

The last level of complexity is the patient's interpretation of the pain information by combining and structuring it with previous experiences, context and reflections in order to know something about the painful experience [48]. Thus, describing the experience of pain requires more cognitive functions than perceiving the pain. This means that we can deduce that any communication of information that requires reflection on pain (such as questions about worst pain or pain quality as in the BPI [106] or the McGill pain questionnaire [105]) requires more complex cognitive processing by the patient.

In our study we found patients who were able to fill in the CPBM but had difficulties answering the MMSE [81]. When answering in the MMSE, the patients are required to recall information such as the current time, place, and context, which probably requires more complex cognitive functioning than describing the perception of pain. In Paper 2, we replaced the MMSE with a less complex cognitive test. The TMT gives information about the patient's attention, speed of cognitive processing, flexibility and scanning ability [186]. This information made more sense to us, and seemed more useful. Additionally, the scanning ability examined by the TMT resembles the process of patients scanning the CPBM. Consequently, using the TMT enabled us to collect information on patients with a severe symptom burden, as well as to include their views and allow them to influence the development of the CPBM. Additionally, a rough estimate of the level of complexity of the CPBM can be placed between the MMSE and the TMT, as we detected patients who were not able to fill in the MMSE, but managed to respond to the CPBM. We also detected patients who were not able to fill in the CPBM, but were able to do the TMT. The latter patients spent a long time on the TMT indicating cognitive impairment. We detected a few patients who were too weakened by disease to be able to use the CPBM, even though they were able to communicate their problems verbally. Thus, we concluded that the current design and platform provided an interface that "most" of the included patients were able to interact with.

In Paper 3, the patients were included from an outpatient clinic. These patients were not as sick and burdened by disease as the previous groups of patients. Because of this, we made no attempts to gather more evidence on cognitive requirements for using the tool, since we did not expect any negative impact from improved cognitive functioning. In Paper 3, the changes made to the program would generally be considered to decrease the complexity and reduce requirements to dexterity, as we enlarged the projections of the body on the screen. This was also the strategy by Bromley et al. when demonstrating the reliability of the paper PBM for cognitively impaired people [118].

The next problem to consider was related to classifying the information that could be collected from the CPBM. The available scientific evidence presented in Section 2.2.2 states that pain could be presented as a hierarchy. Additionally, we presented in the previous section (Section 7.2) how the pain distribution was described in the web application as location, extension and radiation of pain. These

items combined represented the visual cancer pain distribution made by the patient. The structure of the cancer pain distribution on the web application is displayed in Figure 21.

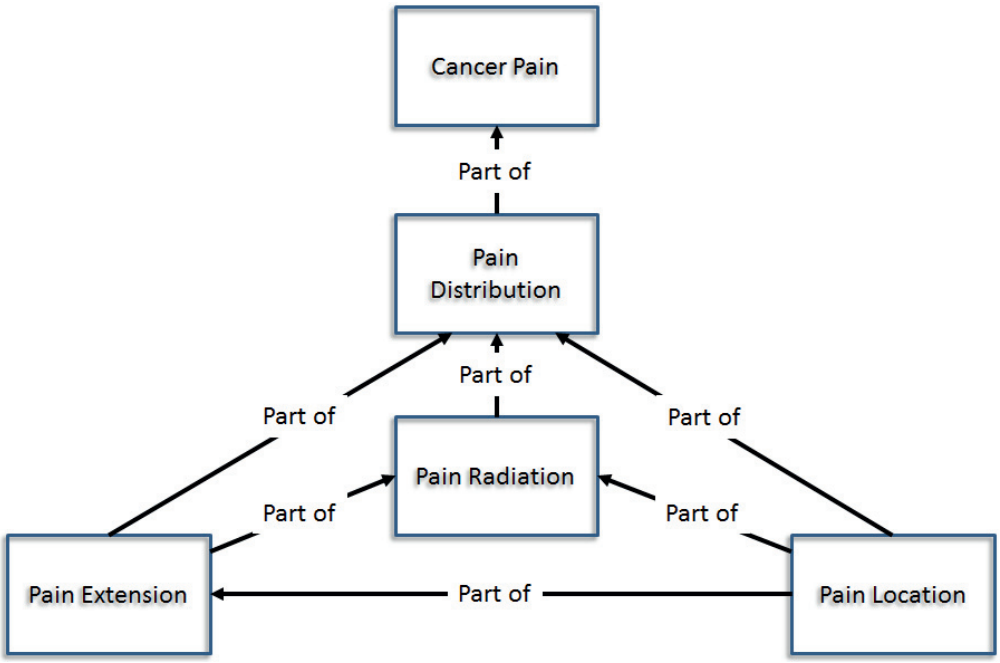

Figure 21: Illustration of the meronomy of cancer pain distribution as described by the web application[14]

This model can be supported by evidence from predominantly non-cancer pain studies and physiology of pain described in Section 2, as well as specialist consensus for pain assessment, and represents the values to compute in the CPBM program. The different values presented have all been associated with a *temporal value* in the program. The temporal aspect is supported by the expert consensus on important pain domains described by Hølen et al. [87], as well as the patients and clinicians in this project.

Pain can be presented with a *distinct pain pattern* such as pain located in the distinct area of a spinal nerve, or glove-and-stocking like pain distribution from chemotherapy induced neuropathy [62]. The *anatomical location* of pain is currently often described by the corresponding anatomical name of the location, and documented in the health record. For our purpose, a presentation using, e.g., a coordinate system could be more useful. This cartography structure has also been proposed by Schott [111]. Alternatively, the dermatomes can provide a numerical identification of pain location. This may be useful for neuropathic pain, and could provide a better description for *pain radiation*. The clinical relevance of *pain extension* has been demonstrated in a study by Fallon et al. showing the reduction of

[14] based on original made by Anders Kofod-Petersen.

pain extension as a result of pain management in a clinical trial [187]. However, the reliability and validity of self-assessment of pain extension have not been demonstrated.

7.4 Usability, reliability and validity

A digital tool used for self-assessment needs to adhere to the highest standards of reliability, and this is especially true for medical tools. Technological equipment such as an intravenous dispenser or ultrasound apparatus have to be certified for use in healthcare, and strict ISO standards have to be followed [188]. However, there are no such requirements for information systems in healthcare. Poor design or usability errors in this field can have great impact, as shown by the usability evaluation of a handheld prescription application that made healthcare providers prone to err [159]. Consequently, demonstration of acceptable usability among end users is important, and is included in the wider definition of reliability and validity of a computerized tool [189].

During the different development studies in this thesis, we have strived to include a diversity of patients with advanced cancer based on their symptom burden, age, and gender. The CPBM has been shown to have a high usability, which paves the ground for reliability and validity evaluations of the assessment tool.

Table 5 presents available evidence on flexibility, reliability and validity of traditional pain body maps, and compares this to the evidence obtained during the development of the CPBM. Flexibility refers to if the tool is valid and useful even for patients who are frail and severely burdened by disease.

Table 5: Comparison of available evidence on computerized and paper pain body maps

Criteria	CPBM	Paper PBM
Flexibility	✓	✓
Reliability		
completeness	Not tested	No evidence
accuracy		
-consistency	Not tested	Statistical evidence
-correctness	✓	No evidence
Validity		
face	✓	No evidence
content	✓	✓

Note that Table 5 does not display information on completeness and correctness of paper PBMs. Despite an extensive search in PubMed and Embase, we were not able to retrieve evidence on these two topics. All evaluations of the CPBM are given by non-statistical measures. As displayed in the

table, the CPBM assessment tool has no proof of evidence on completeness of pain data from patients. Evidence from evaluation of paper PBMs showed that many patients “withheld” information about painful areas when marking [129]. The additional areas were detected during a clinical examination of the patient [129]. Thus, completeness of data on a CPBM is most likely in line with the paper PBM.

Consistency of pain marking is evident in several studies on paper PBMs [116, 117, 190]. Consistency evaluation has not been performed as a separate study for the CPBM. However, patients with different conditions and levels of cognitive functions have performed the "think aloud test", saying out loud where they had pain and what they intended to mark before they identified and marked the painful area(s) on the CPBM. Additionally, the think aloud method vouches for the correctness of the pain marking on the CPBM, but this has not been confirmed by statistical analysis. Bertilson et al. [129] found in a previous study that most of the marked pain areas were correctly identified and confirmed in a clinical examination. The two different narrative methods of evaluation do not provide evidence on the accuracy of the location of pain. However, in both studies (Bertilson et al. [129] and our own) there was concordance between the pain location marked by the patient and what was said aloud (our studies), or found by a clinical examination (Bertilson et al.).

The face validity for the CPBM has been shown in the think aloud test as well as in the post-test interview during development of CPBM V2-4. From both patients’ and healthcare providers’ point of view, the perceived face validity increased throughout the study.

Content validity for a CPBM is more complex to evaluate. Based on several consensus reports, pain location is considered one of the core domains in a cancer pain classification model [86, 87, 147]. As described in Section 7.3, it was important to establish a hierarchical order of the variables of the pain distribution in the CPBM program before associating them with a numerical code. At the bottom of the hierarchy, we have the smallest unit of *pain location* in the CPBM, i.e., a single pixel of the patient's pain marking. All the pain locations (pixels) that are connected define the *pain extension* for the pain site (a contiguous bitmap), and all the extensions collectively define the *pain distribution*. *Pain radiation* is identified by the overlapping of pain extension and dermatomes; the more of a dermatome that is covered by a pain marking, the higher is the probability of existence of pain radiation.

In terms of evidence for validity of location, radiation (and extension), the neuroanatomical pain distribution is considered one of two main diagnostic criteria for proposing a neuropathic cancer pain hypothesis [67], which should be confirmed with a diagnostic test. Additionally, there is evidence for content validity, both theoretical (such as the pathophysiology of metastatic bone disease of the vertebra affecting a spinal nerve) as well as clinical (such as observation of glove and stocking like distribution of pain), representing different cancer pain syndromes [62, 64]. Considering cancer pain as a mixed pain category including both neuropathic and nociceptive pain, the content validity for a

paper PBM presenting pain location is confirmed [62]. However, as reported in Paper 3, the clinicians perceived the CPBM pain drawings to provide more information than they were used to from the paper PBM. Some of the comments were related to the perceived accuracy and the level of detail on the pain drawings.

The content validity of pain location and pain radiation can be anchored in consensus reports as well as basic pain research [48, 62, 64, 87]. The visualization of the extension of pain has not been the subject of much attention in cancer pain research. The patient's self-report on the same variable is probably dependent on qualities of the tool (such as projections), instructions, as well as cognitive and physical abilities.

As described in Section 2.2.4, responsiveness should be included when evaluating an assessment tool. From the patient and clinical evaluation of the CPBM in Paper 3, we found that a paper-based system such as a paper PBM provides less support for pain communication than a CPBM system, provided all quality evaluations have been found reliable and valid. The quality evaluations also apply to the performance of the software tool as well as the computer platform. The CPBM system, provides a history of the patient's pain, and allows for viewing calculations on intensity and location changes over time. However, this latter feature has not been evaluated in this study.

All parts of the digital computerized tool have to perform in a valid and reliable manner, just as any other instrument. All reliability parameters such as completeness, consistency and correctness of data transfer from the CPBM to the web page were verified during the development process of the web application described in Section 4.5.3, and was a part of the process described in Section 7.3.

The CPBM system has not yet been used in clinical practice, which limits the evidence on performance in regard to the clinical needs. However, the development method, usability evaluation and TAM results provide us with core evidence that can be used to predict the success of an information system [191]. Some of the important domains in a complex evaluation such as this include knowledge on system quality, information quality, service quality, system use, user satisfaction and net benefit. A methodological approach to evaluate all these factors requires substantial research, and this has not been a part of the current development project. Nevertheless, the limited data we have obtained is promising.

7.5 Accuracy of the CPBM

No evidence shows that any PBM is 100 percent reliable, and a PBM cannot be a substitute for a clinical evaluation. This was specifically shown in the study from Göransson et al. [166]. For cancer patients there is no evidence from PBM use at all.

The CPBM in this project is developed for patients with severe disease, where subtle changes may be important. We know from previous studies on patient barriers to cancer pain management that not all

information important for decision making may be communicated properly [192]. Consequently, it is unlikely that the tool can replace a face-to-face communication including clinical examination, if the goal is to provide accurate and complete information on all aspects of pain distribution and pain intensity to the clinician. However, new ways of delivering pain management could make tools such as the CPBM a useful supplement for patients not in physical proximity of the clinical service [193].

7.6 CPBM in an eHealth perspective

Patient centered care has been defined in different ways. One crucial criterion is that the care is provided with patients involved in the decision making [194]. Providing pain management based on self-assessment results depends on the patient's evaluation of the severity of the problem. Thus, pain management should be offered when the patient thinks the time is right. This is the recommended strategy for providing symptom control in patients with advanced cancer, as described in Section 2.2.2. From our study results, patients perceived that using the CPBM system in pain communication gave higher confidence and offered better control. This also represents a crucial requirement in patient centered care as defined by Epstein and Street [195]. Improvement of patient involvement and providing a more patient centered service is also a common argument in development of eHealth service.

This project covers many of the attributes of e-Health as defined by WHO, listed in Section 2.3.4. Additionally, the tool developed can be defined as a health information system. Both eHealth and health information systems have a strong association to the technology domain. However, the domain knowledge that serves as the scientific base of this project has its roots in medicine.

The problems we have addressed are medical in nature, and are affected by the increasing number of cancer patients experiencing pain related to the disease or treatment side effects. In order to come to a practical solution, we needed knowledge about the extent of the problem, cause, pain etiology, and on how the disease trajectory is influenced by pain or vice versa. It was also crucial to know how pain was described and categorized medically, to see how the computer program model could fit in.

Furthermore, we needed to collect existing medical information from healthcare providers on current methods of delivery of care, and determine who would be responsible for providing pain management. In this aspect, the pain communication setting is important, and it was important to consider current use and evidence for validity and reliability of paper PBMs. Additionally, it was crucial to get feedback from professionals in healthcare about what was communicated in a pain communication setting, in addition to which information the experts ideally would have like to elicit from the patients.

The next task was to investigate how patients would process information and express themselves, and in which way we could expect the disease to influence these processes. This also included consideration with regard to more patient involvement; mapping patients' benefits, responsibilities,

and abilities in this process. All these factors are important to keep in mind when providing patient centered care [195, 196]. Our aim was to combine the above presented medical and cognitive behavioral knowledge, and tailor it to possible technological options that could reduce the complexity of the task and improve the quality and content of the pain conversation. We needed knowledge on design theory, human computer interaction, and co-design methodology. Nevertheless, this project is heavily dominated by evidence from the medical domain.

Many e-health projects struggle with healthcare involvement or lack of medical engagement [161, 163, 197]. Additionally, many commercially available pain applications do not seem to present any scientific evidence [198]. Strangely enough, the pain applications that are supported by scientific evidence are not commercially available [198]. This could be an illustration of how medical professionals, as well as policy makers, educational and other health authorities, implicitly have defined the eHealth domain as being outside the field of healthcare science. However, based on the medical knowledge required in this development process, this is very hard to justify. In basic research similar problems have been pointed at; e.g. new drugs have been developed, but just a limited proportion make it to the marked [199]. We believe that a translational research effort such as this project may contribute to improving the transfer from science to practical healthcare [200].

Based on the results in this project, the CPBM seems to have an auspicious future in line with many other digital tools. Unfortunately, the current evidence shows a slow and very limited implementation in clinical practice [6, 198]. Paper PBMs were (re)-introduced around 1950, and have since then gradually been validated and found reliable in different patient populations. Such validation is normally a requirement before use in clinical practice. The fact that we have not been able to produce evidence that this validation process has reached cancer patients yet, might indicate limited scientific interest in evaluation of these types of systems, an interest that does not correspond to the perceived clinical usefulness. The real scientific potential in this health information system depends on the patients' ability to provide reliable information that can be processed and combined. Thus, the system could, when deployed in a clinical setting, be in a position to increase the scientific evidence on cancer pain and the efficacy of pain management.

7.7 Limitations

This work has been conducted in a limited sample of patients and clinicians. Involvement of a larger user sample could have been beneficial for providing more solid evidence. Nurses and nurses' assistants, physiotherapists, occupational therapists and other clinical specialists as well as General Practitioners could have provided us with useful information on the perceived usefulness of this tool.

Before starting this project, we could have had a more critical methodological focus. The process of developing an assessment tool for pain could have been performed as a participatory design project,

where the requirements would have been developed by both patients and clinicians from the beginning. This might have affected the choice of platform and interaction between patients and clinicians. In addition, looking at the way assessment of pain is performed, the task is often controlled by nurses. A participatory design study where all involved parties in the process of pain assessment would have been involved from the onset might have influenced the result even more. From a clinical perspective, this was potentially troublesome, when considering the plentitude of already available pain assessment tools [102], which makes selection of the right tool for a certain purpose difficult. Comparison of results of subjective symptoms would also be even more challenging in a research setting. The problem description was therefore from the beginning restricted to aspects surrounding a computer-based PBM.

We now know that our initial approach to this problem was not appropriate for this challenge, but the value of the uncomfortable experience of making an error should not be underestimated. We also experienced some of the challenges of organizing a large international multisite study when collecting the data. Even though explicit information on the intention to let patients do self-assessment was provided, we have reason to believe that this was not followed at every site. This could be related to their common practice for assessment of pain, or to the fact that the program design caused patients too much difficulty in handling the tool. As the validation process demonstrates in Paper 1, the quantitative approach provides limited evidence as long as the qualitative data has not been evaluated or understood.

In project planning, negotiations between available resources and the need to obtain valid data has to be performed. In this project, we investigated requirements for the CPBM system first through a survey, and second in a focus group interview. In hindsight, we might have understood more of the process of assessment for pain management and been able to address the concept sooner if the initial studies had provided more qualitative data. A reliability test should be conducted in patients with advanced cancer before the tool is implemented in clinical practice. However, it is important to consider the reliability evaluation process critically to include all aspects of pain distribution and establish if they have a clinical relevance. Especially the temporal factor as well as fluctuation of pain might pose challenges in this cancer pain domain. Additionally, advanced cancer patients are a heterogeneous patient population, thus criteria that limit the validity and reliability should be taken into account. As our study has shown, physical and cognitive impairment play a role in assessment with a CPBM. Thus, it might be relevant to establish a critical threshold for the required physical and cognitive function that makes self-assessment with this tool feasible.

During this project, Norwegian healthcare providers have commented that an important requirement to any computer program to be used in healthcare is that it has to be integrated in the Electronic Health Record (EHR). The general perception is that any computerized tool that is not a part of the EHR will

not be used. As we understood it, this only applied for the healthcare provider user interface. However, this requirement was not voiced by the Scottish healthcare providers in our study. The requirements from Norwegian healthcare providers seem to represent a very conservative attitude compared to the current use of applications on smart devices.

8 Conclusion

This research project did not follow a linear process. It was multidisciplinary, and required data collection from different stakeholders and by several different methods in order to answer the research questions. In total, the development of the CPBM system has been guided by the involvement of 639 patients and 55 healthcare providers.

This project has documented the development of an information and communication tool for pain assessment in patients with advanced cancer. The overall aim was to develop a CPBM that is flexible enough to be used by the frailest and sickest patients in palliative care, and robust enough to be reliable in a palliative care population. The CPBM has been specifically designed to meet the information requirements made by pain and palliative care experts. The CPBM system consists of a patient interface and a web-based clinical interface. It is perceived to display pervasive and ubiquitous qualities, enabling transparency of pain assessment results to the team of healthcare providers. The transparency is perceived to support follow-up and discussion of pain management between colleagues, and to improve situations related to handover of patients. The system can provide useful processing of data where changes of pain over time are displayed. It is also perceived by the healthcare specialists to visualize clues of the etiology of pain, and to improve rapid recognition of pain syndromes in need of urgent care.

8.1 Research questions revisited

The research questions have been addressed in the following way:

What are the pain and palliative care specialists' wants and needs for a CPBM?

The healthcare providers were clear in voicing the requirement of having one version of the CPBM for all levels of cognitive functioning. This was solved by developing a CPBM that even the frailest and sickest patients could interact with, irrespective of cognitive functioning.

The CPBM should be used for assessment of pain location, intensity and radiation. In addition, specification of pain intensity should be compulsory for all patients. All three required pain features can be assessed by the CPBM, and pain intensity is a compulsory integrated part in the assessment of location.

The specialists agreed that anterior and posterior whole body views were necessary and sufficient for a CPBM for patients with advanced cancer. These views are included in the CPBM. In addition, lateral head and neck views were wanted by the palliative care specialists. These views are offered on CPBM V4.

Are patients able to use the CPBM in a way that provides the clinicians with the necessary information?

All functionalities have been tailored to the patients included as users, and usability has been confirmed by patients as well as healthcare providers. During development and patient testing, clinicians have been involved in evaluating the patients' pain drawings to give feedback on whether the way the pain drawings were made provided useful information. The clinicians perceived that the information from the CPBM provided rapid recognition of pain severity (intensity) as well as rapid recognition of pain distribution.

What are the perceived mutual benefits of the CPBM for patients and healthcare providers in clinical practice?

Patients and healthcare providers considered the CPBM system to be useful in clinical practice for pain communication in a pain management setting. The CPBM system covers the assessment of the pain aspects that clinicians believe are important, visualizes the pain and provides rapid recognition of pain severity and pain distribution. The CPBM system was also perceived to give patients and clinicians more confidence when communicating about pain, by influencing the quality and efficiency of the communication. In addition, the web application displays the historical pain data that was considered very important for the healthcare providers in the focus group interviews.

The visualization of pain was considered a better way to provide understanding of the pain problem by both patients and healthcare providers. Patients believed family and friends might understand their problem better, and healthcare providers thought the communication about the patient's pain would be easier using the patient's own visual description.

8.2 Contribution

The results of this project may provide benefit both for clinical practice and for science.

The benefits for clinical practice include:

- The recommended natural drawing behavior and is found useful and usable by even frail patients with advanced cancer
- The display and archive for longitudinal pain data from each patient in a digital format.
- The visual prompt in the triage color which is suggested to improve the ability to recognize specific pain patterns
- Visualization of pain patterns which is also believed to improve the ability to consider neuropathic origin of pain from a pain drawing

- Better support through this system in a pain conversation setting which could lead to more patient empowerment and a better dialogue between patients and healthcare providers
- A system that could make it easier to provide support to colleagues asking for advice on pain management, and improve documentation in handover of patients
- A tool that could provide more transparency and better support for the team providing pain management for the patient.

Contributions to science include:

- Knowledge on how to involve patients with severe illness in a development process
- Knowledge on how to categorize the user in terms of ability to interact
- Enabling the collection of more evidence on visual pain images of cancer pain syndromes, progression of disease and efficient pain management in clinical practice in advanced cancer patients.

These studies show the extent of medical considerations needed in order to perform this type of research. The method for development requires the ability to use medical knowledge in a team for practical purposes, which is very much what providing healthcare is all about.

8.3 Future work

We have identified a few studies touching upon validation of patients' pain marking on PBMs [129, 131, 201]. However, despite extensive search, we have not been able to find evidence for the reliability and consequently the validity of the patient's graphical annotation of pain on a PBM. Providing evidence for a subjective experience such as pain can be done by performing a clinical examination based on interpretation of the pain drawing made by self-assessment. This test should confirm the accuracy of spatial pain distribution as well as content validity.

The next step in this process is to verify the clinical value of assessment of all aspects of pain distribution for patients with advanced cancer. Provided the patient pain data can be validated and represents useful and important information for clinical decision-making, future work may include options such as image recognition and algorithms for decision support in clinical practice. This will probably also call for a re-evaluation of the projections of the body on the screen. Thus, future work would be to provide an interface where healthcare researchers as well as technologists can access raw data from the patients in order to drive research of visual pain image processing and interpretation of pain data forward. Knowing which patients can provide reliable information (and to which degree they are able to do so) will have great importance if this project will be continued. This is particularly important if the tool should be used as a mobile device outside a clinical practice. Thus, it would be useful to identify an approximate threshold of the limiting factors such as cognitive and physical functions for interacting with the CPBM.

The contributions to science and practice listed in the previous section show the potential of a system like this. The initial idea for this project was to improve a paper assessment tool and digitalize it for a fast growing patient population in need of better systems for optimizing care. However, as soon as this system is prototyped and tested, a wide range of potential research options emerge. Interesting possibilities include longitudinal pain measurement for larger populations, different diseases, and different interventions. Further research can also lead to innovation opportunities such as pattern recognition research or further improvement of the tool. The system could also provide the ability to option evaluate the quality of clinical care by the transparency of archive data, which in turn could lead to further improvements in clinical practice. The current system is just scratching the surface of the opportunities that lie ahead.

The development of eHealth is currently not primarily driven by healthcare providers, even though the potential of these systems to influence the delivery of care is great. Consequently, there is a risk that future healthcare could be framed mostly by technologists and policy makers, while most healthcare providers are busy doing something else. An urgent task for the future will be to increase the sense of responsibility and participation of healthcare providers into this type of technological research and innovation.

Norway has the benefit of having adequate resources for providing good quality healthcare. However, rural and remote areas where highly specialized healthcare provision is scarce constitute a large part of the country. Technology may provide new options for delivery of care, such as virtual hospices for improving access to care [202]. Systems like the CPBM might play a role in this kind of service provision, and this can be good way to give better access to care both in Norway as well as in other countries.

An information system such as this has extensive potential that can be exploited provided adequate financial support and administration in an interdisciplinary team. The rapid development and advances in the IT world pose a substantial challenge to the medical profession. In order to exploit the possibilities of IT in healthcare, the domain representing the intersection between health and technology needs a higher focus from the healthcare domain. Thus, future work should be to advocate more general knowledge provided to healthcare providers about health information technology.

As described in Section 8.1, Norwegian healthcare providers commented that the clinician's interface had to be an integrated part of the EHR in order to be perceived as accessible and useful for clinical practice. This sentiment is likely due to some EHR systems currently in use in Norway, where the

EHR application runs in "kiosk mode"[15], effectively preventing the use of other applications. This is in direct contrast to most modern operating systems, where different software tools are offered as individual applications that can be selected dependent on task and preference without having to be integrated in a central dashboard. A requirement to integrate all new applications in the EHR could represent an obstacle to innovation in healthcare, and hinder use of new technological solutions. Additionally, accessing useful internet resources such as guidelines is currently very limited through the EHRs available in Norway. Ultimately, this EHR-centric view may also affect the current healthcare delivery and hamper the provision of evidence-based medicine. Thus, it would be very useful to conduct a study to evaluate *what* the clinicians actually mean by this type of requirement, and if it is a general opinion of the healthcare providers. Additionally, it would be useful to identify *why* they are led to think this, and whether this phenomenon is restricted to Norway. Finally, we should determine whether and how it might affect the healthcare providers' clinical work.

[15] Kiosk mode is a way to run and lock the program to run on a full screen. The intention is to prevent the user from running anything other than the one program on the screen. Ref: http://www.kioware.com/resources.aspx?resID=45

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Appendix A - PubMed and Embase search strings

1a (pain chart)

pain-chart[tw] OR pain-charts[tw] OR "pain chart"[tw] OR "pain charts"[tw] OR pain-map[tw] OR pain-maps[tw] OR "pain map"[tw] OR "pain maps"[tw] OR pain-diagram[tw] OR pain-diagrams[tw] OR "pain diagram"[tw] OR "pain diagrams"[tw] OR pain-drawing[tw] OR pain-drawings[tw] OR "pain drawing"[tw] OR "pain drawings"[tw]

1b (body chart AND pain)

(body-chart[tw] OR body-charts[tw] OR "body chart"[tw] OR "body charts"[tw] OR bodymap[tw] OR bodymaps[tw] OR body-map[tw] OR body-maps[tw] OR "body map"[tw] OR "body maps"[tw] OR body-diagram[tw] OR body-diagrams[tw] OR" body diagram"[tw] OR "body diagrams"[tw] OR body-drawing[tw] OR body-drawings[tw] OR "body drawing"[tw] OR "body drawings"[tw]) AND (Pain[mesh] OR "Pain measurement"[mesh] OR pain[tiab]) [16]

2

(English[lang] OR German[lang] OR dutch[la] OR french[la])

3a

(Animals[mesh] NOT Humans[Mesh])

3b

(((Child[mesh] OR infant[mesh]) NOT (adolescent[mesh] OR adult[MeSH])) OR child*[ti] OR pediatric*[ti] OR paediatric*)

3c

(("Back pain"[mesh] NOT Neoplasms[mesh]) OR back pain[ti])

3d

Case reports[pt]

Final search combination: (1a OR 1b) AND 2 NOT (3a OR 3b OR 3c OR 3d)

[16] Not English: Painchart, painmap, paindiagram, paindrawing, Bodychart, bodydiagram, bodydrawing

Note: all these specific names for maps/charts (extracted from search results) are included in this search because of the yellow marked parts: Corlett-Bishop body map, Oxford Pain Chart, Knee Pain Map, Quantitative computerized pain drawings (CPDs), Margolis Pain Diagram, McGill Pain Map, McGill Pain Drawing, Cardiff Breast Pain Chart.

Copy&paste version of this search:

(pain-chart[tw] OR pain-charts[tw] OR "pain chart"[tw] OR "pain charts"[tw] OR pain-map[tw] OR pain-maps[tw] OR "pain map"[tw] OR "pain maps"[tw] OR pain-diagram[tw] OR pain-diagrams[tw] OR "pain diagram"[tw] OR "pain diagrams"[tw] OR pain-drawing[tw] OR pain-drawings[tw] OR "pain drawing"[tw] OR "pain drawings"[tw]) OR ((body-chart[tw] OR body-charts[tw] OR "body chart"[tw] OR "body charts"[tw] OR bodymap[tw] OR bodymaps[tw] OR body-map[tw] OR body-maps[tw] OR "body map"[tw] OR "body maps"[tw] OR body-diagram[tw] OR body-diagrams[tw] OR " body diagram"[tw] OR "body diagrams"[tw] OR body-drawing[tw] OR body-drawings[tw] OR "body drawing"[tw] OR "body drawings"[tw]) AND (Pain[mesh] OR "Pain measurement"[mesh] OR pain[tiab])) NOT (Animals[mesh] NOT Humans[Mesh]) AND (English[lang] OR German[lang] OR dutch[la] OR french[la]) NOT (((Child[mesh] OR infant[mesh]) NOT (adolescent[mesh] OR adult[MeSH])) OR child*[ti] OR pediatric*[ti] OR paediatric*[ti]) NOT (("Back pain"[mesh] NOT Neoplasms[mesh]) OR back pain[ti]) NOT case reports[pt]

Embase

(pain-chart.tw. OR pain-charts.tw. OR pain chart.tw. OR pain charts.tw. OR pain-map.tw. OR pain-maps.tw. OR pain map.tw. OR pain maps.tw. OR pain-diagram.tw. OR pain-diagrams.tw. OR pain diagram.tw. OR pain diagrams.tw. OR pain-drawing.tw. OR pain-drawings.tw. OR pain drawing.tw. OR pain drawings.tw.) OR ((body-chart.tw. OR body-charts.tw. OR body chart.tw. OR body charts.tw. OR bodymap.tw. OR bodymaps.tw. OR body-map.tw. OR body-maps.tw. OR body map.tw. OR body maps.tw. OR body-diagram.tw. OR body-diagrams.tw. OR body diagram.tw. OR body diagrams.tw. OR body-drawing.tw. OR body-drawings.tw. OR body drawing.tw. OR body drawings.tw.) AND (exp Pain/ OR exp pain assessment/ OR pain.ti,ab.)) NOT ((exp Animal/ OR exp Animal experiment/) NOT Human/) AND (English.la. OR German.la. OR dutch.la. OR french.la.) NOT (((exp Child/ OR exp infant/) NOT (exp adolescent/ OR exp adult/)) OR child*.ti. OR pediatric*.ti. OR paediatric*.ti.) NOT ((exp Backache/ NOT exp Neoplasm/) OR back pain.ti.)

Note: we did not exclude the controlled term 'Case study', because in Embase indexing this includes 'large case series'.

Paper I

Original Article

Development and Testing of a Computerized Pain Body Map in Patients With Advanced Cancer

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Abstract

Context. Pain localization is an important part of pain assessment. Development of pain tools for self-report should include expert and patient input, and patient testing in large samples.

Objectives. To develop a computerized pain body map (CPBM) for use in patients with advanced cancer.

Methods. Three studies were conducted: 1) an international expert survey and a pilot study guiding the contents and layout of the CPBM, 2) clinical testing in an international symptom assessment study in eight countries and 17 centers ($N = 533$), and 3) comparing patient pain markings on computer and paper body maps ($N = 92$).

Results. Study 1: 22 pain experts and 28 patients participated. A CPBM with anterior and posterior whole body views was developed for marking pain locations, supplemented by pain intensity ratings for each location. Study 2: 533 patients (286 male, 247 female, mean age 62 years) participated; 80% received pain medication and 81% had metastatic disease. Eighty-five percent completed CPBM as intended. Mean ± SD number of marked pain locations was 1.8 ± 1.2. Aberrant markings (15%) were mostly related to software problems. No differences were found regarding age, gender, cognitive/physical performance, or previous computer experience. Study 3: 70% of the patients had identical

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markings on the computer and paper maps. Only four patients had completely different markings on the two maps.

Conclusion. This first version of CPBM was well accepted by patients with advanced cancer. However, several areas for improvement were revealed, providing a basis for the development of the next version, which is subject to further international testing. J Pain Symptom Manage 2014;47:45–56.

Key Words

Advanced cancer, symptom assessment, computer technology, patient-reported outcomes, computers, pain body map

Introduction

Pain is a common symptom in cancer,[1] and a European pain survey showed that 69% of the respondents reported pain-related difficulties with everyday activities.[2] Pain management is thus an inherent and important part of comprehensive cancer care.[3–5] Previous studies have established a need for consensus regarding pain assessment in cancer,[6,7] and international expert surveys have defined pain location as a core dimension in pain assessment tools.[7,8] Pain location and radiation/extension have important implications for treatment as these factors may indicate the cause of the pain. Therefore, these pain dimensions require specific and valid assessment methods that are feasible for clinical use.

Pain body maps (PBMs) have been used for pain assessment over the past 30–40 years. A PBM (also called pain map/chart/diagram/drawing) is a body diagram on which patients mark the locations of their pain. PBMs have been used in research for different pain types such as postoperative, rheumatic, cancer, and chronic nonmalignant pain,[9–12] but specific reports from clinical studies are few. In general, PBMs have demonstrated high validity and high test-retest and inter-rater reliability;[9,10] they also may be used by elderly and disabled persons.[13,14]

Pain maps are included in a number of frequently used paper- and pencil-based questionnaires in cancer, for example, the McGill Pain Questionnaire,[15] the Brief Pain Inventory (BPI),[16] and the Edmonton Symptom Assessment System (ESAS).[17] Nevertheless, no international consensus has been established on the ideal contents of a PBM for use in general cancer or palliative cancer care or on how it should be presented.[18]

Advanced technology facilitates electronic symptom registration by patients and health care providers and promotes data sharing between care teams, which makes follow-up of patients not in physical proximity to the care team possible. Rapid presentation of results may improve doctor-patient communication.[18,19] Computerized versions of pain body maps (CPBMs) make detailed pain markings possible, for example, with incorporation of pain intensity ratings for each location and descriptions of pain quality, depending on the sophistication of the software. A CPBM may be integrated into other computerized tools and used in combination with different software systems, Web applications, and hand-held devices.

User-friendliness and needs and limitations of the target group are crucial factors to consider in the development of all tools, both on paper and computers, especially in patients with a high symptom burden.[7,8,19] One study demonstrated good feasibility and discriminant validity of a CPBM in chronic pain patients and healthy controls.[20] So far, few studies have investigated the development and use of a CPBM in patients with advanced cancer. Two pilot studies showed promising results for pain assessment and provision of physicians' decision support[21] when using a computerized version of McGill's Pain Questionnaire.[15] These results were supported by another study in cancer patients and a general population sample with pain.[22] The revised version of ESAS, ESAS-r,[23] is available as an iPad application,[24] but we have not been able to identify clinical studies presenting results from this use.

The European Palliative Care Research Collaborative (EPCRC) was a four year translational research project funded by the European Commission.[19,25] A main objective was to develop a computerized tool for assessment and classification of cancer pain, including the development of a CPBM. Development of CPBM was a stepwise process comprising three studies with the following aims: Study 1: conducting an international expert survey and a pilot study to guide the selection of the contents and body projections of CPBM; Study 2: testing the feasibility of CPBM in an international, multicenter study, in relation to age, performance status, cognitive function, educational level, and computer experience; and Study 3: comparing patient pain markings on CPBM vs. a paper version of PBM.

Study 1. Expert Survey and Pilot Study

Methods

Expert Survey. Ten international and 26 Norwegian pain and palliative care experts were invited to participate in a Web-based survey regarding the contents and clinical requirements of a CPBM for patients with advanced cancer. The international experts were recruited from within EPCRC,[25] and the national experts were physicians and researchers from pain clinics and palliative care programs in Norway. In addition, an open invitation to participate was posted on the EPCRC Web site. The experts were approached on the basis of their longtime clinical and research experience regarding pain assessment. No prior knowledge about computerized assessment was required.

Experts were asked to rate the importance of using a CPBM for assessment of pain location and the relevance of including the following three dimensions: pain intensity, pain radiation, and pain character. These dimensions were selected based on a review rating important dimensions for pain assessment in palliative care.[8] The experts also were asked if they wanted a pain intensity score for every location that was marked. Answers were rated on a 0−10 numeric rating scale (NRS) (0, no agreement; 10, best possible agreement). The survey could be accessed for two weeks with a reminder after one week. All responses were anonymous.

Pilot Study. The study was conducted with a convenience sample of 28 oncology inpatients and outpatients at St. Olavs Hospital, Norway, who had incurable metastatic or loco-regional disease and tumor-related pain. Patients were presented with three different software versions of CPBM and asked which one they preferred for marking pain locations. First, black and white, shaded gray, and shaded color versions, respectively, of a body drawing were presented separately to the patients on the computer screen. Second, three options for the actual marking of painful areas were tested, all using a stylus on the touch-sensitive screen: 1) circling the area by drawing an outline on the screen, 2) shading the area by scrawling on the screen, having the computer automatically and simultaneously creating a corresponding outline, or 3) shading the area by scrawling, with the computer enveloping the area on completion of the drawing.

Patients also were presented with two options for scoring pain intensity. When a painful area was marked, a 0−10 NRS popped up for scoring the pain intensity in that particular location. This automatically led to a change in the color of the already marked pain location, based on a predefined color for each number on NRS. Two different layouts of NRS with different sizes of the buttons for marking pain intensity were tested.

Development of the software prototype was a collaborative effort between health care providers and software developers. Experience from a previous tool,[26] with a body divided into regions that patients could choose as pain markers, helped guide the development. A more flexible solution that enabled dynamically marking pain location supplemented with pain intensity was desired, and the prototype was developed iteratively based on feedback from health care providers in an evolutionary development process.[27,28] Hewlett Packard Development Company, L.P., HP Compac TC4200L 1200 tablet computers were used. The software was developed using JAVA and Eclipse for touch-screen computers running Windows XP.

The pilot study was approved by the Regional Committee for Medical and Health Research Ethics, Central Norway, and was conducted in accordance with the rules of the Helsinki Declaration. Written informed consent was obtained from all participants.

Standard descriptive statistics were used, using the PASW 18 statistical package (SPSS Inc., Chicago, IL).

Results

Expert Survey. Seven international and 15 national experts (58%) responded. There was high consensus, with a mean score of 9.6 on the 0–10 NRS, that a CPBM should be used for assessing pain location. The importance of assessing pain radiation received a mean rating of 8.0, intensity 7.8, and pain character 6.6. The two projections—anterior view of the whole body and posterior view of the whole body—received ratings above 9 (9.6 and 9.3, respectively). Lateral views of the head and neck were rated 5.9; all other projections were rated less than 5. Fourteen (64%) experts preferred a compulsory rating of pain intensity as part of the map. There was no consensus regarding the use of different CPBM versions for different levels of cognitive functioning (yes, 10; no, 12).

Pilot Study. The software options were tested by 15 male and 13 female patients with advanced cancer, mean age 61 years (range 32–80) and mean Karnofsky Performance Status (KPS) score of 79 (range 60–100) (data not tabulated). Nineteen patients (68%) preferred the shaded color version of CPBM. Thirteen patients (46%) preferred marking the painful area by scrawling on the touch-sensitive screen with the computer automatically enveloping the area while drawing, whereas six wanted to scrawl and have the computer envelop the area when the drawing was completed. Eight preferred just to circle the area, and one patient expressed no preference. All patients preferred the version with the larger radio buttons for scoring the pain intensity on NRS.

Study 2. Testing CPBM in EPCRC-Computerized Symptom Assessment (CSA) Study

Methods

Based on the results from the pilot, a refined version of CPBM was developed. This version supported scrawling of pain locations and indicating pain intensity through line color. As with the prototype, the refined version was developed iteratively in an evolutionary development process that included feedback from health care providers.[27,28] The final version was quality assured by professional testers.

This application was tested as part of a large international multicenter study, EPCRC-Computerized Symptom Assessment (CSA), which included more than 1000 patients from 17 centers in eight countries from October 2008 through 2009.[27] Four language groups were included: English, Norwegian, German, and Italian. The inclusion criteria were a verified cancer diagnosis, incurable metastatic or locally advanced disease, age ≥18 years, ability to complete the survey, and provision of written informed consent.[27]

All data collection was performed on touch-sensitive computers. The registration consisted of two parts, one to be filled in by the health care professionals, the other by the patients. All data were entered by tapping directly on the screen with a stylus. The health personnel part encompassed sociodemographic and medical variables, the Mini-Mental State Examination (MMSE),[29] and KPS.[30] The patient part comprised one set of items, primarily focusing on cancer-related symptoms, physical functioning, depression, and preferences for computerized or paper-based symptom assessment. All patients were presented with one screening item about worst pain intensity from BPI.[16] If they reported pain intensity of ≥1 on the 0–10 NRS, patients were automatically routed to a set of pain questions, which also included CPBM. The questionnaire matrix is described in detail elsewhere.[27] No specific training beyond a very simple, introductory demonstration was provided, but the research nurse was present to assist if necessary. The same ethical considerations applied as in the pilot study.

CPBMs were examined by two physicians. They independently evaluated the consistency of the markings on the anterior and posterior views with respect to body half (right/left), number, size and location of anatomical areas marked, and whether they perceived the information on CPBM as unequivocal or difficult to interpret. The maps were labeled as "acceptable" or "not acceptable" based on the consistency of markings, after a common, final

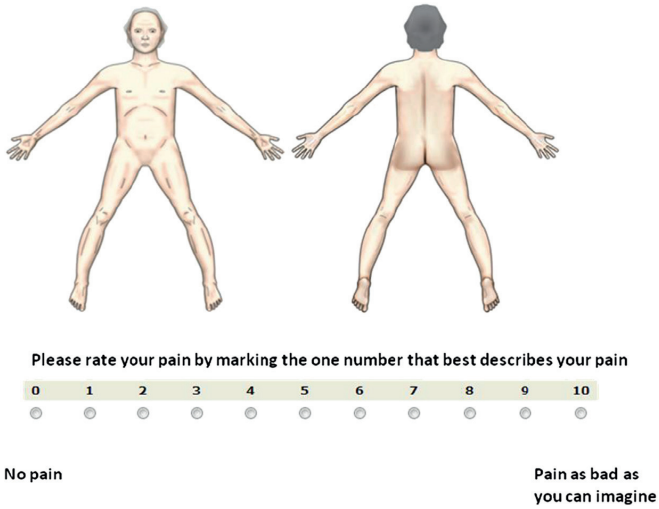

Fig. 1. CPBM with pain intensity scale for each pain location.

evaluation. Examples of two CPBMs from this study are shown in Fig. 1.

Differences across the patient groups ("acceptable" vs. "not acceptable" CPBMs) were investigated using Pearson's Chi-square and independent sample t-tests for categorical and continuous variables, respectively. Because of the exploratory nature of this cross-sectional, descriptive study, sample size and power calculations were not performed. The scoring of pain intensity for each pain site was not subject to specific analyses in the two clinical studies—EPCRC-CSA and the study comparing CPBM and the paper map—because of the small sample size in each subgroup. The same applied to differences across countries, as a result of an overrepresentation of Norwegian maps. A *P*-value of 0.05 or less was considered statistically significant. Analyses were performed using IBM SPSS Statistics 19 (SPSS Inc., Chicago, IL).

Results

A total of 1017 patients provided records that could be analyzed.[27] Among these, 535 patients scored ≥1 on the initial pain screening question and were presented with CPBM. Two body maps were excluded because they had no marked areas. The patient sample ($n = 533$) comprised 286 males and 247 females, with a median age of 63 years (range 20–90 years). The majority (70%) were inpatients (Table 1). The most prevalent diagnoses were gastrointestinal (22%), lung (18%), and breast (15%) cancer.

A total of 453 maps (85%) were judged to be acceptable, that is, the painful areas had been marked in a way that conveyed unequivocal information to the two physicians evaluating CPBMs with respect to both pain location and intensity. The number of marked areas varied from one to eight, with a mean ± SD of 1.8 ± 1.2. Eighty maps (15%) displayed one or more aberrant markings resulting in ambiguous or no information for the physician. These maps were labeled "not acceptable." In 49 cases, the area marked on the anterior view was not consistent with the area marked on the posterior view. In most of these cases, the patients obviously had mixed up right and left on the body drawings on the screen.

The color of the marked areas representing pain intensity was gray in 10 cases. This color did not represent a number on NRS and thus provided no information. Seventy-six patients had marked areas on top of other marked areas. This may have represented different pains in the same location, but often these areas were marked with the color gray, implying a mistake. Forty-four patients had markings on CPBM that were just a single

Table 1
Patient Characteristics in the EPCRC-CSA Study

Patient Characteristics	All CPBMs	"Acceptable" CPBMs[a]	"Not Acceptable" CPBMs[b]
Number of patients (%)	533	453 (85)	80 (15)
Sex, *n* (%)			
Male	286 (54)	240 (53)	46 (58)
Female	247 (46)	213 (47)	34 (42)
Age, mean (SD)	61.6 (12.6)	61.5 (12.6)	62.2 (12.3)
MMSE score, mean (SD)	27.6 (2.8)	27.6 (2.9)	28.1 (2.4)
KPS score, mean (SD)[c]	67 (16.2)	67.5 (16.0)	65.8 (17.3)
Pain intensity,[d] mean (SD)	4.8 (2.7)	4.8 (2.7)	5.0 (2.8)
Treatment setting, *n* (%)[c]			
Inpatients	373 (70)	324 (72)	49 (61)
Outpatients, *n* (%)	158 (30)	128 (28)	30 (38)
Level of education, *n* (%)[c]			
9 years	188 (35)	162 (36)	26 (33)
12 years	197 (37)	167 (36)	30 (38)
College/university ≤4 years	78 (15)	66 (15)	12 (15)
University >4 years	66 (12)	56 (12)	10 (13)
Experience with computers, *n* (%)[c]			
None	159 (30)	135 (31)	24 (32)
Little	109 (20)	94 (22)	15 (20)
Some	111 (21)	96 (22)	15 (20)
A lot	127 (24)	107 (25)	20 (27)

EPCRC = European Palliative Care Research Collaborative; CPBM = computerized pain body map; MMSE = Mini-Mental State Examination; KPS = Karnofsky Performance Status.
[a]Computerized pain body maps that provided unequivocal information about the pain location.
[b]CPBMs that did not provide unequivocal information about the pain location.
[c]Missing: treatment setting: $n = 2$; KPS: $n = 11$; level of education: $n = 4$; experience with computers: $n = 27$.
[d]On the pain intensity screening item: worst pain last 24 hours, scored on a 0–10 numeric rating scale.

point or a line within or outside the body outline.

No statistically significant differences were found between the patients with "acceptable" vs. "not acceptable" CPBMs with respect to age, sex, KPS, and MMSE scores (Table 1), nor in relation to prior experience with computers.

Study 3. Comparing CPBM and the Paper PBM

Methods

The comparative study was performed in a subgroup of patients included in the EPCRC-CSA study at St. Olavs Hospital, Norway, supplemented by a few patients who were too frail to complete the EPCRC-CSA study. These patients also underwent an MMSE.

The two maps were presented to the patients in a pre-assigned random order. The time span between completion of the two maps was 20–30 minutes. This gap was chosen to try to reduce possible recall bias between assessments, while at the same time ensuring a stable pain condition to avoid inconsistent markings because of pain fluctuations. The patients marked the location of their pain on CPBM before or after completing a regular paper PBM from BPI,[16] which is used daily in the hospital. All patients were asked if they preferred the paper version or CPBM after completing the registrations.

The two versions underwent independent evaluations by two physicians. They counted the marked areas and described each pain location using conventional anatomical terms. The descriptions were then compared to ascertain if the two maps had conveyed the same information, and each pair of maps (paper and CPBM) was rated as either "identical" or "different." The two sets of descriptions were then evaluated by the physicians together. In cases of doubt, the original body maps were reviewed once more. Simple descriptive statistics were used. The ethical considerations were the same as in Studies 1 and 2.

Results

Ninety-two patients were included in the comparative study; 83 were recruited from the EPCRC-CSA study (Fig. 2). In 65 cases (71%), the physicians found that the patients

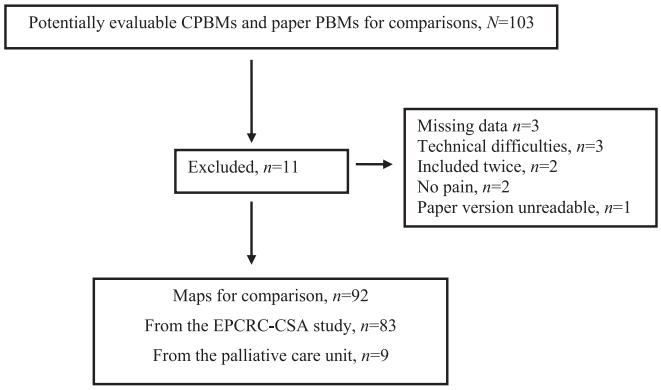

Fig. 2. Overview of the computerized and paper pain maps evaluable for comparison. CPBM = computerized pain body map; PBM = pain body map; EPCRC = European Palliative Care Research Collaborative.

had marked the same number of areas and the same anatomical locations on CPBM and the paper PBM. Mean number of marked areas were 2.7 and 2.4 on the "identical" and "different" maps, ranging from 0 to 7 and 1–12, respectively (Table 2) (Fig. 3).

The remaining 27 pairs differed in various aspects. In seven cases, the markings on CPBM and the paper PBM were completely different and conveyed different information; three of these patients had obviously mixed up left and right. In the remaining 20 cases, relatively similar anatomical locations were marked, but there were still slight differences; most often, fewer areas were marked on the computerized maps. In one case only, CPBM had more marked areas than the paper PBM.

The main characteristics of the groups with "identical" and "different" maps are shown in Table 2. No statistically significant

Table 2
Patient Characteristics in the Comparative Study

	"Identical" Maps[a]	"Different" Maps[b]	*P*-value
Number of patients (%)	65 (71)	27 (29)	
Sex, *n* (%)			
Male	40 (62)	19 (70)	
Female	25 (38)	8 (30)	
Age, mean (SD)	66 (11.9)	67 (11.9)	
MMSE score, mean (SD)	28 (2.4)	27 (1.9)	
KPS score, mean (SD)	68 (16.2)	66 (11.4)	
Painful areas marked, mean (SD)	2.7 (2.5)	2.4 (1.8)	
Treatment setting, *n* (%)			
Inpatients	55 (85)	25 (96)	0.04
Outpatients	10 (15)	2 (4)	
Level of education, *n* (%)[c]			
9 years	18 (28)	11 (41)	
12 years	21 (32)	9 (33)	
College/university ≤4 years	13 (20)	2 (7)	
University >4 years	10 (15)	5 (19)	
Experience with computers, *n* (%)[c]			
None	16 (25)	6 (22)	
Little	6 (9)	9 (33)	
Some	19 (29)	7 (26)	
A lot	14 (22)	3 (11)	

MMSE = Mini-Mental State Examination; KPS = Karnofsky Performance Status.
[a]Maps that showed identical markings on the computerized and paper versions.
[b]Maps that showed different markings on the computerized and paper versions.
[c]Missing: level of education: identical maps, *n* = 3 (5%); experience with computers: "identical maps," *n* = 10 (15%), "different maps:" *n* = 2 (7%).

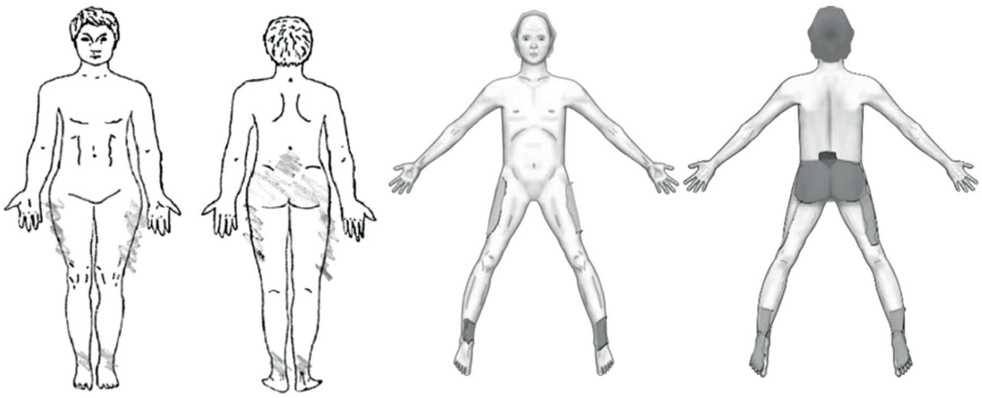

Fig. 3. Examples of identical pain markings on the paper and computerized versions. Colors representing the pain intensity on the computerized pain map are not shown in this black/white version.

differences were found between the two groups, except for a significantly higher proportion of inpatients in the group with "different" maps ($P = 0.04$). A closer examination of the maps, however, revealed that the patients with "different" maps obviously had had more difficulties marking CPBM than the patients with "identical" maps, as shown by aberrant shapes, markings outside the body contour, and markings with single points or straight lines only. The order in which the body maps were presented to the patients had no influence on the results: "different" vs. "identical" maps, or on which version the patient preferred.

Sixty-two (73%) of the 92 patients preferred CPBM to the paper map. Only four patients preferred the paper map; 16 patients expressed no preference. Those who preferred CPBM had a mean age of 64 years (range 20–83 years), a mean KPS score of 65 (range 40–90), and a mean MMSE score of 28 (range 16–30), not significantly different from the remaining patients. Both physicians found CPBMs easier to read and evaluate than the paper maps.

Discussion

This article describes the development of a first version of a CPBM for use in patients with advanced cancer. The development was conducted according to the stepwise, international methodology used in the EPCRC project[19,25] and included an expert survey, a pilot study, and two clinical studies, after a thorough examination of the existing literature. This or similar methodologies have been used in the development of several well-validated questionnaires[31,32] to ensure a uniform high quality.[33] This is also the best way to achieve consensus and ensure widespread use. The patient studies of CPBM showed that this form of assessing pain location was well accepted by patients with advanced cancer and that the majority were able to complete the maps as intended.

Members of the international expert panel almost all agreed that a CPBM should be used for assessing pain location, in line with previous reports emphasizing pain location as one of the key variables in a pain classification system[34] and for pain assessment in palliative care cancer patients.[7,8] This and other results from the panel led to the development of the first version of a CPBM that provided options for distinct markings of multiple pain locations, thereby also indicating pain radiation. CPBM was supplemented with the automatic presentation of scales for rating pain intensity for each location. We believe that this results in a better and more detailed pain assessment, especially in patients with fluctuating pain of varying intensity that may be the result of tumor invasion, bone metastases, neuropathic pain, etc.

The prototype was then pilot-tested in a patient sample with advanced disease. Because

any symptom measure should be easy to administer and process, yield precise and immediate results, and, above all, be acceptable to patients, patients in the target groups should be involved in the development process.[33,35] In our study, this resulted in useful and accurate feedback on the layout and interface of CPBM.

One also can argue that patients could have been involved before the development of the prototype, in line with the user-centered design philosophy used in modern software development.[36,37] In hindsight, it could be that some of the shortcomings of the software could have been detected at an earlier stage, despite being time-consuming in the development process. However, the initiation of this project came from clinical work and demonstrated a high degree of user-friendliness in the target group.

The feedback from experts and patients guided the development of CPBM, before the international testing in the EPCRC-CSA study. The international acceptability of CPBM was substantiated by the fact that 85% of the sample was able to complete CPBM in a way that gave unequivocal information to the physicians. Furthermore, no significant differences in any of the well-known variables for study compliance (age, gender, performance status, etc.)[26,27] were found across "acceptable" vs. "not acceptable" CPBMs. Although we were surprised that KPS scores did not seem to exert an influence here, one could argue that KPS is primarily a measure of physical performance, whereas interacting with computers relies more on cognitive functions. The average MMSE score among participants was high, 28 (maximum 30), indicating that most patients were cognitively intact.

Before study start, we expected that previous experience with computers and level of education would mirror the computer literacy and influence the ability to use and the preference for CPBM. This was not the case, as there were no differences in previous computer experience associated with these factors. However, we did not ask about the actual use of computers and degree of access to the Internet, which may be good indicators of computer literacy. Also, the significance of computer literacy for this specific task is difficult to ascertain because similar programs are not in frequent use by patients in general.

The comparative study showed that the majority of the patients had identical markings on the computerized and paper PBMs, regardless of which one they completed first. Most of the "different" markings were found on CPBMs, with aberrant shapes and dots, making us think that this could be a problem with the software. The screen was relatively sensitive, which might have contributed to unintentional dots and lines. Although an option for erasing erroneous markings was incorporated, thorough evaluation of CPBMs revealed that this function was rarely used. The fact that some patients had mixed up the right and left sides of the body on the two versions could have been avoided by clearly marking this on the screen. However, a paper map does not necessarily serve as the gold standard for validating correct markings. To investigate this in more detail, further comparative studies should use an interactive method specifically investigating the process when completing the maps.

The majority of the patients who were asked to participate in the comparative study were inpatients who either aborted or who were not asked to participate in the EPCRC-CSA study. This may indicate a higher disease burden overall in comparison with the patients in the EPCRC-CSA study. In this respect, it is promising that three-quarters had identical markings, although we are well aware that the next comparative study should be part of a larger international validation study that enables more subgroup comparisons with respect to pain intensity, cognition, and performance status.

The strengths of this study are first and foremost related to the stepwise systematic and internationally anchored development that is part of the promising international collaboration on pain assessment and classification carried out by the European Palliative Care Research Centre,[38] with support from, among others, the European Association for Palliative Care Research Network.[39] The value of input from patients and pain specialists early in the development phase was an important asset for the software development, as was the close dialogue between developers and health care providers. The usefulness of commercially developed software is often limited by lack of detailed knowledge about the end users, in this case patients with advanced disease and health care providers.

Although a healthy bias cannot be ruled out because of the inclusion procedures in the EPCRC CSA study,[27] it was promising that the first version of CPBM was so well accepted by patients, although 15% of the patients marked their maps in a way that did not convey unequivocal pain information. Regardless of the cause, be it technical problems or difficulties on the part of the patients, any pain assessment tool should be regarded as a facilitator for symptom evaluation and not a substitute for direct doctor-patient communication. Also, more knowledge about specific variables that reduce patient compliance or increase the validity and reliability of computerized tools is necessary. This warrants large international studies, with an even distribution of countries, languages, and medical and sociodemographic characteristics. We know that paper- and pencil-based questionnaires might remain the preference for a number of patients and settings. So far we know little about the feasibility of using computerized technology in, for example, groups with lower education levels and immigrant subgroups, etc., in the Western world; this also calls for specific validation studies.

The use of different electronic devices, for example, computers, cell phones, and tablets offers several benefits for patients and heath care providers. However, the enthusiasm for rapid results must be viewed against the fact that introducing new technology implies costs in terms of money, training time, and education and relies on the buy-in from stakeholders. Poor compatibility and ethical restraints often hinder direct transfer to patient records and limit the usability in clinical settings.[19,27]

Additional body projections may be included in a future CPBM to improve the description of pain extension. Also, three-dimensional interactive CPBMs have been tested in patients with low back pain, yielding good visual displays of the width, height, and depth of the pain.[40,41] Other domains besides pain location and intensity, such as pain radiation and pain quality, also may be incorporated into a CPBM. Based on our results, we are in the process of improving CPBM for further patient testing and international validation in palliative care cancer patients.

Conclusion

Results from the present study show that CPBM worked well and was well accepted in patient samples with advanced cancer. Areas of improvement were revealed and are being incorporated into a new CPBM version that is subject to additional clinical testing.

Disclosures and Acknowledgments

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Paper II

Is not included due to copyright

Paper III

Pilot testing of a Computerized Pain Body Map – facilitating coordinated management of neuropathic cancer pain

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Abstract

Quality pain management implies a thorough pain assessment with structured communication between patients and healthcare providers. Pain distribution is an important dimension of cancer pain. Assessment of pain distribution is commonly performed on a pain body map. This study explores how a computerized pain body map (CPBM) may function as a communication tool and visualize pain in patients with advanced cancer.

In previous studies, we have developed a tablet-based CPBM for use in cancer patients. The aim of the present study was to adapt the CPBM program to patients with neuropathic cancer-related pain, and to develop a separate interface for clinicians. We also wanted to investigate the perceived usefulness of this system among patients and their care providers. Both patients and healthcare professionals perceived the visualization of pain in the CPBM system as a positive contribution to clinical pain management, and to improve collaboration between healthcare providers.

Keywords

Cancer pain, computerized pain body map, pain assessment, usefulness, visual aid

Introduction

Efficient pain management requires good communication and access to all relevant information. Even though pain is a universal human experience, pain is subjective, and there is no common language presenting a precise and universal description of the problem. Also, individuals have varying ability to express their pain. Assessment tools have been developed to address this challenge [1] and structure information related to the severity of the problem, the impact, and the effect of the pain management [2].

Pain is a highly prevalent problem in patients with cancer, and increasingly so with advanced, incurable disease [3-5]. Cancer pain may be caused directly by the tumor, or result from cancer treatment [2, 5-7]. Pain in patients with advanced cancer is broadly classified into 'common' nociceptive pain that arises from tissue damage and is due to activation of pain receptors[8], and neuropathic pain, which is caused by a lesion of the somatosensory nervous system giving an 'abnormal' activation of pain pathways [8]. In clinical studies, cancer related pain of predominantly neuropathic origin is reported with a high prevalence, indicating under-recognition and under-treatment in clinical practice [7, 9].

Collecting information from patients for pain management is performed in an iterative way. Decisions are based on available historical data, information on the current problem, and available treatment options. Consequently, the communication between patients and healthcare providers (HCPs) must adapt to the severity of the patients' disease, taking the possible impact of treatment side effects and progression of the disease into account. Pain distribution and changes in pain patterns may be related to specific pain syndromes in need of urgent care, or may represent progression of disease in need of early detection. Neuropathic pain distribution has often a more distinct

anatomical pattern dependent on cause and location [6, 7]. These factors make visualization of pain an important part of the assessment.

For most patients with pain, management of their symptoms will require involvement from several HCPs such as physicians, nurses, physiotherapists or occupational therapists. Currently, handover of patients between HCPs is supported by written or oral communication. However, evidence shows that pain is poorly documented in the patient's health record [10-12] causing reduced transparency within the treatment team and reduced interdisciplinary influence on decision making.

Visualization of the pain on a pain body map is a way to reduce the complexity for patients, describing the pain distribution by drawing the painful areas on a body image [13-15]. This method has been shown to be reliable for patients with different chronic pain conditions as well as cognitive impairment [14-16]. A body map is also shown to be an easy and reliable tool for HCPs interpreting the pain drawings [17, 18].

In recent years, several computerized pain body maps (CPBMs) have been introduced [13, 19-21]. These tools have mostly been developed for chronic pain conditions such as low back pain, post stroke pain, or chronic pain in general [13, 21]. However, publications documenting these tools provide limited evidence on patient involvement during their development.

Our group has aimed to develop a CPBM for the frailest and sickest patients with advanced cancer. In previous studies we have investigated how theses patients interacted with the tool [22], and how cognitive and physical impairment affected the interaction [22, 23]. From these studies we identified a set of requirements for the Graphical User Interface (GUI), size and weight of the computer, and quality of the touch screen. The result was a new CPBM with acceptable usability for even very frail patients with advanced cancer [23].

The primary aim for this project was to further develop the CPBM to fit the needs of patients with neuropathic cancer related pain. This included investigating the patients' views on the CPBM as a communication tool for a clinical purpose. A second aim was to collect feedback from HCPs on the features and functionalities of the CPBM, as well as the perceived implications of the system for clinical practice.

Methods

Two studies are presented.

Study 1: Pilot testing of the tablet-based CPBM in patients with cancer-related neuropathic pain.

Study 2: Norwegian and Scottish HCPs' perceptions of and views on the system (the CPBM for patients and a corresponding web page for clinicians).

Participants

Study 1: Patients referred to the Oncology Outpatient Clinic at Edinburgh Cancer Centre for management of neuropathic cancer related pain were recruited to the study. Inclusion criteria were age above 18 years, advanced cancer, neuropathic pain due to cancer or anticancer treatment, and ability and willingness to provide written informed consent. Neuropathic pain was defined as having a LANSS (Leeds assessment of neuropathic symptoms and signs) score ≥ 12 [24] and neuropathic pain components confirmed by a clinical examination [24, 25].

Demographic and disease specific information was taken from the medical record. The patients were asked about their level of education and current use of computers and touch screen devices.

Study 2: Physician specialists working in palliative care services in five different geographical areas (three in Norway and two in Scotland) were contacted by e-mail and invited to participate in a focus group evaluating a digital pain assessment tool. The physicians were encouraged to pass the invitation on to 2-3 colleagues working in palliative care (full time or part time). A group of general practitioners (GPs) responsible for palliative care admissions in a community health care centre in a rural area was also invited.

Digital tools

A paper mock-up (Fig. 1), a CPBM application for iPad, and a webpage displaying the patient data from the iPad registrations (Figs. 2 and 3) were developed and used during the study.

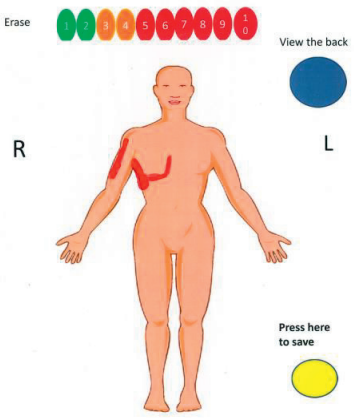

Figure 1. Paper mock-up of a CPBM

The laminated mock-up included two pages; a menu for selection of enlarged body parts, and the corresponding images for marking the pain. The iPad CPBM presented the same features as the paper mock-up.

Data from the iPad application was transferred to a server. The pain drawing data was prosessed and presented for HCPs via a web interface. The patient drawings could be displayed either as a layered presentation showing the composite changes in pain over time (Fig. 2), or as a side-by-side presentation of the individual body maps (Fig. 3). The system presented the changes in pain (location and intensity) in a table, or listed on the screen above the CPBM. The system also provided the option to annotate the patient drawings. The processed patient data included changes in pain intensity (difference between current and highest previous pain score), extension of the marked area in percent of available surface, as well as the exact location of the marked area. This was defined by the neuroanatomical location as described by the segmental innervation of spinal and cranial nerves (dermatomes).

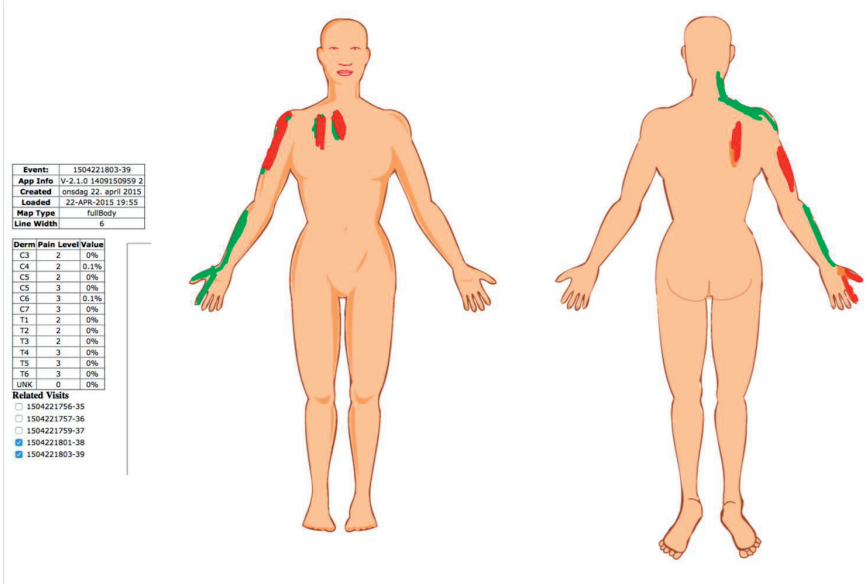

Figure 2. Layered presentation of two CPBMs from the same patient on the clinical interface

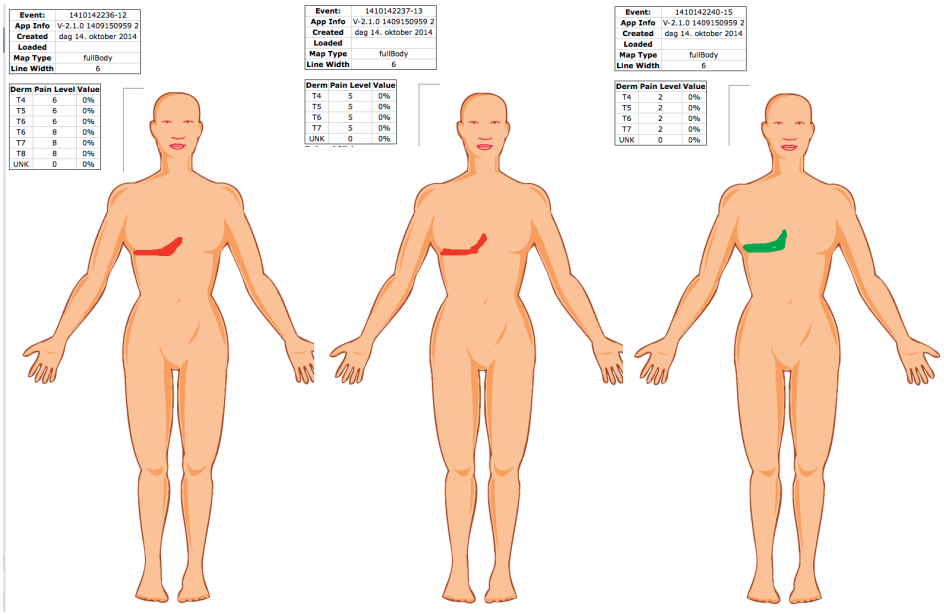

Figure 3. Side by side presentation of three front CPBMs from the same patient on the clinical interface

Questionnaires on technology acceptance and usability

The questionnaires were used to standardize the test situation and guide the collection of information [26, 27]. The System Usability Scale (SUS) is a questionnaire examining how well an application is adapted to the user in terms of effectiveness, efficiency, and satisfaction [28]. Patients rate their agreement to the statements from 1 (strongly disagree) to 5 (strongly agree).

The second questionnaire used in this study was an adapted version of the Technology Acceptance Model (TAM), assessing perceived ease of use and perceived usefulness of an application [29]. In Study 1, patients evaluated the CPBM, and in Study 2, HCPs evaluated the whole system (CPBM and webpage). Answers were scored on a 1-5 numerical rating scale (NRS). In study 1, a question about sharing pain data with family

and friends was added to the TAM questionnaire. In Study 2, the following questions were added; 'Do you believe that using this system (iPad and corresponding webpage) can improve the communication between you and other health care providers?' and 'How would you compare this tool to traditional paper-based pain body maps?' Several of the respondents also chose to give written comments to questionnaire items. These comments were included in the qualitative analysis.

Procedure

Study 1 The purpose of the study was to tailor the CPBM to patients with cancer related neuropathic pain. The procedure followed a methodology for software development [23]. The patients were given a demonstration of the tool and instructions for using a stylus. Selection of pain intensity was necessary to 'activate' the screen, by touching a number on the 1-10 NRS, displayed as a triage system, inspired by the Edinburgh Pain Assessment Tool (EPAT) [30] (1-2 green, 3-4 amber, and 5-10 red). The patients were given a detailed instruction to mark the painful areas in a way that would make the HCP understand where they had pain and the extension of their pain. During the task the patients were observed by the researcher. After the usability test, the patients were given the two questionnaires, and finally subjected to a post-test interview about their interaction with the tool and their evaluation of the CPBM.

The patients' markings on the CPBM were also used to guide the development of a web-application to process the data from the iPad.

Study 2: The physicians were presented with the CPBM and the corresponding webpage.

The study consisted of three steps: 1) Presentation and demonstration of the system, with the option to try it hands-on; 2) TAM questionnaire; and 3) a focus group interview.

Scenarios

Study 1: Testing by patients was performed in connection with a visit to the palliative and supportive care specialist at the Oncology outpatient clinic.

Study 2: The clinicians were presented with a scenario describing a breast cancer patient with severe pain who visited different HCPs responsible for her pain management at different points in time. The patient was admitted to hospital due to new, intractable pain in her back and persistent pain in the region of primary surgery. HCPs performed a clinical examination, made a treatment decision, and initiated treatment and follow up including tracking of previous assessments of the patient's pain. After discharge from hospital, pain management was performed in collaboration between pain specialists at the hospital and the GP who shared the same visual pain data on the webpage. During the presentation, the scenario was illustrated by data from the CPBM system.

Focus group interviews

The focus group interviews [31] followed a semi-structured interview guide developed by the authors, and aimed to elicit the perceived usefulness of the CPBM for facilitating pain communication and supporting clinical decision making. The participants were asked to discuss aspects of the patient scenario and the CPBM system based on their own professional experience.

Data processing and analysis

During the usability test, areas needing improvement were identified based on observations of 4-5 patients. In addition, comments, suggestions and questions from the patients were reported and integrated into the evaluation of the program.

Answers to the SUS and TAM questionnaires were analyzed using descriptive statistics by SPSS 21 (IBM, SPSS software). The focus group data was analysed and categorized into focal themes by two of the researchers (EAAJ, KH). The categories were refined in an iterative process focusing on consistency in thematic coding and interpretation [31, 32].

Research Ethics

The patient study (Study 1) was approved by the South East Scotland Research Ethics Committee 01, Scotland, UK. Each patient provided written informed consent before participation.

Results

Study 1, Patient study

We recruited 33 patients with verified neuropathic pain related to cancer or anti-cancer treatment. Patient characteristics are listed in Table 1. All patients were outpatients and had a Karnofsky performance status (KPS) score in the range 50-90 [33].

Table 1. Patient characteristics

Age (mean and range)	62 (39-79)
Gender	Female 15 Male 18
Education 12 years or less of school College or university degree	 19 14
Touch screen device usage Current user No previous use	 22 11
Time since cancer diagnosis (mean and range)	3 years (0-14 years)
Cancer diagnosis Breast cancer Colorectal cancer Myeloma, Lymphoma, Multiple myeloma, Myelofibrosis Others (e.g. Desmoid tumour, Pancreatic cancer, Mesothelioma, Cervical cancer)	 6 9 10 8
Anticancer treatment Chemotherapy (e.g. Cisplatin, Oxaliplatin, Bortaxomib, Taxotere) Radiotherapy/Brachytherapy Surgery	 29 12 20

Observation

Two thirds of the patients were familiar with tablet devices and applications, and recognized and commented on this during the presentation. Eleven of the participants had never held or interacted with a tablet prior to the testing. Observation of the patients gave no indication that interaction with and interest in the tool were influenced by previous experience using touch screen devices.

Four patients were presented with the mock-up (Fig 1). All four found the navigation easy and that the mock-up gave sufficient area to mark their pain on. The same features were transferred to the iPad for further testing.

All patients understood and were able to follow the instructions for use. We gave them a stylus for marking on the screen, but observed some trying to use a finger instead. This did not work well, since the finger covered the area the patient intended to mark. Consequently, the finger was perceived to increase complexity and inaccuracy when marking the painful areas. This was particularly important when marking small areas like fingers and toes for neuropathic pain (Fig. 4).

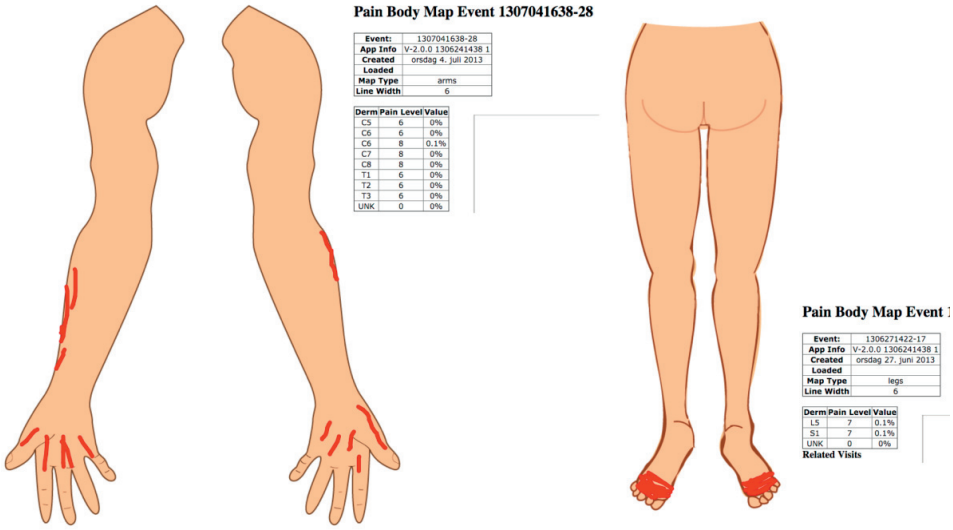

Figure 4. Marking of neuropathic pain distribution on hands and feet

We presented a menu of images of enlarged body parts for patients to choose from. The anterior and posterior whole body projections covered most of the screen, including side views of the head. The patients found all projections easy to use except from an image of two arms unattached to the upper body. For a couple of the patients this image presented

problems related to locating the intended side (left or right). No additional projections for marking pain were requested by the patients.

Patients were, in general, positive to the CPBM tool, and commented on how they would like to use it for private purposes.

Questionnaire results

The SUS and TAM questionnaires indicated that the patients found the CPBM easy to use. The majority of the patients thought that use of the CPBM would make it easier to communicate their pain and give them a higher sense of control in the pain communication with their HCPs (Tables 2 and 3).

Table 2. Results from the System Usability Scale (SUS) questionnaire from 33 patients pilot testing the CPBM (1, strongly disagree; 5, strongly agree).

Item from the System Usability Scale	Mean score (n=33)
I think that I would like to use the pain body map system frequently	4.3
I found the pain body map unnecessarily complex	1.6
I thought the pain body map was easy to use	4.7
I think that I would need the support of a technical person to be able to use the pain body map	1.3
I found the various functions in the pain body map were well integrated	4.3
I thought there was too much inconsistency in this system	1.7
I would imagine that most people would learn to use the pain body map very quickly	4.5
I found the system very cumbersome to use	1.4
I felt very confident using the pain body map	4.5
I needed to learn a lot of things before I could get going with the pain body map	1.4

Table 3. Results from the Technology Acceptance Model (TAM) questionnaire from 33 patients pilot testing the CPBM (1, strongly disagree; 5, strongly agree).

Item from the Technology Acceptance Model questionnaire, patients	Mean score (n=33)
Using the pain body map improves the quality of the communication of pain	4.3
Using the pain body map gives me greater control over the communication of pain	4.4
The pain body map enables me to accomplish the communication of pain more quickly	4.5
The pain body map supports critical aspects related to pain communication	3.9
The pain body map makes it easier to communicate pain	4.5
Overall I find the pain body map useful for pain communication	4.6

Post-test interviews

Evaluation of content

Most patients liked the triage of three colours. They commented that it made selecting pain intensity easier. One patient did not want the triage presented as a traffic light system, because fine changes in intensity over time would not be displayed by a change in colour.

Context of use

The majority of the participants approved of the system and thought it would be very helpful in a conversation with their treating physician or pain specialist. Self-monitoring of pain was also considered helpful, observing changes on a day-to-day or through the day basis. One patient suggested that longitudinal self-monitoring as opposed to one single measure would be more useful in the conversation with the physician. Several patients liked the idea of using the CPBM for communication with family and friends. The patients evaluated the tool from their personal perspectives. The sharing of

information was based on their own personal needs, and not on serving the needs of a HCP.

Two patients did not see any point in using the tool and would rather communicate with the pain specialist without the support of a pain drawing. One of the two said he would communicate better and more quickly without having to use the tool.

Suggestions for improvement

The suggestions for improvement were mainly related to integration of a feature showing when the markings were made (temporal domain). The patients also wanted to annotate pain in relation to activity, e.g., pain when walking or standing.

Study 2 – HCP study

Nineteen HCPs were included in the study. All HCPs were experienced physicians practising palliative care as a palliative medicine specialist, oncologist, pain specialist, or GP, in Norway (N=15) or Scotland (N=4).

TAM questionnaire

The HCPs perceived that using the CPBM system would improve the pain communication between patients and HCPs. They also perceived the system to be a helpful tool when communicating with a colleague about a patient in pain. The results from the TAM questionnaire are displayed in Table 4.

Table 4. Results from the Technology Acceptance Model (TAM) questionnaire from 19 health care professionals (HCP) evaluating the CPBM system (1, strongly disagree; 5, strongly agree).

Item from the Technology Acceptance Model questionnaire, health care professionals	Mean score (n=19)
Using the pain body map system (patient using tablet and me using the website) improves the quality of the communication of pain	4.1
Using the pain body map system (patient using tablet and me using the website) gives me greater control over the assessment of pain	4.1
The pain body map system (patient using tablet and me using the website) enables me to improve the communication of pain	4.0
The pain body map system (patient using tablet and me using the website) supports critical aspects related to pain communication	4.1
The pain body map system (patient using tablet and me using the website) makes it easier to communicate pain	4.0
Overall I find the pain body map system (patient using tablet and me using the website) useful for pain communication	4.2
I believe the pain body map system (patient using tablet and me using the website) can be useful in communication between me and other healthcare providers	4.2

Focus group interviews

Five focus group interviews were conducted. The HCPs' overall impression of the system was good support for pain assessment by improvement of the pain communication with the patient as well as support for communication between colleagues.

The HCPs' responses in the group interviews were analysed and categorized by three focal themes: *technical aspects, clinical aspects,* and *organizational aspects* pertaining to the use of the CPBM. The HCPs' main perceived strengths and concerns related to the CPBM system are listed in Table 5.

Table 5. Focal themes from five focus group interviews with health care professionals (n=19) evaluating the CPBM.

Features of the CPBM	Technical aspects	Clinical aspects	Organizational aspects
Perceived strengths	Access to patient data from webpage	Historical data Visualization of pain distribution	The CPBM perceived as a boundary object in communication
	Patient App independent of network	Pain drawing perceived as the 'patient's voice' Sharing of pain drawing	Strengthening the role of the nurse
Clinicians' concerns	Connectivity issues: access to wireless network, range and stability of the network	Digital communication to replace face to face contact	Workflow organization and defining responsibilities in the work process

Technical aspects

A system providing access to patient data independent of administrative healthcare level, discipline and location was considered a great benefit.

HCPs working in hospitals had experience of areas with no or limited wireless network coverage.

Participants in the Norwegian focus groups expressed concerns related to the lack of integration of the clinician's webpage into the electronic health record (EHR). These HCPs assumed that to log on to an additional webpage outside the EHR would be too cumbersome in clinical practice.

Compromising patient security and privacy was mentioned in several groups when discussing current guidelines, norms, and regulations for implementation of digital tools

in healthcare settings. The clinicians showed a high level of awareness of issues pertaining to information security and interoperability of digital tools.

The simplicity of the tool was considered a great benefit among many of the HCPs,

> "*the pain body map can also engage the patients a bit more because I think patients struggle sometimes with some of the questions we ask them*."

Clinical aspects

The HCP interface of the CPBM was perceived to display historical pain data from the patient in a good way,

> "*currently pain management tends to be supported by a paper pain assessment tool*",
>
> "*during the conversation with the patient we don't have a presentation of the history as displayed here*".

This type of information was considered important in palliative care where changes in pain intensity or location could indicate treatment response and/or disease progression. The HCPs also considered the pain distribution on the CPBM to be more accurate than the drawings they were used to. The concepts of sharing visual information and visualisation of pain as displayed were commented on,

> "*could possibly change the way we communicate about pain today*."

One theme for the focus groups was whether the visual pattern on the patient`s pain drawing could give additional information with regard to pain etiology. One participant outlined a case in which a written referral from a GP described a patient with back pain,

which later proved to be a case of spinal cord compression. The description of the patient's pain from the referral letter did not trigger a rapid response from the HCP, but

> "*if the patient would draw his or her pain and you would see it on the screen, you'd be like: 'I've seen that picture before'* "

and the HCP commented that it would have been more likely that the severity of the situation would have been understood.

The different colours visualized on the screen were seen as a strength,

> "*one of the strengths of the tool is in terms of cross-disciplinary discussion*. *The visualization of the pain can't be ignored.*"

One comment was about using the CPBM in reports,

> "*It becomes easier to write a report since all the information is in a drawing.*"

Some of the participants compared the system to how some HCPs practise pain assessment today, with the HCP asking the patient where it hurts, and filling in the painful areas on a paper PBM on the patient's behalf. In the interview, the researchers emphasized that the patients must fill in the CPBM themselves, giving no room for the HCP to influence the patient data before viewing it on the screen. However, some of the clinicians uttered concerns that easy access to information from digital devices could replace the face-to-face contact between patients and physicians,

> "*the iPad should not be a substitute for a doctor's appointment.*"

Organizational aspects

From an organizational point of view, the clinicians considered the webpage to be a "shared space" that could be used to reach a common understanding when discussing a patient's pain problem between hospital physicians, the GP, the physiotherapist, and/or community nurses. This was considered a great benefit, and more reliable than the traditional oral or written exchange of information.

This way of organizing information was considered an opportunity for transparency and more effective pain management, as well as simplifying sharing of information. The CPBM was also perceived to support a hand-over situation, either between colleagues working in the same organization, or between colleagues working at different levels of healthcare delivery.

The patient voice perspective was also commented on, especially when nurses ask doctors to provide better pain management on behalf of a patient in pain. The CPBM was considered a valuable tool and even described as a "*powerful*" tool, enabling the nurse to highlight the "*patient's voice"* and consequently give added credibility to the nurses' concerns on behalf of the patients,

> "*using the CPBM would both change the way we work and might also change the way we communicate and the content of the communication."*

Some of the HCPs expressed concern about using technology such as the CPBM in clinical care, and argued that in order to implement the tool, a work process would need to be defined in terms of responsibilities along the chain of healthcare delivery,

> "*use of the same tool and providing sufficient training require a lot of effort*"

However, if patients would understand the context and the questions asked during the pain assessment, they might be more involved in the pain conversation, the HCPs opined. Eventually this could also support shared decision making in pain management.

Suggestions for improvement

The HCPs had some of the same suggestions for improvement as the patients: to include a temporal dimension, pain in relation to activity, and medication. The option for annotation was already included in the webpage and could be used for these purposes. The HCPs also suggested additional ways to display longitudinal data to provide a quick visual interpretation, e.g., a graph for pain intensity.

Many of the physicians suggested inclusion of pain qualities. Some thought that information about pain quality should be entered by the patients, while others thought this was something that patients and HCPs should discuss during the consultation and jointly annotate on the webpage.

Discussion

In this project we have redesigned the CPBM to fit the needs of patients with neuropathic cancer related pain. Patients in this study confirmed that the the tool provided a good interface for a visual presentation of the neuropathic pain they experienced. Patients as well as HCPs thought the tool would be useful in a pain communication setting. Additionally, the HCPs found the display of historical data as well as the visual prompt useful for decision-making and communication.

The HCPs in this study were interested in the tool and how it might influence and be useful in their clinical work. Although pain in this patient population is highly prevalent,

commercially available digital tools usually lack scientific evidence and are therefore not eligible for clinical practice[34]. On the other hand, scientifically tested pain tool applications are mostly not commercially available and therefore not a part of clinical practice [34].

Aspects of assessments

The goal of a pain assessment is to map a subjective experience to create a common understanding of the problem before dealing with it. A mandatory prerequisite is the evaluation of the validity of the data. Observations in this study confirmed that patients with cancer related neuropathic pain were able to recognize the area on the CPBM to mark their pain, and could use the CPBM to provide useful information for clinicians. Visual representation of pain is an easier and more efficient way of communicating than a written text [13]. In this study we explicitly asked patients to provide as accurate information as possible about pain location, extent, radiation and intensity. The accuracy of the information was confirmed by the patient. The diagnosis of neuropathic pain was verified by a physician, but the accuracy of the information on the CPBM was not confirmed by a clinical examination. However, the information retrieved from examining the pain pattern and reviewing historical data on the web page, adds to the clinical information without depending on the patient's memory.

The green-amber-red triage system was perceived useful for selecting pain intensity by the patients, as well as for visualization of severity by the HCPs. A recent study on a pain intensity triage similar to the one in the CPBM, also associated with an algorithm for pain management, showed promising results in prompting clinical action [35]. Prompting action was also one of the perceived qualities from the HCPs in our study. Additionally, previous studies have suggested that frail and cognitively impaired patients, e.g., patients with dementia, prefer fewer response options than the commonly

used NRS 0-10 [36]. Thus, both the numbered groups and the visual colour code may help patients categorizing numbers on an intensity scale.

Clinical decision making

The prevalence of cancer related neuropathic pain varies between studies [5, 9, 37]. However, due to increased survival rate of cancer patients, and the profile of side effects of cancer treatments, the prevalence of neuropathic cancer pain is likely to increase. Thus, a timely recognition of the problem is needed.

In the present study, HCPs considered pain drawings as one way to highlight neuropathic pain patterns. A neuropathic pain pattern is proposed as a compulsory diagnostic criterion for neuropathic cancer pain, in addition to a history of a relevant lesion affecting the somatosensory system [38]. Even though pain information was regarded as very useful and important for decision making among the clinicians in our study, evidence indicates that pain is poorly reported in the health record [10, 11, 39].

Patient involvement

Both patients and HCPs perceived that using the CPBM system for pain communication facilitated sharing of pain information in an accurate and accessible manner.

In a previous study we demonstrated how usability problems in an earlier version of the CPBM could hamper patient involvement in the pain assessment [23]. The current version is developed with and for users with special needs, in a similar way as previously documented [40]. Thus, tailoring the ICT tool to the patient user must be considered another key prerequisite to increase user involvement in communication and shared decision-making.

Coordination of services

The CPBM system is a simple tool connecting patients and HCPs. Its features are very similar to the paper PBM, but, as our study shows, it is perceived to be substantially different in terms of usage. The system was perceived to have potential for organizational impact which could change and improve clinical practice, allowing for more transparent decision making and easier information sharing across services. This shows how a small scale system may influence healthcare delivery [41] as well as display the same qualities and challenges as a large scale EHR system [42, 43].

The patients in this study have a chronic condition, and live their lives outside the hospital. Complex pain management often requires specialist support. An information and communication tool that can connect the patient with the team of health care providers and facilitate assessment and follow-up may contribute to more efficient pain management. These aspects are central to patient centered care [44, 45].

Currently, there are few ICT systems focusing on the quality of the treatment. The comparison of longitudinal data from the same patient in different settings and situations could provide some of the needed information on treatment response or progression of disease [44, 45]. The concept of sharing longitudinal information about pain across levels of services represented a new way of working for the HCPs involved in the present study, both in Norway and Scotland. The HCPs considered that access to the same information could make the hand-over situation safer, and made it easier to give professional support to other HCPs.

Limitations

The testing of clinician software in the present study was performed in a selected group of stakeholders. The actual stakeholders for pain management in patients with palliative

care needs are a much wider group. Contributions from nurses, more GPs, physiotherapists and even occupational therapists would have strengthened our data.

The patient population included in this study did not include patients with cognitive impairment.

The tool was tested and evaluated by clinicians in a hypothetical setting. This means that their feedback was related to the idea of the tool and not hands-on testing.

Further work

The safety and efficiency of the CPBM system in clinical practice need to be examined in a study designed for this purpose. In this context, the proposed definition of safety is related to reliability in regard to recognition of patients with severe pain. The proposed definition for efficiency is related to the recognition of patients with mild pain. Clinicians and patients in the present study have also made valuable suggestions for improvement which need to be considered.

This study also provided us with an interesting observation. HCPs in Norway and Scotland responded differently to using internet-based tools in clinical practice. In Norway, the general idea was that the CPBM concept needed to be integrated into the EHR in order to be perceived as a viable option, whereas this was not mentioned among the respondents from Scotland. The different perceptions might be based on how Norwegian clinicians are conditioned by using the current EHR system, but this should be explored in further studies.

Rapid recognition of pain patterns that allow clinicians to identify syndromes that need immediate medical attention, e.g., spinal cord compression, is also an important part of clinical decision making. This requires more evidence on the visual presentation of pain, which needs to be explored in further studies.

Finally, there is a large gap in knowledge regarding how to improve the clinical decision making process. There are currently many analogue and digital tools available to support this process, but evidence shows that improvement of the decision making process has to be seen in a much wider context, including, e.g., behavioural and educational issues[46].

Conclusion

Our study confirmed the usability of the CPBM in patients with cancer related neuropathic pain. Both patients and HCPs considered the CPBM system to be useful in a pain communication setting. The webpage presenting the data to HCPs was seen to provide easy and rapid recognition of pain intensity and location, as well as changes in both. The HCPs especially reported satisfaction with the historical pain information, which they perceived not to be readily available in the current patient record. The CPBM concept was perceived to support clinical decision making, increase patient involvement as well as have the potential to improve coordination of services. In conclusion, this means that the CPBM system was perceived to facilitate and improve coordinated pain management.

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Competing interests

The authors declare they have no financial competing interest.

Authors' contributions

EAAJ, AK-P, KH and DFH contributed to the writing of the manuscript. EAAJ, MF and AK-P were responsible for Study 1; EAAJ, KH and DFH for Study 2. All authors approved the final manuscript.

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