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Pain Assessment in Palliative Care

Validation of methods for self-report and behavioural assessment

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Smertemåling i palliativ medisin: Validering av metoder for smertemåling ved selvrapportering og ved standardisert registrering av smerteatferd

Smerte er et hovedsymptom blant kreftpasienter og flere studier har påpekt viktigheten av valid smertemåling for å kunne gi adekvat smertebehandling. Smerte er et subjektivt symptom og den enkelte pasients selvrapporterte smerte er derfor den viktigste komponenten i smertemålinger. Det finnes en rekke måleinstrumenter for smerte og European Association for Palliative Care (EAPC) anbefaler multidimensjonale målinger ved Brief Pain Inventory (BPI).

Mange pasienter får redusert kognitiv funksjon mot slutten av sykdomsløpet. For pasienter som ikke kan rapportere smerter selv, vil skjemaer for standardiserte registreringer av tegn på smerte utfylt av helsepersonell og/eller pårørende være et nødvendig alternativ. Doloplus-2 er et anbefalt verktøy for slike smerteregistreringer, men det finnes lite empirisk materiale om de psykometriske egenskapene.

Hovedmålet med prosjektet var å fremskaffe ny kunnskap om smertemåling i palliativ medisin. En del av dette var å vurdere hvilke smertedimensjoner som er relevante for smertemåling i palliativ pleie og videre å evaluere to av de mest anbefalte smertemålene: BPI for selvrapportert smerte og Doloplus-2 for observasjonsbasert smertemåling.

Et panel på seks eksperter i palliativ medisin anbefalte at et optimalt smertemål skal dekke smertedimensjonene intensitet, temporært mønster, behandlingseffekt samt lindrende og forverrende faktorer, lokalisering og smertens innvirkning på funksjonsnivå. Ingen av dagens smertemål dekker alle disse dimensjonene på en tilfredsstillende måte.

For å utforske hvordan kreftpasienter rapporterer smertens innvirkning på funksjonsnivå ved BPI testet vi BPI i en pasientgruppe med fremskreden kreftsykdom og i en med kroniske, ikke-kreftrelaterte smerter. Smertemålene fra de to populasjonene ble sammenliknet og vi fant at mens kreftpasientene rapporterte at smerter i høy grad påvirket deres fysiske funksjon, anga de kroniske smertepasientene at smerter i første rekke påvirket deres psykologiske tilstand. Resultatene tydet dessuten på at kreftpasientene fant det vanskelig å si om deres nedsatte funksjonsnivå skyldtes smerte eller kreftsykdom.

Doloplus-2 ble oversatt til norsk og ble vurdert som brukervennlig for klinisk bruk. I pilotstudien var kriterievaliditeten tilfredsstillende. Hovedstudien viste imidlertid at Doloplus-2 er for lite smertespesifikt og krever kompetanse i å vurdere atferd som skyldes smerte og atferd som er forbundet med angst, forvirring og andre demensrelaterte faktorer.

Oppsummert viser avhandlingen at de tilgjengelige smertemålene har vesentlige mangler og videre forskning er nødvendig for å forbedre smertemål for klinikk og forskning.

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Ovennevnte avhandling er funnet verdig til å
forsvares offentlig for graden PhD i klinisk medisin.
Disputasen finner sted i Auditoriet i Laboratoriesenteret, St. Olavs Hospital
fredag 7. november 2008, klokken 12.15

"When the right thing can only be measured poorly, it tends to cause the wrong thing to be measured only because it can be measured well. And it is often much worse to have good measurement of the wrong thing –especially when, as is so often the case, the wrong thing will in fact be used as an indicator of the right thing –than to have poor measurement of the right thing" (Tukey 1979).

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List of original papers

This study is based on the following original publications, which are referred in the text by study or paper and belonging roman numerals I – IV.

I) Hølen JC, Hjermstad MJ, Loge JH, Fayers PM, Caraceni A, de Conno F, Forbes K, Fürst CJ, Radbruch L, Kaasa S. **Is the content of pain assessment tools appropriate for use in palliative care?** *J Pain Symptom Manage. 2006 Dec;32(6):567-80.*

II) Hølen JC, Lydersen S, Klepstad P, Loge JH, Kaasa, S. **The Brief Pain Inventory: Pain's Interference With Functions is Different in Cancer Pain Compared With Noncancer Chronic Pain.** *Clin J Pain. 2008 March/April; 24(3):219-225.*

III) Hølen JC, Saltvedt I, Fayers PM, Bjørnnes M, Stenseth G, Hval B, Filbet M, Loge JH, Kaasa S. **The Norwegian doloplus-2, a tool for behavioural pain assessment: translation and pilot-validation in nursing home patients with cognitive impairment.** *Palliat.Med.* 2005;19:411-7.

IV) Hølen JC, Saltvedt I, Fayers PM, Hjermstad MJ, Loge JH, Kaasa S. **Doloplus-2, a valid tool for observational pain assessment?** *BMC Geriatrics 2007, 7:29.*

Abbreviations

AB	Aberdeen low back pain scale
AD	Alzheimer's disease
AQoL	Assessment of quality of life instrument
BPI	Brief pain inventory (short form)
CAS	Coloured analogue scale
CAT	Computer adaptive testing
CNPI	Checklist of nonverbal pain indicators
DDS	Descriptor differential scale
DPQ	Dallas pain questionnaire
EAPC	European association of palliative care
EORTC	European organisation for research and treatment of cancer
EPIC	The expanded prostate cancer index composite
EQ-5D	Euro QOL Group
ESAS	Edmonton symptom assessment scale
FACS	Facial action coding system
FACT-G	Functional assessment of cancer therapy scale
FIQ	Fibromyalgia impact questionnaire
GCPS	Graded chronic pain scale
HRQOL	Health related quality of life
IASP	International association for the study of pain®
IBQ	The illness behaviour questionnaire
IPAT	Initial pain assessment tool
IRT	Item response theory
MDASI	M.D. Anderson symptom inventory
MIDAS	Migraine disability assessment scale

MOS-116	Medical outcome study 116 item core set
MPAC	Memorial pain assessment card
MPI	West Haven-Yale multidimensional pain inventory
MPQ	McGill pain questionnaire
NCCP	Noncancer chronic pain and Non-malignant chronic pain are used synonymously
NPAD	Neck pain and disability scale
NRS	Numerical rating scale
PAQ	Pain assessment questionnaire for a patient with advanced disease
PC	Palliative care
POS	Palliative care outcome scale
PRI	Pain rating index (in MPQ)
QLQ-C30	EORTC's 30 items quality of life questionnaire version 3
REK	The Regional committee for medical research ethics, Central Norway
RPS	Regional pain scale
RSCL	Rotterdam symptom checklist
SF36	Medical outcome study 36-item short form health survey
SMFA	Short musculoskeletal function assessment questionnaire
TIQ	Therapy impact questionnaire
VAS	Visual analogue scale
WBPQ	The Wisconsin brief pain questionnaire
WHO	The world health organization

Study objectives

The overall objective of this thesis was to improve our knowledge of pain assessment of particular relevance for palliative care. We wanted to evaluate two highly recommended tools for pain assessment in PC patients; the BPI for self-report and the Doloplus-2 for behavioural rating of pain. The research questions were as follows:

1. Which dimensions of pain are most relevant for self-reported pain assessment in PC (Paper I)?
   a. Which pain dimensions are assessed by existing tools for pain assessment?
   b. Is the content validity of the existing tools satisfactory in a PC setting?

2. How do patients in PC report pain's interference with functions as measured by the BPI (Paper II)?
   a. Does the BPI discriminate between interference on functions caused by disease and such interference caused by pain?

3. Does the Doloplus-2 have criterion validity in patients who are unable to self-report pain due to cognitive impairment (Papers III & IV)?
   a. Which pain behaviours, as measured by the Doloplus-2, contribute most in behavioural pain assessment (Paper III)?
   b. Is the Doloplus-2 feasible in clinical use (Papers III & IV)?
   c. Does the Doloplus-2 have satisfactory inter-rater reliability (Paper IV)?
   d. What constitutes a valid pain criterion in those unable to self-report pain (Paper IV)?

1. Introduction

The Norwegian cancer incidence was 24488 in 2006 (Cancer Registry of Norway 2007). In Norway the survival from cancer disease has slightly increased over the last years, and the most recent report shows five-year relative survival probabilities after a cancer diagnosis at 57% for male and 63% for female patients (Cancer Registry of Norway 2007). The incurable patients will eventually require palliative care (PC), and for these patients success in treatment will be measured by degree of symptom control and levels of health related quality of life (HRQOL).

Pain is reported to be one of the most frequent and disturbing symptoms in cancer patients. Pain is of subjective nature and it is addressed through the HRQOL-concept. Despite massive research on pain treatment and assessment, studies still demonstrate that many patients receive less than optimal treatment. In order to improve cancer pain treatment one challenge is to find and use assessment tools that are able to assess the important aspects of pain in frail patients with several concurrent symptoms often combined with deteriorating cognitive function.

The present study was part of a larger European multi-centre study, the "Palliative Assessment Tool -Computerized" (PAT-C) which was organized and conducted through the European Association of Palliative Care Research Network (EAPC 2006). The overall objective was to improve clinical symptom management and individual assessment of symptoms while minimizing the burden of the patient by developing a computer-based tool for self-reported assessment of symptoms and functioning in PC patients. Pain was one of the symptoms to be assessed, the others were physical functioning, depression, cognitive functioning and fatigue. The PAT-C project was refined in a new application to EU which granted the research group money for a five years project in PC. The main focus in this thesis is on pain in patients with advanced disease who receive PC, either in a hospital situated PC unit or in a nursing home.

1.1 Palliative care

Palliative care (PC) was first recognized as a medical speciality in Great Britain in 1987 and defined as:

"the study and management of patients with active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life" (Doyle et al. 1993).

The World Health Organization (WHO) published the following definition of PC in 2002:

"Palliative care is an approach that improves the quality of life of patients and their families facing the problems 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" (Sepulveda et al. 2002).

The modern school of PC builds on the work of the hospice movement and especially the pioneering work of Dame Cicely Saunders (Doyle et al. 1993).

Medical care can be divided into the two categories of curative treatment and PC. The categorization is based on the intention behind the treatment, but will often overlap in the care situation (Kaasa 1998). Palliative care is not medicine exclusively for the dying. Patients who receive treatment with a curative intention may also benefit from palliative treatment. However, PC and the hospice movement are most central in care for patients with advanced disease. While the mainstream hospital part of medicine often regards death as a medical failure, palliative medicine and the hospice movement endorse death as a meaningful process and strive for the maintenance of dignity and quality of life in the last part of life (Randall and Downie 2006). Palliative care research is still in its early development (Jordhoy et al. 1999), but it has received rapidly increasing attention recently.

In this thesis, PC is not strictly limited to care for dying patients in a very late or terminal phase, but understood as the part of medicine that focuses on symptom alleviation in seriously diseased patients. A main focus in PC is symptom control to increase or conserve the patient's HRQOL. The positive effects of treatment will be weighted towards side-effects to reach an optimal balance, often described in terms of highest possible level of HRQOL.

Cancer is the primary diagnosis in most patients in Norwegian PC units. These patients report high levels of several co-occurring symptoms (Kaasa 1998;Teunissen et al. 2007) and cognitive failure is also common (Radbruch et al. 2000;Tuma and

DeAngelis 2000). A study indicated that the median number of symptoms per cancer patient upon initial referral to a PC unit was 11 (range: 1 – 27, N=1000), and that the 10 most prevalent symptoms were pain, fatigue, weakness, anorexia, lack of energy, dry mouth, constipation, early satiety, dyspnea, and weight loss (Walsh et al. 2000). A recent study confirms the high number of co-occuring symptoms in advanced cancer patients. At admission to a PC hospital unit these patients (N = 77) experienced fatigue (97%), cachexia (96%), pain (88%), constipation (69%), nausea and/or vomiting (53%), and dyspnea (49%) (Tsai et al. 2006). It is a general challenge to assess subjective symptoms in frail-old patients suffering from several symptoms and of whom several have reduced cognitive function, but it is possible to achieve rather complete self-reported data even in those with highly pronounced symptomatology (Stromgren et al. 2002).

Norwegian nursing home patients are usually older than 80 years, they have an average of 5 - 7 serious diagnoses and 95% of the inpatients will eventually die in the nursing home (Husebø and Husebø 2005). A Norwegian study focused on the place of death for cancer patients and found that those who died in nursing homes were older (median 77 years), more often living alone (58%), the majority were females (66%), they reported more disabilities from other causes than cancer, and had poorer performance status (Karnofsky index) compared to those who died in hospitals or at home (Jordhoy et al. 2003).

Palliative care units at hospitals and nursing homes share similar challenges leading to the national five year project: *Hospice and palliative care for the elderly*. The aim was to achieve better PC for all elderly regardless of age, diagnoses and place of residence (Husebø and Husebø 2005). From 2004 project-based annual grants have been given to establish and operate palliative beds or units in nursing homes, but no permanent arrangement has yet been set up to secure these beds and competence (Kaasa et al. 2007). The recently developed Trondheim model is also trying to close the gap between hospital PC units and nursing homes by establishing two short-term units specializing in palliative treatment and care at an intermediary level between ordinary nursing homes and hospitals (Garåsen et al. 2005). In the National Strategy for Cancer 2006-2009 one of the major challenges is to organize and finance new and existing PC units and beds in nursing homes (Helse og Omsorgsdepartementet 2006).

1.2 Pain

During the past 60 years, pain assessment and management have become increasingly recognised as important. The understanding of pain as a subjective experience is equally "recent". Melzack and Wall's publication of the gate control theory in 1965 (Melzack and Wall 1965) was a breakthrough in the understanding of the pain phenomenon. Previously, pain had been seen by most as a more or less objective by-product of tissue damage and disease (Loeser 2001). The gate control theory postulated that the pain experience consists of three different components: sensory-discriminative, motivational-affective, and cognitive-evaluative:

"It is assumed that these three categories of activity interact with one another to provide perceptual information on the location, magnitude, and spatiotemporal properties of the noxious stimuli; a motivational tendency toward escape or attack; and cognitive information based on past experiences and probability of outcome of different response strategies. All three forms of activity can then influence motor mechanisms responsible for the complex pattern of overt responses that characterise pain."(Melzack and Katz 2001) pp.35-36).

The heightened level of attention towards pain was followed by the formation of The International Association for the Study of Pain (IASP) in 1973. IASP proposed the following pain definition which has become widely recognized:

"Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Notes:

The inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment.

Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life. Biologists recognize that those stimuli which cause pain are liable to damage tissue. Accordingly, pain is that experience we associate with actual or potential tissue damage. It is unquestionably a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience. Experiences which resemble pain but are not unpleasant, e.g., pricking, should not be called pain. Unpleasant abnormal experiences (dysesthesias) may also be pain but are not necessarily so because, subjectively, they may not have the usual sensory qualities of pain" (IASP 2005).

According to the Gate control theory and the IASP definition, the pain experience is understood as a complex perceptual and cognitive process in which both biology and psychology influence each other. Individual evaluative and response patterns of both biological and psychological origin make pain a subjective symptom. A simple theoretical model of nociceptive pain is illustrated in figure 1. It should be noticed that the injured person has to define the experienced sensation as pain in order to get it measured.

Figure 1, pain

Damage of tissue ⟶ Nociception ⟶ CNS/Brain ⟶ Perceived Pain ⟶ Expressed pain

Personality and biological components   Cognition   Measurement
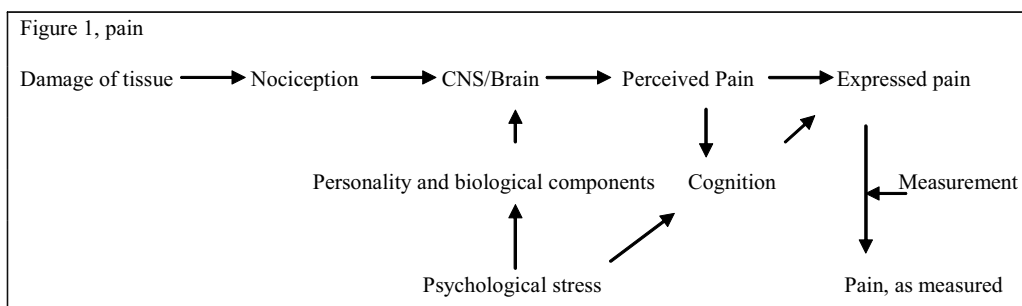
Psychological stress   Pain, as measured

Figure 1 describes the pain phenomenon from the initial damage of tissue, through the complex biological and psychological processing, to final assessment (Enhanced version of figure presented by (Kaasa 1998) p.303).

More recently Melzack has proposed a more general "neuromatrix model" reducing the importance of the gate control in the dorsal horns of the spinal column and increasing the importance of the individual's genes and processes in the brain (Melzack 1999;McDowell 2006). Certain brain mechanisms recognize the body as a whole. They constitute a widespread network of neurons with feedback loops within the cortex, thalamus and the limbic system. A pain stimulus will travel in repeated cycles between these systems where perception of the stimulus will be blended with cognition, emotions, personality and the person's previous experiences and learning effects related to pain. The result is an individual neurosignature based on the individual's biological (genes) disposition of reacting to stress stimuli that in turn characterizes the person's basic way of reacting to a pain stimulus (McDowell 2006).

Pain is the most common symptom leading people to seek medical treatment in the USA (Turk and Melzack 2001). Pain is the second most prevalent symptom and the most distressing one among cancer patients receiving PC (Brescia et al. 1992;Perron and Schonwetter 2001;Kaasa and Loge 2003;Stromgren et al. 2006). Approximately 70% of cancer patients with metastatic disease experience pain (Breitbart and Payne

2000). A recent Norwegian prevalence study (N=309), measuring pain for the past 24 hours at a single fixed day at 13 Norwegian hospitals, found that 51% of the cancer patients had pain (Holtan et al. 2005). The pain prevalence varies greatly between different types of cancer and also within the cancer disease trajectory. Only 5% of the leukaemia patients experience pain compared to 85% of the patients with bone or cervix cancer (Breitbart and Payne 2000). Divergent results are published on the relationship between gender, age and the prevalence of cancer pain. A recent Norwegian study found no significant differences on pain from gender or age (Holtan et al. 2005). Holtan *et al.* (2005) also addressed the prevalence of cancer pain among hospitalized cancer patients and discovered that 39% of those who had severe pain (NRS-11 $\geq$ 5) were not on opioids. Twenty-seven of the patients (N=309) reported high pain intensity while not receiving any analgesics, and 22 patients had more than six episodes of breakthrough pain a day, indicating under-treatment with analgesics (Holtan et al. 2005). The study concluded that in spite of increasing attention and knowledge with regard to pain management, patients in general do still not receive adequate palliation, and that better systematic assessment is recommended (Holtan et al. 2005).

A study by Ross and Crook found that 76% of the elderly patients who received nursing assistance at home experienced pain (Ross and Crook 1998), Ferrell *et al.* found that 71% of the nursing home residents experienced pain during the past week (Ferrell et al. 1990), Weiner *et al.* found pain problems in 68% of the nursing home residents (Weiner et al. 1998), and a study by Parmelee *et al.* documented pain complaints in 47% of nursing home residents (Parmelee et al. 1993). It has recently been stated that 45% to 80% of nursing home patients experience clinically significant pain that is insufficiently treated (American Geriatrics Society 2002). In addition to cancer pain, older people are more likely to suffer from chronic pain conditions from arthritis, bone and joint disorders and back (American Geriatrics Society 2002).

1.3 Pain assessment

Pain control is regarded as a crucial part of PC (Caraceni et al. 2002;Cella et al. 2003) and pain assessment is a premise to understand and adequately treat pain (Camp-Sorrell and O'Sullivan 1991;McCaffery 1992;Turk and Melzack 2001). Development of efficient assessment tools for diagnosis, audit, and the monitoring of individual

care and population effects of regiments of treatment are consequently central for both the practice and research in PC.

In order to provide an assessment tool for all situations, it should be short and easy to complete as most patients will be significantly physically and mentally reduced during the progress of disease. Furthermore, the tool should ideally be applicable in the cognitively impaired and for patients' self-reports and proxy rating.

Pain assessment is based upon the patients' self-report of their pain experiences, psychophysiological assessments or by observations of pain behaviour. Tools for pain assessment should be standardized and the psychometric performance of the tools should be documented for use in the given population. Pain assessments in children and adults have usually been treated separately. The present focus is pain assessment in adults by self-report or by behavioural assessment.

Subjective experiences like pain are challenging to assess and quantify into standardized scores.

"The frequency, severity, and disruptiveness of pain in cancer are matters of great interest to pain researchers and clinicians alike. For health care personnel, assessment and management of pain represents frustrating clinical problems" (Daut et al. 1983) p. 197).

This statement is from 1983, but still relevant. In a study among 897 physicians providing care for cancer patients, poor pain assessment was found to be the most important barrier against appropriate pain management (Von Roenn et al. 1993), and in a recent report the National Institute of Health states that better pain assessment is needed (Patrick et al. 2004). Cleeland warned about undertreatment of cancer pain in elderly patients in 1998 (Cleeland 1998). Studies demonstrate that pain is still unsatisfactorily managed in cancer patients and inadequate pain assessment is suggested as one of the contributing factors (Caraceni and Portenoy 1999;Higginson et al. 2003;Holtan et al. 2005). With this background in mind, it is evident that more efforts are needed in order to improve the assessment of pain so more optimal treatment can be offered. The research literature flourishes with different approaches to pain assessment and with different tools for this purpose. The first upcoming choices are usually between assessment tools based upon patients' self-report or proxy ratings/behavioural assessments and between a unidimensional or a

multidimensional approach to pain. The tool should also be both valid in the given population and feasible for the purpose of the assessment.

1.4 Assessment by self-report

As pain is a subjective symptom, the patient's self-report is regarded as the golden standard for assessment (Ingham and Portenoy 1998;Smith 2005). There is a wide variety of questionnaires differing in length and content (Jensen and Karoly 2001;Jensen 2003). Most tools are paper based, and the patient fills in the most appropriate response alternative or an administrator interviews the patient and marks the responses. Recently, the paper and pencil methodology has been experimentally transferred into computerized questionnaires, which take advantage of computer technology in order to make adaptive tests (Cella et al. 2005;Bjorner et al. 2005). Patients receiving PC are often frail, and have deteriorating health and multiple symptoms. These factors impact on the possibility to conduct the pain assessment. Assessment tools for PC must be short and easy to understand as assessment burden is an important aspect in frail patients. Yet they need to be comprehensive enough to cover the complicated pain cases that may be experienced by patients with advanced disease. Self-report based pain assessment tools can roughly be divided into unidimensional tools that only target one pain dimension like intensity or quality and multidimensional tools that target more than one dimensions of pain such as intensity, pain's interference with functions and temporal patterns.

1.4.1 Unidimensional pain assessment

The most frequently used unidimensional tools are single-item scales, usually a coloured analogue scale (CAS), numeric rating scale (NRS), verbal rating scale (VRS) or visual analogue scale (VAS) to measure pain intensity (here presented in alphabetical order):

Coloured Analogue Scale

The CAS is a device with a slider over a laying triangle varying from narrow (10 mm) and white at the end labelled "no pain" to wide (30 mm) and dark red at the end labelled "most pain" (Hicks et al. 2001). The patient's score is displayed by the marker in numerical values at the back of the scale, usually 0 - 10. The CAS is

developed for pain assessment in children, but proved effective for elderly as well (Scherder and Bouma 2000).
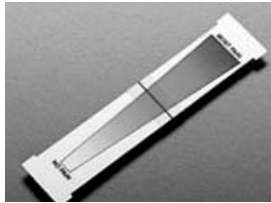
Numeric rating scales

Several different NRS designs are available but they have all in common two anchor points with increasing numbers in-between. The anchor points are usually named *no pain* at the left end and *worst possible pain* at the right end. Between the anchor points are numbers for example from 0 - 10 or 0 - 100. The number of response alternatives is reflected in the name, for example NRS-11 referring to a scale with eleven response options (from 0 - 10). An advantage with the NRS is that it can be administered verbally.

NRS-11: Please rate your pain by circling the one number that best describes your pain:

No pain   0   1   2   3   4   5   6   7   8   9   10   Worst possible pain

Verbal Rating Scales

The VRS consists of ranked word descriptors. The number of words is usually a trade off between sensitivity and complexity in completing the assessment, with four and five words as popular compromises (See table 1). Patients select the word that best describes their sensation. This can be achieved either by the patient marking the word or by interview. The VRS is considered as the most easily understandable of these scales, thus suitable for those unable to understand the NRS but still able to self-report.

VRS-4: Please rate your pain

1. No pain   2. Mild pain   3. Moderate pain   4. Severe pain

Visual Analogue Scale

The VAS is a straight 10 cm line between two anchor points usually named *no pain* and *worst possible pain*. The patient is instructed to put a mark with a pencil at the line equivalent to the experienced pain intensity. The score is calculated by measuring the distance from the zero point (no pain) to the mark in millimetres. The VAS is a continuous scale, but still limited with start and end points. It is well documented that the VAS should be used with caution in elderly patients and in those with advanced sickness as it is more demanding to understand than scales such as VRS and NRS (Herr and Mobily 1993;Benesh et al. 1997;Gagliese 2001).

VAS: Please cross the line at the point that best describes your pain

No pain ─────────────────── *Worst possible pain*

The single-item scales are popular tools for unidimensional pain assessment. These instruments produce valid results and they are translated into many different languages (Caraceni et al. 2002). Studies suggest equally satisfactory predictive validity and compliance in all these scales in chronic pain populations (Jensen et al. 1986), while patients with advanced cancer disease have higher completion rates using VRS and NRS compared to the VAS (Herr and Mobily 1993;Benesh et al. 1997;Gagliese 2001). NRS is generally recommended as the most practical tool (Jensen et al. 1986;Chibnall and Tait 2001). Unidimensional tools with few items can be easy to use when the purpose is to assess pain intensity and relief. On the other hand, they say little about the nature of the pain experience, temporal aspects, causes and consequences for the patient.

1.4.2 Multidimensional pain assessment

Several authors have stressed that pain is multidimensional (Millard 1993;de Conno et al. 1994;Melzack and Katz 1994;Shannon et al. 1995;Zimmerman et al. 1996;Caraceni et al. 1996;de Wit et al. 1999;Chung et al. 2000;Campbell 2003). Cancer pain has a nociceptive basis, but other influential factors call for a multidimensional understanding and assessment procedure (Millard 1993). Pain intensity is the most salient dimension but the report of pain is also related to cultural background, past experiences, the meaning of the situation, personality, level of arousal and emotions (Turk and Melzack 2001). Assessment of dimensions additional

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to intensity is essential when the purpose is to capture the total pain problem. Dimensions like pain quality, a description of the sensory experience of the pain, and pain's interference with different functions and QoL are commonly assessed dimensions among numerous others.

The Expert Working Group (on pain) of the EAPC recommends the Short Form McGill Pain Questionnaire (SF-MPQ (Melzack 1987)) for characterization of pain syndromes and assessment of pain quality and the Brief Pain Inventory short form (BPI-sf (Pain Research Group at MD Anderson Cancer Centre 2006b)) is recommended for multidimensional assessment of pain (Caraceni et al. 2002). Consequently, those two tools constitute a standard for self-report based multidimensional cancer pain assessment.

The McGill Pain Questionnaire including both the short form (SF-MPQ (Melzack 1987)) and the standard version (MPQ (Melzack 1975)), are dictionaries in the language of pain. The MPQ is constructed to measure three dimensions of pain; sensory-discriminative; motivational-affective; and cognitive-evaluative (Melzack and Katz 1994). The construct is a lexical approach where words describing sensory qualities, affective qualities and a scale of evaluative words describing overall pain intensity (a verbal rating scale) are grouped together and the patient is instructed to mark the appropriate descriptors. The SF-MPQ is a widely used tool for assessing pain quality (diagnostic properties of pain) and the main component consists of 15 adjectives that describe different pain sensations (4 affective and 11 sensory) (Melzack 1987;Melzack and Katz 2001). The patients are instructed to rate each descriptor on an intensity VRS-4, no pain - mild - moderate - severe. The present pain intensity is rated on the so called Present Pain Index which is a combination of a VRS-6 and a VAS (Melzack and Katz 2001).

The Brief Pain Inventories (Cleeland 1991) are available as full version (Pain Research Group at MD Anderson Cancer Centre 2006a) and as short version BPI-sf (Pain Research Group at MD Anderson Cancer Centre 2006b). The tools measure pain intensity, pain location, effects from pain medication, and pain's interference with functions. The full version Brief Pain Inventory also records patient's illness history, temporal pattern, relieving and exacerbating factors, and pain quality. The BPIs are of the most frequently and widely used tools for multidimensional cancer pain assessment and BPI-sf has also been validated as a measure for cancer pain in

many cultures and languages (Caraceni et al. 1996;Wang et al. 1996;Uki et al. 1998;Ger et al. 1999;Saxena et al. 1999;Radbruch et al. 1999;Mystakidou et al. 2001;Klepstad et al. 2002;Badia et al. 2003;Yun et al. 2004).

Even though the sf-MPQ and the BPI-sf are recommended for multidimensional assessment, they are also criticised. The Expert Working Group of the EAPC found the sf-MPQ was more demanding to use than other tools, an experience shared by others (Millard 1993;Caraceni et al. 2002;Campbell 2003). Furthermore, the Pain Rating Index (PRI) is problematic since descriptors assessing distinct pain qualities are combined into subscales and information concerning the specific pain qualities endorsed by the patients is lost (Holroyd et al. 1992). The recommended area of use for the MPQ is also limited to situations where researchers want to describe characteristics of different pain syndromes, according to the EAPC.

The EAPC recommends the BPI-sf for general assessment in PC. Twycross *et al*. (1996) presented a study on both BPI versions, the full and the short. The full version BPI was found troublesome to use and less than 60% of the patients completed all items. The study concluded by presenting three arguments against the full version BPI; *too burdensome for the patient to complete; too burdensome for the clinician to analyse the "data mountain" created; and too difficult to interpret with a time frame of "in the last week",* while the BPI-sf was judged as not comprehensive enough (Twycross et al. 1996) p.280). The Norwegian BPI-sf validation study questioned the validity of the interference scales. A concern was raised regarding the patients' ability to report pain's interference with functions without bias from decreased function caused by other factors (Klepstad et al. 2002), and this concern was documented in a recent study which indicated that patients have limited ability to make valid attributions of pain's interference on functions using the BPI-sf (Stenseth et al. 2007). Cleeland, the constructor of the BPIs, reports findings from one study comparing the full version Brief Pain Inventory scores from oncology patients to patients with non cancer chronic pain (NCCP) (Cleeland 1989). He observed that almost all NCCP patients reported high pain intensity (ceiling), making such assessment problematic. Pain's interference was on the other hand more evenly distributed in both patient populations. Cleeland did not explore the possible causes for the differences in the two patient populations. Recently, in two studies the BPI-sf was validated for pain assessment in patients with NCCP (Tan et al. 2004;Keller et al. 2004), but none of

these studies addressed possible differences in how patients with cancer and NCCP report pain using the BPI-sf. Pain is different in these two populations. Comparison of pain reports from both groups can disclose new aspects regarding the content validity of the BPIs - is pain's interference with functions reported similarly by both groups or must patients' diagnoses be taken into account.

As described, the BPIs are highly recommended and frequently used tools for self-reported multidimensional cancer pain. However, studies report that it may be too demanding to use for patients in PC and there is no evidence that the pain dimensions in the BPIs are the most informative to assess. Multidimensional assessment is recommended by many, but to our knowledge, evidence-based information regarding the content of the pain assessment tools is too scarce. At present, we are not aware of any studies that have specifically addressed the content of pain assessment tools with specific relevance for cancer pain assessment in PC. Information on the relevance of the different pain dimensions is needed before recommendations on specific assessment tools can be given.

1.5 Behavioural pain assessment

As self-report of pain is regarded the gold standard, observational assessment of behaviour indicative of pain has come to be the preferred method only in patients who are unable to self-report, e.g. young children and those with cognitive failure (Prkachin et al. 1994). Cognitive impairment is common in patients with advanced disease. Between 50% and 71% of nursing home residents are cognitively impaired (Ferrell et al. 1995;Matthews and Dening 2002), and a Norwegian study reported dementia in over 75% of nursing home residents and in 21% of those above 75 years living at home (Engedal et al. 1988). A recent review reported prevalence rates in PC patients ranging from 14% to 44%, rising to 90% prior to death (Hjermstad et al. 2004).

Several studies have investigated the cognitively impaired patients' ability to self-report pain using one or more methods for pain assessment (Smith 2005). However, these studies have excluded patients who were noncommunicative (Smith 2005). The development of formalized and systematic methods for behavioural pain assessment begun in the early eighties (Labus et al. 2003). The American Geriatrics Society (AGS) provides a guideline on the management of persistent pain in older persons

with severe dementia that are noncommunicative (American Geriatrics Society 2002). Such patients should be observed for nonverbal pain behaviours and changes in activity and function that may be suggestive of pain. The AGS gives no clear recommendations of specific tools for pain assessment, but highlights that this is an important area of ongoing research. It is stressed that the presentation of pain behaviours, particularly in those with dementia, can be quite variable (American Geriatrics Society 2002). For example, one patient might present with increased irritability and pacing, while another presents with withdrawal and refusal to eat. Consequently, it is very important to determine the patient's baseline behaviours and then monitor for changes over time that may indicate the presence of pain (American Geriatrics Society 2002). It should also be noted that some patients do not demonstrate pain typical behaviours when experiencing severe levels of pain (American Geriatrics Society 2002) e.g. a patient that presents "more and stronger" facial indicators with increasing pain may get a frozen facial expression when experiencing severe pain, while another patient presents even more facial expressions.

Behavioural assessment of pain by observation rests upon three key assumptions (Villanueva et al. 2003):

1. Facial expressions, verbalizations, changes in mental status, body posture, and movement patterns can indicate the presence of pain (Hurley et al. 1992;Weiner et al. 1999;Hadjistavropoulos and Craig 2002;American Geriatrics Society 2002).

2. Pain can interfere with activities of daily living (ADL), such as sleep, social activities, washing, dressing and eating (Cleeland 1991;Hurley et al. 1992;American Geriatrics Society 2002).

3. Caregivers can reliably observe and rate such behaviours.

The presence of pain behaviours is well accepted. The essential question is whether standardized observations of these are valid as indicators of pain since it may be a considerable problem to separate signal from noise.

Behavioural assessment procedures commonly take place by one person observing and rating pain indicative behaviour in another person. Behaviour can provide indications of the presence of pain, information about pain location, severeness, and cause (Craig et al. 2001). Facial expressions are the most recognized and explored area of pain behaviours and studies have documented their validity and even that

different diseases may result in different facial expressions (Prkachin et al. 1994;Craig et al. 2001;Manfredi et al. 2003). Most efforts have been used on the Facial Action Coding System (FACS) which is an elaborated model of all the facial muscles that control the various actions that are identified as associated with pain (Ekman and Friesen 1978). The FACS can be used to validate the presence of pain behaviours by observers coding the facial expressions of people who are introduced to different pain stimuli or are in a known painful situation. A study of 28 patients complaining of chest pain demonstrated that all the patients with true myocardial infarctions (in opposition to those with other diagnoses) displayed similar patterns of facial expressions, like lowering the brow, pressing the lips, parting the lips, and turning the head left (Dalton et al. 1999). Pain behaviours can be divided into those that are intended to communicate pain to others e.g. calling for attention, and those that are performed to relieve pain like supporting a hurting arm. Most behavioural pain assessment tools encompass both behavioural types. Behavioural assessment may also be used in combination with self-report as a comprehensive evaluation of patients, for example in cases where there may be doubts with regard to the patients' self-reports.

Behavioural pain rating tools are seemingly rough measures aimed at the detection of pain, not the quantification of it. The number, degree, and frequencies of different pain behaviours may indicate the severity of pain, but we are not aware of any validated tool for the assessment of pain interference or intensity by observations. An obvious obstacle for behavioural pain assessment tools is the fact that proxy raters and patients' self-reported pain experience only demonstrate moderate correlation at the best. Labus *et al*. (2003) reviewed 29 studies, the majority of the samples in these studies (58.6%) suffered from chronic pain, acute (13.8%), post-surgical (6.9%), and mixed pain (20.7%), in order to explore the degree of association between patients' self-reports of pain and observational pain ratings (Labus et al. 2003). The association was only moderate and they conclude in accordance with other studies by recommending to combine observation and self-report ratings (Keefe et al. 2001;Labus et al. 2003). A study by Prkachin *et al.* (1994) where five observers (undergraduate students) watched videotapes of patients with shoulder pain indicated an equivalent mismatch between patients' self-report and behavioural ratings by "pain judges", and it was further emphasized that the judges underestimated pain and that

the less trained judges overlooked valuable information in the facial expressions (Prkachin et al. 1994).

Divergences between behavioural ratings and self-reports are problematic, and in patients who are able to self-report, studies which compare observation and self-report have disclosed and highlighted insufficiencies in behavioural pain assessment. Consequently, observational methods of behaviour should only be used as stand-alone measures in patients where no other alternatives exist (Keefe et al. 2001). Behavioural pain assessment tools are intended to guide the proxy rater with regard to which behavioural clues that might indicate pain. On the other hand, behavioural pain clues like facial expressions, protection of sore areas and unexplained agitation should be well known to health care providers with some competence in pain. The question to remain is weather these tools can replace competence in pain and consequently have value in situation where other pain expertise lacks and if they can have a unique value in standardizing proxy rated pain scores.

1.5.1 Behavioural pain assessment tools

Although data on the performance of the different behavioural pain assessment tools are limited, a recent review rated 12 tools according to several quality criteria evaluating their psychometric aspects (Zwakhalen et al. 2006b). The tools could receive an overall judgement score from zero, denoting poor performance, to 20, indicating excellent performance with regard to issues of validity and reliability. Five English language tools received a review score of 10 or higher: the Abbey Scale (Abbey et al. 2004), the Pain Assessment for the Dementing Elderly (PADE) (Villanueva et al. 2003), the Pain Assessment in Advanced Dementia Scale (PAINAD) (Warden et al. 2003), the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC) (Fuchs-Lacelle and Hadjistavropoulos 2004), and the Doloplus-2 (Lefebvre-Chapiro 2001). All the tools cover facial expressions, abnormalities in body postures/movements like guarding sore areas, impaired movement and verbal expressions. The Abbey Scale, Doloplus-2, PADE and PACSLAC all include items on interpersonal communication, social life, participation in activities, and changes in daily routines. Looking at differences between the tools, the Abbey Scale and the PACSLAC include items on physiological changes (temperature and pulse (flushing or pallor). The Abbey Scale also assesses physical changes such as skin tears and pressure areas. The PADE includes a Visual Analogue

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Scale for pain intensity and the PAINAD assesses breathing and consolability. The number of items ranges from 5 (PAINAD) to 60 (PACSLAC). All tools are constructed for administration by health care providers, but to our knowledge none of them claim any criteria with regard to the administrators' competence. All tools include domains that may not exclusively be affected by pain. The review suggested that the Doloplus-2 and the PACSLAC were the most promising (Zwakhalen et al. 2006b). All these tools are developed and tested in either nursing home residents, veterans or in patients at geriatric hospital wards.

1.6 Psychophysiological assessment

Methods for psychophysiological assessment of pain are in an early phase of development. Such assessments feature blood-flow based neuroimaging, tests of heart rate and blood pressure, skin conductance and measures of muscle tension with electromyographic recordings (Flor 2001). These assessments are complicated to conduct in daily clinical work, and at present it is not obvious how such measures can address pain as defined by IASP. The subjective experience cannot be properly assessed by today's technology. Hence, psychophysiological measures are mainly developed for supplementary assessments to self-report in chronic non-malignant pain conditions. These measures need to be validated and calibrated for patients with advanced metastatic disease with major pathological findings. In some patients, psychophysiological results can be integrated as a part of a communicative treatment process teaching the patient how to cope with pain or as supplements in diagnostics in complex cases (Flor 2001). Such assessments are not a part of pain assessment in PC and will not be further discussed in this thesis.

1.7 Psychometric properties of assessment tools

Validity and reliability are cardinal properties of all assessment tools. An illustration of both is pistol shooting at a target. If a series of bullets is centred you have reliability, even though the hits can be outside the bull's eye. Validity is when the hits are centred on the bull's eye, the optimal is when all hits are centred indicating top validity and reliability. Tests have to be reliable to be valid. The validation of an assessment tool is the process of determining whether the tool really assesses what it is believed to assess and whether it is useful for the intended purpose (Fayers and Machin 2007).

Validity regards the tool's ability to measure what it is supposed to measure. Validity is closely related to the operationalization of the phenomenon. To develop a valid pain assessment tool one needs to choose a proper definition of what pain is. This definition has to be operationalized into a measurable construct. Issues of validity contain a set of different methods for testing whether a measure has any systematic errors affecting its ability to measure the original construct. Construct, content, and criterion validity are all important aspects of the validity of assessment tools (Fayers and Machin 2007). All three cover the tool's ability to measure the given phenomenon and that alone.

Content validity is subjective and qualitative: does the instrument contain the appropriate items, in terms of relevance and breadth of coverage? All the relevant issues should be covered by items in the tool. When the assessment tool has a comprehensive coverage of the phenomenon that it is intended to assess, it will increase the tools specificity and sensitivity (Fayers and Machin 2007). This is important to disclose differences between groups of patients. If the tool lacks items on one aspect of the phenomenon it will obviously also lack the ability to differentiate patients who are different on those parts but equal on the assessed parts of the phenomenon. Tests of content validity include judgements by expert panels who evaluate the face validity of the test (Bland and Altman 2002); does the test cover what is known to be relevant aspects of the phenomenon, and does it contain aspects believed to be irrelevant. Studies on the content validity of pain assessment tools are scarce.

Criterion validity regards the comparison of the assessment tool against the true value or a value that is an accepted indication of it (Bland and Altman 2002). Pain is a subjective symptom and there is no access to the true value. Instead the patient's self-report of pain is regarded the "gold standard" and this is used as if it was the true value. Patients with cognitive impairments may be unable to self-report pain. The alternatives are then to compare the relevant assessment tool against values obtained from well-established pain assessment tools for this population, against in-depth interviews or observer's assessments (Fayers and Machin 2007). Tests of criterion validity demand a reflexive model (Hellevik 1991), here illustrated by the theoretical model of pain with two operationalized sub-models; a pain score based on an expert's clinical evaluation of the patient and a score from the Doloplus-2, a behavioural pain

assessment tool (Figure 2). Correlation between those two models indicates that they measure the same phenomenon. Often, one of the sub-models is an accepted valid measure of the phenomenon (in this case a clinical evaluation by an expert). When the new measure correlates with the criterion it has criterion validity.
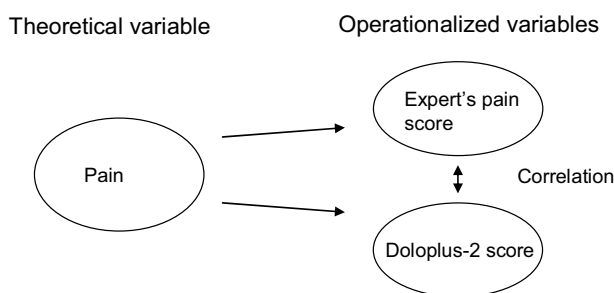
Figure 2:

Figure 2 presents an indirect method for testing the criterion validity of the Doloplus-2. The assumption is that the expert's pain score is a valid representation of the true pain value and that a high correlation between the expert and the Doloplus-2 indicates that the Doloplus-2 assesses pain.

The criterion validity can also be described by its predictive validity which regards the ability of a measure to predict future events. An indication of predictive validity will be that a pain score is successively reduced with repeated measures after the administration of analgesics.

Construct validity is assessed quantitatively, and consists of several sub concepts. The purpose is to examine whether the tool assesses the concept that it is intended to assess (Bland and Altman 2002;Fayers and Machin 2007). The first step is to form a hypothetical model of the phenomena in interest and the relationship between them. The second step is to test this model empirically. The construct validity may be satisfactory if the data supports the hypothesis. To establish construct validity is a thorough process and involves repeated testing. The aim is at best to collect data that support the fact that the tool really assesses the intended phenomenon (Fayers and Machin 2007). The analyses of construct validity are usually translated into looking for evidence that the items behave in the expected manner, given our hypothesized scale structure (the constructs)? Hence the construct validity has to do with within-instrument correlations between items/items, scales/scales and items/scales. Comparison of known-groups is one way to assess construct validity. One expects

that the assessment tool should be sensitive towards known-group differences. Convergent validity is another aspect that regards the correlation between scales and items that assess what is believed to be related phenomena (Campbell and Fiske 1959). The opposite is discriminant validity that regards the tools ability to discriminate between phenomena that are believed to be unrelated by finding low levels of correlation, both can be tested in a Multitrait-Multimethod matrix of intercorrelations among tests representing at least two traits, each measured by at least two methods (Campbell and Fiske 1959). Validity is found when tests of the same trait correlates higher than they do with measures of different traits.

Reliability regards the random errors in a measure. The assessment tool's reliability concerns its ability to produce reproducible and consistent results (Fayers and Machin 2007). Reliability has a time aspect in test-retest situations and a person aspect in inter-rater reliability. Both kinds concern the test's ability to produce consistent results independent of time and person. In pain assessment it is important that a tool produces the same results in the same person at each assessment, independently of the test situation and the administrator of the tool, as long as the pain level is unchanged. Reliability can be expressed by a correlation coefficient ranging from 0 (no) to 1 (perfect). The Intra Class Correlation coefficient (ICC) is the most common method for assessing reliability with continuous data (Fayers and Machin 2000). A high ICC is produced when a large proportion of the total variance is related to the between patient variability. A coefficient above 0.70 is usually regarded as acceptable (Fayers and Machin 2000). Internal consistency is a central characteristic in multi-item scales. Cronbach's alpha is a common measure for internal consistency. It is a function of the average correlation between the items in the scale and the number of items and it increases when either of this increases (Bland and Altman 1997;Fayers and Machin 2000). Cronbach's alpha is often used as a measure of reliability, but it is also closely related to construct validity in terms of the focus on inter-item relationship. It can be a valuable estimate when evaluating the usefulness of different items in a scale. If the removal of an item from a scale only results in a little decrease in the Cronbach's alpha, the item can usually be removed from the scale.

A challenge with the scales used in pain assessment is so-called floor and ceiling effects. This may be illustrated by clusters of assessment scores either at the bottom (floor) or at the top end (ceiling) of the scales. The phenomenon affects the scale's

ability to discriminate between subjects that are believed to have different true scores. A ceiling effect may also occur with repeated measurement over time if pain increases. A patient, who initially rates pain intensity at 9 on a scale from 0 to 10, encounters trouble when the pain increases and the next true score would have been 12, but the scale does not go beyond 10, thus creating a ceiling effect. Ceiling effects are most frequent in single item scales, however, a broader approach to ceiling effects that also applies to multidimensional tools, is addressed in theories about response shift (Schwartz and Sprangers 2000). In assessments of subjective health and quality of life, patients' frames of reference tend to shift according to current health status. That leads patients to adjust their expectation due to their current status. Anticipated decreases in assessed status due to worsening symptoms may fail to appear in the assessment scores. And effects of successful interventions may be invisible for assessment (status quo), because the patient, in the mean time, has reduced his tolerance for pain and thus reports identical pain scores as before the treatment. The response shift phenomenon can such bias longitudinal/repetitive pain assessments due to changes in patients' experience of pain over time due to coping and lowering/heightening of frames of reference (Schwartz and Sprangers 2000).

1.8 International standardization

There is no international standard for pain assessment neither in clinic nor in research. Instead of consensus there is an abundance of different tools in use. This prevents meta-analyses and the communication of assessment results within the research communities (Quigley 2002;Nicholson 2004). Thus there is a need to develop an international standard for pain classification and assessment. A standardization of pain assessments is likely to improve clinicians' and researchers' interpretations of pain scores and it may allow for a much needed opportunity for comparing results from different research projects. Today researchers conduct almost identical pain research with slightly different outcome measures. It will be much more efficient to coordinate pain research if one can achieve a standardization of pain measures. New pain tools with improved psychometric properties and feasibility may accelerate the will among researchers to reach standardization.

2. Material and methods

2.1 Setting

This thesis is based on studies performed within the Pain and Palliation Research Group at NTNU / St. Olav's University Hospital, Trondheim, Norway. The group is multidisciplinary with (in alphabetic order) nurses, physicians, physiologists, physiotherapists, psychologists and statisticians. The group enjoys close collaboration with other European palliative care researchers, mostly through the EAPC Research Network (www.eapcnet.org). One of several objectives for the group is to contribute to improved pain assessment through systematic research.

2.2 Patient cohorts

This thesis consists of four studies in principally two patient populations; cancer patients and demented nursing home residents. The cancer patients were recruited from the Department of Oncology and the Palliative Care Unit at St. Olav's University Hospital while the demented patients came from nursing homes in the Trondheim region and from the Geriatric Ward at St. Olav's University Hospital. In addition, patients with noncancer chronic pain (NCCP) from the National Centre of Expertise for Pain and Complex Disorders at St. Olav's University Hospital were included as a comparison group for cancer pain patients.

Table 1: Overview of study samples

Patient samples	N	Sex (% men)	Age median	Study
Cancer	300	55	63	II
NCCP	286	34	44	II
Demented nursing home	59	20	82	III
Demented nursing home/ Geriatric ward	73	26	85	IV

2.3 Study designs

Study I combined a systematic literature review with an expert group evaluation of the relevance of the pain dimensions found. Two literature searches were conducted

in order to find pain assessment tools. A systematic search was conducted on the search terms *pain assessment* and *pain measurement*. To include a tool from the systematic search the title or abstract should describe: a) A self-report method used for pain assessment or the name of an assessment tool explicitly used for self-report of pain and b) a sample with adult advanced cancer patients receiving palliative care. The search was a computerized literature search in Pubmed (MEDLINE), Cancerlit, PsychInfo, and Cinahl. The Cochrane Library review group for Pain, Palliative & Supportive Care was also consulted and a book search was conducted in the Norwegian library database BIBSYS (international). The search was restricted to publications in English. Case reports, editorials, letters, and commentaries were excluded. The systematic search was supplemented by a broader ad-hoc search in MEDLINE for pain assessment tools used in other populations (without criterion b in the systematic search). Because of the vast amount of publications on pain assessment in general, the following MEDLINE limitation options were deployed: English language, abstracts available, humans, all adult (19 years or above), and full text. After the literature search, all pain assessment tools and the papers describing the construction of the tools were examined for information about the content expressed by their pain dimensions and the items covering them. In line with the study objectives, an international expert panel was established. The experts were instructed to rank the different pain dimensions, which were found in the literature, according to their relevance for pain assessment in PC. The items in the identified tools were allocated to appropriate dimensions by the first author and then this assignment was reviewed by the experts.

This study was the first step of the "Palliative Assessment Tool - Computerized" (PAT-C) project, which aimed at developing a computer-based tool for assessment of symptoms and functioning in PC patients (PAT-C at EAPC web 2006). To be able to select appropriate pain dimensions and items of relevance for a PAT-C Pain Assessment Tool, there was a need to define which dimensions, and the operationalization of them into items, that fall within the scope of pain assessment in PC patients. The European Organisation for Research and Treatment of Cancer (EORTC) describes the generation of new QOL issues and symptom assessment tools in three steps (Sprangers et al. 1998). The first step involves literature searches where the aims are to review the existing knowledge on the field of interest and to derive potentially new relevant and improved issues. The second step involves experts on the

field who should be instructed to provide feedback on the appropriateness of the content and the breadth of coverage. In step three the patients are consulted, usually in a pilot test of the new assessment tool. Study I covers the two first steps with literature searches and expert panel.

The patients with cancer and NCCP took part in Study II (study objective 2) where the aim was to explore how pain's interference with functions is reported through the BPI. All patients completed the BPI-sf and the European Organisation for Research and Treatment of Cancer's quality of life questionnaire (EORTC QLQ-C30) (Aaronson et al. 1993) which is a widely used HRQOL questionnaire with well documented reliability and validity in patients with cancer and recently validated in patients with NCCP (Aaronson et al. 1993;Hjermstad et al. 1995;Wisloff et al. 1996;Fredheim et al. 2007). Background information on sex, age and diagnoses\pain conditions was collected from all patients. A research nurse browsed through the journals of all in-patients at the cancer department in order to find eligible candidates for study participation. The patients were usually approached in their room and asked to complete the questionnaires on the same day. The EORTC QLQ-C30 and the BPI were presented as a one questionnaire package. This material was originally collected for the Norwegian validation study of the BPI-sf and for a pharmacological study on morphine (Klepstad et al. 2002;Klepstad et al. 2003), but the data was made available for the present study. The patients with NCCP were consecutively recruited by the staff at the pain clinic and they received the same questionnaire package by mail. Their responses were mailed back before their first consultation at the pain clinic.

Study III and IV include institutionalized patients with cognitive impairment from a geriatric hospital ward and from five different nursing homes. These patients were selected as appropriate for testing the feasibility and validity of the Doloplus-2 (study objective 3). All patients were cognitively impaired and evaluated as unable to self-report pain by the nursing home personnel. Each patient was examined by an expert in pain assessment and treatment, who rated pain on a numerical rating scale (See Appendix). These ratings were used as pain criterion. All administrators were trained in Doloplus-2 assessment according to the guidelines provided by the French developers (Appendix). Cognitive function was assessed by the Mini Mental State Examination (MMSE), and the ability to perform activities of daily living was evaluated with the Barthel Index (these tools are described in chapter 2.4).

In study III the Doloplus-2 was translated into Norwegian according to international guidelines (Cull et al. 1998). The criterion validity of the Doloplus-2 was tested by comparing Doloplus-2 scores against the pain experts' proxy-pain ratings on a NRS-11. The Doloplus-2 was administered by nurses and nurse assistants who were accompanied by two final year medical students. The administrators completed a debriefing questionnaire about their experiences with the tool and its translation (Appendix).

In study IV further tests of the criterion validity of the Doloplus-2 was performed with a similar design. The Doloplus-2 was administered by the attending nurse. In 16 patients the Doloplus-2 was independently administered by two nurses, blinded to each other, in order to evaluate the inter-rater reliability. Similarly were 15 patients evaluated by the regular expert in addition to two independent geriatricians (all blinded) in order to evaluate the validity of the pain criterion.

Both the cancer and the nursing home groups in these three studies consist of patients where life prolonging and/or palliation were the major aims for treatment and care.

2.4 Assessment tools

The assessment tools that were used in the studies are presented in the Appendix.

Table 2: Overview of the assessment tools that were used in each study

Tool	Study(ies)
Barthel index	III & IV
Brief pain inventory-sf	II
Doloplus-2	III & IV
EORTC QLQ-C30	II
Karnofsky performance status	II
Numerical rating scale	III & IV
Mini mental status exam	II, III & IV

The following assessment tools were used in the studies:

Self-report tools (alphabetically)

2.4.1 Brief Pain Inventory short form (BPI)

The BPI-sf has mainly replaced the full version in use. BPI refers from here to the short version. The BPI is a self-report pain assessment tool and the patient is instructed to report pain as intensity and as interference with seven different functions (Cleeland 1991;Pain Research Group at MD Anderson Cancer Centre 2006b). The intensity scale contains four items measuring worst, least and average pain intensity (usually during the past 24 hours or past week) and intensity now. The interference scale includes seven items which assess pain's interference with general activity, mood, walking ability, normal work, relations with other persons, sleep, and enjoyment of life. The response alternatives are all numerical rating scales running from 0-10 (NRS-11). The intensity items are bounded by the words "no pain" and "pain as bad as you can imagine" and the interference items with "does not interfere" and "interferes completely". In addition, the patient reports pain localization on a body map drawing and details on their current pain medication and its effectiveness. The BPI has been validated as a measure for cancer pain in many cultures and languages (Caraceni et al. 1996;Wang et al. 1996;Uki et al. 1998;Ger et al. 1999;Saxena et al. 1999;Radbruch et al. 1999;Mystakidou et al. 2001;Klepstad et al. 2002;Badia et al. 2003;Yun et al. 2004) and it is recommended as a cancer pain assessment tool for palliative care patients by the Expert Working Group of the European Association of Palliative Care (Caraceni et al. 2002). The Norwegian translation has demonstrated satisfactory psychometric properties in advanced cancer patients (Klepstad et al. 2002).

2.4.2 European organisation for research and treatment of cancer's core quality of life questionnaire (EORTC QLQ-C30)

The EORTC QLQ C-30 consists of 30 items for patients' self-report of functions, symptoms and quality of life (Aaronson et al. 1993). Norm data for the EORTC QLQ C-30 have been published for the Norwegian general population and the scale has been examined for test\retest reliability which was satisfactory in a Norwegian cancer population (Hjermstad et al. 1995;Hjermstad et al. 1998). Response categories are verbal rating scales running from 1= *not at all* to 4 *very much* for the items on symptoms and functions and from 1= *very poor* to 7= *excellent* on the QOL items. Twenty-four items are clustered into multi-item scales; Physical, Role, Cognitive,

Emotional, and Social; three symptom scales: Fatigue, Pain, and Nausea and vomiting; and a global health and QOL scale. The last six are single items covering: dyspnoea, sleep, appetite, constipation, diarrhoea, and the financial impact of the disease and treatment. The two pain items address pain intensity and pain's interference with daily activities.

For the functioning scales and the global health and QOL scale, a high score represents good functioning. In the symptom scales a high score represents a high level of symptoms. All scores are transformed into a 0 to 100 scale after the following procedure, score = :

Function scales: 100 – (mean score -1)* 100/range

Symptom scales: (mean score -1)* 100/range

Global QOL scale: (mean score -1)* 100/range

Single items: (mean score -1)* 100/range

2.4.3 Numerical rating scale (NRS) for pain

This unidimensional single-item scale was used for proxy ratings of pain by the pain experts in studies III and IV. These ratings were used as pain criterion. Each patient was rated by one expert. The experts based their judgement upon information in the medical record, information from the nurse responsible for the patient and the patient's primary contact (usually an enrolled nurse), information from the patient (if possible) and a clinical examination. The experts were instructed to rate the intensity of each patient's pain on a NRS-11 from zero (no pain) to ten (worst imaginable pain). Each patient was rated by the expert for pain in movement and rest separately. The scale is further described in the previous chapter *1.4.1 Unidimensional pain assessment*.

Observer rated tools (alphabetically)

2.4.4 Barthel Index

Ability to perform activities of daily living (ADL) was evaluated by the original 10-items Barthel Index (Mahoney and Barthel 1965) in studies III and IV. This tool describes the ability to perform ADL on a scale from 0 - 20. The items cover the activities of controlling the bladder and bowels, maintaining personal toilet,

bathing/showering, feeding, moving from chair to bed and up again, getting on and off the toilet, indoor mobility, dressing and ascending/descending stairs. The ratings are indented to suggest how much assistance the patient needs. Barthel index scores from 20 to 15 indicate independence to mildly disabled ADL function, 14 - 10 indicate moderately disabled, while a score of 9 - 0 indicates that the patient is severely disabled to very severely disabled (Wade and Hewer 1987). The Barthel Index was scored by a nurse who had worked closely with and knew the patients and who was trained in using the Barthel Index.

2.4.5 The Doloplus-2

The Doloplus-2 tool consists of one page with all ten items, one page with a lexicon describing the different items, and finally there is a user guide available. The Doloplus-2 should be used by a trained health care worker, familiar with the patient's habits and regular condition, who observes the patient's behaviour and rates pain according to the degree of presence of certain behavioural clues (Lefebvre-Chapiro 2001). The Doloplus-2 includes three hypothesized domains; somatic, psychomotoric and psychosocial. The somatic domain consists of five items, the psychomotoric domain has two items, and the psychosocial domain has three items. Each item has four response alternatives with a scoring range of 0 to 3. A score of 0 indicates that the patient behaves normal on the given item, 1 signifies some pain related behaviour, 2 more pain behaviour, and a score of 3 means that the patient demonstrates high levels of pain-related behaviour. The possible total score ranges from 0 to 30. Based on their clinical judgement, the developers of the French version recommend that a total score of 5 points or more should be regarded as a sign of pain that may require treatment with analgesics (Doloplus-2 Instructions for Use, Appendix). However, this cut-off has not been validated and the tool developers point out that the Doloplus-2 does not rule out pain as an option even below a score of five. The Doloplus-2 Instructions for Use also informs users only to rate those items found suitable for each patient.

2.4.6 Karnofsky Performance Status (KPS)

Performance status was rated with the Karnofsky Performance Status (Karnofsky and Burchenal 1949;Patrick and Deyo 1989) in the cancer patients included in Study II by one of the investigators. The KPS has demonstrated good construct and predictive

validity and good inter-rater reliability as a global indicator of the functional status of cancer patients (Yates et al. 1980). The KPS is a numerical rating scale that measures physical function, general health status and medical requirements. It contains 11 categories and a score of 0% means death while 100% indicates normal performance, no complaints, no evidence of disease.

2.4.7 Mini Mental State Examination (MMSE)

Cognitive function was assessed by the Mini Mental State Examination (MMSE) (Folstein et al. 1975;Folstein et al. 1984) in studies II, III and IV. The MMSE contains 11 items and covers the person's orientation towards time and place, motor skills, recall ability, short-term memory, and arithmetic ability. It rates the level of cognitive function on a scale from 0 - 30. Patients with scores from 30 - 21 are regarded as normal in cognitive function to mildly cognitively impaired, scores from 20 - 11 denote moderately cognitive impairment, while patients scoring 10 - 0 are classified as severely cognitively impaired (Perneczky et al. 2006). The MMSE is a screening test for cognitive loss and cannot be used to diagnose dementia (Folstein et al. 1975).

2.5 Statistical analyses

The results are presented as means for normal distributed variables or medians for non-parametric variables while the distribution of the data is generally presented using standard deviation, 95% confidence intervals or range as appropriate or according to the different directions given by the journals.

In study II, 300 patients with cancer and 286 patients with NCCP completed the BPI and the EORTC QLQ-C30. The pain interference items were indexed into total interference, interference with physical, and interference with psychological functions. A number of different regression analyses were used in order to explore the relationships between patient groups (cancer and NCCP), levels of pain intensity, age, sex, and different dimensions of HRQOL on pain's interference with functions. The dependent variables were pain interference on physical and on psychological functions in two separate analyses. Independent variables were pain intensity and patient group, and a possible interaction between them. For statistical testing purposes, in order to account for significant non-linear relationships, we used fractional polynomial regression (Royston and Altman 1994;Royston and Sauerbrei 2004). Using fractional polynomials, it is possible to model nonlinear relationships

with a low number of terms (usually one or two per covariate) in the regression model. Polynomial regression, on the other hand, typically requires more terms and also approximates data sets less well, especially at the end values of the scales. Possible effects on the results by adjusting for age or sex, as well as for all EORTC QLQ-C30 scales, were studied by entering these one at a time in the regression models. Model selection in fractional polynomial regression was performed as described by Royston and Altman (1994). This is an adapted stepwise forward selection procedure using the likelihood ratio (LR) statistic. Significance testing in the selected fractional polynomial regression model was carried out using Student's t statistic. Two-sided P-values <0.05 were considered significant.

In study III, the criterion validity of the Doloplus-2 scores was estimated by comparing it against the pain experts' pain ratings on a NRS-11 with a univariate regression analysis. This ability of the Doloplus-2 to explain the expert's ratings was expressed through the squared regression coefficient R^2. Univariate regression analyses were also performed to explore how each item could explain the expert score alone, and a step-wise (forward) regression analysis produced the best model (sequence) of items for explaining the expert score. The Doloplus-2 administrators completed a debriefing questionnaire.

In study IV, univariate regression analyses were used to estimate the ability of the Doloplus-2 to explain the expert's ratings (only one expert in study IV). This ability was expressed through the squared regression coefficient R^2. The contribution of each item in explaining the expert score was estimated with entering one item at the time in a univariate regression analysis to avoid problems of colinearity. The inter-rater reliability of the Doloplus-2 was evaluated in 16 patients by comparing the ratings of two independent Doloplus-2 administrators with intra-class correlation analysis. The performance of the pain expert was evaluated by comparing his pain ratings with the equivalent ratings of two geriatricians in 15 patients, with intra-class correlation analysis. Both intra-class correlation analyses were significance tested with F-tests.

Statistical analyses were performed with the SPSS statistical software versions 11, 12, and 14 (SPSS inc., Chicago, Il, USA) and Stata version 9 (StataCorp, College Station, Texas, USA).

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2.6 Ethics

The Regional Committee for Medical research Ethics in Central Norway (REK) approved the protocols for study II, III and IV. A majority of the participating patients in these studies were in a vulnerable situation with advanced disease and/or reduced ability to give informed consent. Research on such patients puts an extra obligation on the researchers in evaluating the ethical aspects of the research. It is important to give the patients relevant and understandable information about the study and any participation should be totally voluntary.

The cancer patients in study II were informed prior to the data collection and gave informed consent for voluntary participation. The patients with NCCP in study II completed the BPI and the EORTC QLQ-C30 in front of their consultancy at the National Centre of Expertise for Pain and Complex Disorders at St. Olav's University Hospital of Trondheim. These data were made available to us as a part of evaluating the clinical procedures for pain assessment in the clinic. All data were made anonymous before the researchers got them for analyses. The procedure was suggested and approved by REK. The cancer patients and the patients with NCCP completed questionnaires (BPI and EORTC QLQ-C30) that also are parts of the regular clinical routine, thereby minimalizing the patient burden.

According to the Oviedo Convention by the Council of Europe on human rights and biomedicine, research on patients unable to give informed consent should only be performed when the results of the research have the potential to produce real and direct benefit to his or her health, research of comparable effectiveness cannot be carried out on individuals capable of giving consent and when the person do not object to participate (Council of Europe 1997). A close relative of each patient in Study III and IV was informed about the study and patients were not to be included if the relative refused (no one did). Participation in these studies was considered to be of very little burden and risk to the patients who could also benefit directly from the pain consultations that came with the participation. All patient identifiable data were made anonymous at the institutions before the researchers got them.

2.7 Financial support

The studies in this thesis were financially supported by the Research Council of Norway and the liaison committee between NTNU and Health Region Central Norway. There were no conflicts of interests in this work.

3. Results, summary of papers

Paper I:

Pain assessment tools - is the content appropriate for use in palliative care?
The main objective of this study was to evaluate the importance of different pain dimensions for pain assessment in PC.

A total of 402 different citations were retrieved through the *systematic literature search* for self-report methods used for pain assessment in a sample with adult advanced cancer patients receiving PC.

Examinations of the titles and the abstracts identified 48 papers that met our inclusion criteria. Sixteen different tools for pain assessment used in PC studies were retrieved. The *ad-hoc search,* to identify self–report based assessment tools for adults in all populations, resulted in a total of 18021 hits. When this search was limited according to the search criteria, the numbers were reduced to 1391.

The literature searches generated a total of 80 different assessment tools containing at least one pain item. The tools contained 1011 pain items in total. Examination of the searches identified 11 different pain dimensions. The dimensions for "pain relief (exacerbating/relieving factors)" and "benefits from treatment" were collapsed into one dimension named *treatment and exacerbating/relieving factors* after the initial suggestion of one expert and the approval by the others. The rationale was to make one dimension that included non-treatment and treatment factors (medical and non-medical) that influenced upon the pain. The number of pain dimensions was thus reduced from 11 to 10. The expert panel evaluated the 10 dimensions for their relevance for pain assessment in PC research and clinic in the following order: Pain intensity, Temporal patterns, Treatment and exacerbating / relieving factors, Pain location, Pain interference, Pain quality, Pain affect, Pain duration, Pain beliefs, Pain history. The five first dimensions were evaluated as important by all experts, while the rest of the dimensions were omitted by one or more experts. The three most frequently assessed dimensions in the retrieved pain assessment tools were: intensity in 55 tools, interference in 37 and beliefs in 22, while duration and history were assessed in six and four tools respectively.

Three of the reviewed tools covered all of the five highest ranked dimensions: the Aberdeen Low Back Pain Scale (AB) the World Health Organization Quality of Life Assessment Tool – Pain Module (WHQOL-Pain) and the Pain Assessment Questionnaire for a patient with advanced disease (PAQ). The PAQ and the WHQOL-Pain included several dimensions in addition to the five which were recommended by the experts and is consequently more burdensome to complete. The AB is only suited for back-pain assessment. None of these assessment tools from the literature searches cover the five most recommended dimensions satisfactorily.

Most items were related to interference (231, ranked in fifth place), and intensity (138, ranked in first place). Temporal pattern, ranked as the second most important dimension, was covered by 29 items only. The expert panel allude that many tools include dimensions and items of limited relevance for patients in PC. Hence, the content validity of the existing tools is questionable in PC.

Paper II:

The Brief Pain Inventory: Pain's interference with functions is different in cancer pain compared with noncancer chronic pain.

The aim of the study was to explore how patients in PC report pain's interference with functions as measured by the BPI.

We hypothesized that cancer patients would report higher pain interference on physical functions than NCCP patients due to their advanced disease. The cancer patients reported higher values of physical interference than NCCP patients with the same level of pain intensity ($p < 0.001$). NCCP patients reported higher values of psychological interference than cancer patients ($p = 0.023$). For total interference these effects eliminated each other. When adjusting for the EORTC QLQ-C30 subscale for physical function the group effect became insignificant for physical interference ($p = 0.30$), while the results still remained significant when adjusting for age, sex, and the EORTC QLQ-C30 subscales. The results from the EORTC QLQ-C30 demonstrated a lower level of physical functioning in the cancer patients (physical function mean score: Cancer = 38, NCCP = 51). Adjusting for the QLQ-C30 subscale for physical function eliminated the group difference on pain interference with physical functions, denoting that level of physical functioning is more important for reports of pain's interference with physical functioning than level of pain and group identification. The NCCP patients have a linear relationship between intensity and pain's interference with physical function while the relationship reaches a ceiling effect already at a pain intensity of four in the cancer patients. This is caused by several cancer patients reporting very high pain interference and no pain to moderate pain.

The patients with NCCP reported more pain's interference with psychological function than the cancer patients and these results were also found in the EORTC QLQ-C30 data which indicate that the NCCP patients demonstrate poorer psychological functioning. The NCCP patients report lower emotional and social functioning than the cancer patients, but most significant is a substantially higher level of insomnia reported by patients with NCCP (Insomnia mean score: Cancer = 35, NCCP = 66).

The results indicate that the patients are unable to report isolated pain's interference using the BPI. The level of physical functioning is more important for reports of

pain's interference on physical functioning than level of pain and patient group. Patients' diagnoses have to be taken into account when interpreting assessment results of pain's interference with functions.

Paper III:

The Norwegian Doloplus-2, a tool for behavioural pain assessment: translation and pilot-validation in nursing home patients with cognitive impairment.

The present pilot study aimed at translating the Doloplus-2 into Norwegian and testing its criterion validity and clinical feasibility.

The Doloplus-2 was translated according to international guidelines provided by the EORTC. The final translation was spread in the study group and consensus was reached. According to contextual differences the backward translations differed a bit, but the content was similar. The Doloplus-2 administrators fully approved the final translation of the tool.

Fifty-nine patients with a primary diagnosis of dementia were recruited, of whom 47 were women. Median age was 82 years. Barthel index scores had a median of 15. The MMSE scores had a median of 9.

The mean pain expert score (NRS-11, pain-in-movement and pain-at-rest averaged) was 1.3 (SD= 1.6). Thirty four patients were rated with positive pain scores by the expert and 25 were rated with zero, as pain free. Twenty-nine patients had a Doloplus-2 score ≥ 5, signifying pain possibly requiring treatment according to the recommended Doloplus-2 cut-off score guideline (Appendix).

Among the patients that the experts rated as pain free, six had a Doloplus-2 score of zero and 19 had scores <5, leaving five false positives. Of the 59 cases, the Doloplus-2 produced false negatives at ten occasions. A false negative occurs when the Doloplus-2 score is below the defined cut off point of five in the same case as the expert rated above zero (NRS-11). A univariate regression analysis was performed to explore how well the Doloplus-2 could explain the experts' pain scores. The unstandardized residuals had a standard deviation of 1.02. The Doloplus-2 explained 62% (R-square) of the pain distribution.

Univariate regression analyses were performed with each item against the expert score variable (in order to avoid colinearity). The results in Figure 3 show how much variance each item explains in the expert score independent of the other items in the Doloplus-2.

Figure 3: Item contribution
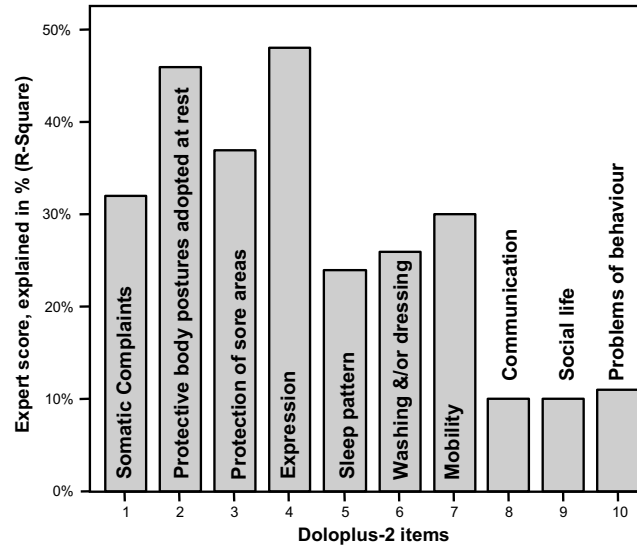
A stepwise (forward) regression analysis demonstrated that *Facial expressions* explained 48% (R-squared=.48) of the expert score alone. The analysis then included the items for *protective body postures adopted at rest*, *communication,* and *somatic complaints* as the items that consecutively could explain most of the remaining unexplained variance. Together they explained 68% of the total variability.

The debriefing of the administrators disclosed that Doloplus-2 was helpful in detecting and assessing pain and it was easy to administer. The administrators reported that the items for psychosocial reactions should be cautiously scored as many patients have abnormal social reactions as a result of their dementia and not as a result of pain. It is therefore important to know the patient's habits and regular behavioural patterns before scoring such behaviour as pain related.

Paper IV:

Doloplus-2, a valid tool for observational pain assessment?
The main objective of the present study was to test the criterion validity of the Doloplus-2.

A total of 73 patients were included from three different sites. The mean age of the sample was 84 years, and 74% were female. The median MMSE score was 10. The Barthel Index scores had a median value of 9.

The pain expert rated 47 patients as in pain, and 26 were rated as without pain. The mean pain expert score for pain-in-movement (NRS-11) was 1.5 (SD= 1.5). The inter-rater reliability was estimated as the association between the pain expert's ratings and two geriatricians' ratings of the same patients (N=15) with an intra-class correlation of 0.74 with a 95% confidence interval from 0.5 to 0.89.

The mean Doloplus-2 score was 7.47 (SD=5.08) with a range from 0-22. Five patients received a Doloplus-2 score of zero. Among these, three were also rated as not in pain by the expert, while the other two received a score of zero at rest and two in movement.

The regression analysis of the Doloplus-2 scores against the expert scores produced an R^2 of 0.023, implying no criterion validity of the Doloplus-2 in this data set. The inter-rater reliability between the Doloplus-2 administrators assessed by the intra-class coefficient was 0.77, with a 95% confidence interval of 0.47 - 0.92.

To explore the data more closely we analysed each study site separately. No significant results were obtained while looking at the complete data from the three sites; however, an association was found between the pain expert and the geriatric expert nurse (GN, the most competent administrator) who administered the Doloplus-2 in 16 patients in the Section of Geriatrics, with an R^2 of 0.54. Univariate regression analyses of the different Doloplus-2 items (full sample) showed small but significant relationships between the Doloplus-2 item for *protective body postures at rest* and the expert's pain-in-movement score (R^2=0.12, p=0.003) and for the Doloplus-2 item *pain complaints* and the expert's pain-at-rest score (R^2=0.13, p= 0.002). The Doloplus-2 identified a high number of false positive pain cases according to our pain criterion. A combination of more than one pain expert, other behavioral pain assessment tools, a verbal rating scale for self-report of present pain intensity and test-

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treatment with analgesics could constitute a comprehensive and promising pain criterion in future studies.

4. Discussion

This thesis has aimed to establish some recommendations for valid and comprehensive pain assessment in all patients in PC - both for those who are able to self-report pain, and for those who are not able to. Our results indicate that the recommended tools for both self-report and behavioural pain assessment have short-comings and questions are raised with regard to the validity of both the BPI pain interference dimension and the Doloplus-2. A panel of PC field experts gave recommendations on the content for future self-report based pain assessment tools. In behavioural pain assessment there is a need for further testing of the available tools for use in patients with cognitive failure and pain.

The validity of our results depends on the design of our studies and on the inclusion of subjects. Validity of studies can be divided into internal and external validity (Juni et al. 2001). Internal validity regards whether the design of the study is appropriate for providing evidence about the given topic, is systematic errors minimised? External validity refers to whether one can make generalisations from the results to the general population at stake. Are the results valid for the population which the subjects are part of and maybe also for other similar populations than those in the studies? The limitations within the studies and the implications from the results will be discussed. The following discussion is divided into two parts, one for self-report and one for behavioural assessment.

4.1 Pain assessment by self-report

4.1.1 Study I

In Study I we wanted to evaluate the appropriateness of the content of pain assessment tools for use in PC. Study I builds on and follows a well accepted EORTC guideline for establishing new standards for symptom assessment, by combining literature searches and panels of field experts (Sprangers et al. 1998). However, some limitations should be taken into account. As described in the paper, the area of pain measurement is huge and it was impossible to make a complete systematic search within the limits of the study. The systematic search, that was restricted to studies in PC populations, was therefore accompanied by a limited ad-hoc search for all pain assessment tools. This resulted in 80 assessment tools that included at least one pain

item. We are confident that this strategy revealed enough tools for pain assessment to produce a comprehensive description of the pain assessment tools in use today. The expert panel consisted of six experienced pain and PC specialists from five European countries, all members of the EAPC Research Network. The expert panel was structured by a Delphi method process. The aim of Delphi methods is to elicit and develop individual responses to the questions. Communication in the expert group was anonymous, in the sense that all feedback from the members of the expert panel was sent to the coordinator who then structured the different experts' views and sent it back to the whole group without identification of individual contributions. The advantage of such a method is that social interaction between the members of the panel is minimised in order to receive all members' individual views. Of the experts, five were male and one was female. One could have wished for a more even distribution between men and females. All the experts were physicians. In opposition to tools developed for cancer pain, the tools developed for complicated cases of NCCP have more focus on pain affect and quality and these tools are often developed by non-physicians e.g psychologists (Paper I). The constructor of the MPQ is also a psychologist and pays great focus to pain quality. The expert panel acknowledged the importance of the pain quality dimension, but it was expressed that this is more important in pain diagnostics and not for monitoring pain treatment in patients with advanced disease, a view supported by the EAPC's previous publication with recommendations for pain assessment (Caraceni et al. 2002). During the review process nurses, psychologists and physiotherapists have been invited to comment on the recommendation from the expert panel, and all have approved these results. The rationale behind this choice of experts was that we wanted a highly competent statement with relevance for both clinic and research. Consequently, we invited leading capacities in the field. The panel could have been strengthened by additional participants, presumably also from outside Europe.

Another limitation of the study is the lack of involvement of patients themselves in the process both to identify pain domains important/relevant to them and to select/review pain items to be used in the assessment. The patients could have been involved in this first process, but as our primary aim was to improve pain treatment we found it most appropriate to ask the physicians to tell us what information they

need from the pain assessment in order to provide optimal treatment. The choice of skipping the patients' perspective at this point limits the results.

As described, our study protocol followed the EORTC guideline for developing new assessment tools and as a next step in our development of a new pain assessment tool we did involve patients. The five expert-recommended dimensions were operationalized with items that we retrieved form the literature search in Study I. These items were also evaluated by the expert panel and assigned to what they perceived were the appropriate dimensions. A questionnaire with 58 items on the five dimensions was constructed and administered to seven cancer patients from the palliative medicine unit and 14 NCCP patients from the pain centre (spring 2004). They completed this questionnaire before they were interviewed with regard to their assessment experience with the EORTC debriefing guide (Cull et al. 1998). A main finding was that especially the cancer patients found it difficult to reply to items about pain interference. It may be speculated whether the pain interference dimensions would have reached the top five if we had taken the patient perspective into account in the first place and this reservation towards the assessment of pain interference inspired us to perform study II.

4.1.2 Study II

Through the literature review in Study I it was clear that the BPI could be complicated to understand and burdensome to complete for patients in PC. Additionally, our experience from the debriefing of the patients' responses to the 58-items questionnaire and our clinical experience in the research group had taught us that the patients could find it difficult to respond to the items on pain's interference with functions.

In study II we wanted to explore the construct validity of the pain's interference with functions assessments in the BPI in PC patients.

Some factors may have influenced the validity of our results. We chose the BPI-*average pain intensity* item as the pain intensity criterion. In our opinion this item is better suited as criterion than *worst* and *least* pain intensity, since these items are more concerned with floor and ceiling effects. Also, it is reasonable that the pain experienced most of the time is more important for pain's interference than short periods with least/worst pain intensities. A test was performed with the pain *worst*

item instead of the item for average pain intensity and the results were similar. We could have calculated the pain intensity index (summing or averaging the four intensity items), but the amount of missing items would have increased further and we found it more appropriate to use the *average pain* item which emphasizes the patient's subjective averaged experience of pain in contrast to calculating an average index score.

We chose to split the pain's interference with functions index into one dimension for physical and one for psychological functions in accordance with the factor structure that was demonstrated in the Norwegian validation study of the BPI (Klepstad et al. 2002). The cancer patients report higher levels of pain's interference with physical functions, while patients with NCCP report higher interference with psychological functions. The value of using separate interference scales for psychological and physical functions was hereby manifested as the group differences were invisible in the total interference score.

There was a gap of five years between the data collections in the two populations. For the cancer patient population at St. Olav's University Hospital there have been no major changes in treatment policies during the interval between the data collections. Therefore we do not believe this time frame has introduced any bias in the data analyses. The mode of administration differed between the two populations. The cancer patients completed the questionnaires at the hospital while the NCCP received them in the mail prior to the hospital consultation. Consequently, the cancer patients were already in a care situation when completing the questionnaires while the patients with NCCP were waiting for help at home. Many patients with NCCP have a history of search for medical care without satisfactory effect on their health status. These patients presumably look forward to the consultation at the pain clinic and one has to take into account that their situation may contribute by creating a bias through patients who are especially aroused with regard to pain and even some who may instrumentally report worse symptoms in order to get help. One might speculate weather this is reflected in the data that actually demonstrated worse pain in the patients with NCCP compared to those with advanced cancer. If this difference in mode of administration contributes mainly on the absolute scores and less on the correlation between pain intensity and pain's interference, it will be of less importance for our main findings. However, we do not know how this has affected the

results and it would have been preferable if the patients with NCCP had been re-assessed when they had settled after the consultation at the pain clinic. A recent study by Fredheim *et al.* (2008) found that the patients with NCCP reported poorer HRQoL in 11 of 15 EORTC QLQ-C30 scales (including pain) compared to cancer patients in palliative care (Fredheim et al. 2008). This study supports our findings. It is discussed whether this gap between HRQoL in patients with NCCP and advanced cancer disease may be explained by the *Calman gap*. Calman explained such differences as a consequence of differences between experienced and expected health status (Calman 1984). While the patients with advanced cancer to a larger degree accept that their health status decreases, the patients with NCCP may struggle more with maintaining a normal level of functioning. This may lead to frustration and feelings of loss when they realise that they do not perform as well as they expect to do.

The number of patients who completed the questionnaires was different in the groups, maybe as a consequence of different data collection procedures. The NCCP patients may have perceived the completion of the questionnaires as more relevant and important for their own treatment as their completion rate was higher than in the cancer group. However, this finding could also reflect worse health status in the cancer group leading to more missing items. These data support our hypothesis that the BPI is too complicated and burdensome to use in patients with advanced disease.

Another limitation regards the fact that most cases are concentrated in the central part of the pain scales and we have fewer observations in the top and bottom of the score distribution. However, the main results are found as group differences within the central parts of the scale (e.g. between intensity scores of 3 to 7 in pain interference with physical functioning), at those parts with most observations.

The selection of patients into the study was skewed with regard to pain. All participating cancer patients were on opioids and the NCCP patients were recruited from a specialized pain clinic at a university hospital, denoting that they had been ill for a long time. However, a positive consequence of this selection, for the study, was that these patients had pain.

In conclusion, assessment of pain's interference with physical functions seems to be biased by general level of physical function in cancer patients. A recent study supports this conclusion by reporting that the interference scales could be invalid in

cancer patients, since they tend to be influenced by their general level of functioning while responding to items regarding pain limited functioning (Stenseth et al. 2007). In our data, the patients with NCCP report more pain's interference with psychological functions with increasing pain intensity compared with cancer patients. Cleeland suggested that assessment of pain intensity is less valuable compared to assessment of pain's interference in patients with NCCP (Cleeland 1989). Our results may indicate the opposite for cancer patients in PC. According to the present results the assessment of pain's interference with functions is complicated and the patient's diagnosis should be taken into account for valid interpretation of such scores.

4.1.3 Summary

Our two studies on self-report based cancer pain assessment indicate a shortage in the existing alternatives; the tools' content is not optimal, they are burdensome to use and parts of the assessments may be invalid (e.g. assessment of pain's interference with functions as done in the BPI). As a response to these challenges we established and co-ordinated a panel of PC experts in clinic and research, who gave recommendations for the development of new and improved pain assessment tools.

4.2 Behavioural pain assessment

Both studies III and IV focus on the psychometric properties and clinical feasibility of the Doloplus-2 and are mainly discussed together in the following section. Studies III and IV both tested the criterion validity of the Doloplus-2. The further focus in study III was on the translation of the Doloplus-2 into Norwegian and on the exploring of the feasibility of the tool in Norwegian nursing homes. In study IV the additional foci were on the inter-rater reliability of the Doloplus-2 and on the use of a pain expert as a criterion for pain. In these two studies the Doloplus-2 demonstrates low criterion validity, which may indicate poor content and construct validity. Both our studies indicate that the psychosocial domain performed inadequately and this finding was recently supported in another study (Zwakhalen et al. 2006a). To study cognitively impaired nursing home residents was a greater challenge than we had anticipated. The diagnostics of the patients were not as comprehensive as one could have wished for and the personnel at the nursing homes are few per resident and there is a general lack of educated personnel. A recent study that explored the validity and clinical usefulness of the Doloplus-2, the Pain Assessment in Advanced Dementia Scale

(PAINAD) (Warden et al. 2003) and the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC) (Fuchs-Lacelle and Hadjistavropoulos 2004) also failed to report a robust conclusion with regard to the validity of the Doloplus-2 due to problems with the design (Zwakhalen et al. 2006a).

4.2.1 Subjects

Most patients were demented and stable in level of cognitive function while a minority of the patients, especially some patients at the Geriatric ward in study IV, had acute incidents of delirium and unstable levels of cognitive function. Apart from that, all the patients in the studies were judged as too cognitively impaired to make valid self reports of pain. They were a heterogeneous group with regard to age, level of cognitive function as measured by the MMSE, level of independence in ADL as measured by the Barthel Index, and general health status. In study III we approached nursing homes where we knew that the patients were diagnosed with cognitive failure. At these special shared house wards for demented people we had an appropriate population for testing a behavioural assessment tool. However, our results indicate that the level of pain was low in this particular group. Consequently, we aimed at other nursing home patients in study IV where we included patients from regular nursing homes (in opposition to shared housings for demented) as well as patients from the geriatric ward at St. Olav's University Hospital.

4.2.2 Pain

It is a limitation in these two studies combined that the patients were clustered at the low pain levels, a fact that may have negative effect on both the internal and the external validity. In international studies the pain prevalence in nursing home patients is generally reported between 45% to 84% (Herr 2002;Manfredi et al. 2003). In Norwegian nursing homes, pain has also been regarded as prevalent and described by prevalence numbers of 47% to 53% (self-report) and 44% to 67% (nurses' reports) (Jordhoy et al. 2003;Nygaard and Jarland 2005a;Nygaard and Jarland 2005b). According to our pain experts, 58% in the first Doloplus-2 study and 64% in the second study had a positive pain score (NRS-11 > 0). Consequently, our prevalence numbers are in accordance with other studies. However, these prevalence numbers regards positive pain scores, and that may not be equivalent to clinically significant pain.

The study by Jordhoy *et al.* (2003) assessed pain by EORTC QLQ-C30 and reported mean values of pain intensities at trial entry 45 (± sd 30), follow-up mean score of 48, and one month before death the mean score was 58 (possible range of scores 0-100), while the two studies by Nygaard and Jarland only report presence of pain. This may be a consequence of the fact that most behavioural tools are concerned with counting the presence of pain behaviours, not with ranking pain intensity. It is our experience that it is more difficult for patients with cognitive impairment and for proxy raters to report intensity than just the presence of pain or no pain. Therefore we do not know whether our patients' low levels of pain are unrepresentative or not, but Jordhøy et al's (2003) data did also report the pain levels to be moderate. It is problematic when pain frequencies are presented as pain prevalence. A pain score of one or two on a NRS-11 may not constitute a clinically significant level of pain and consequently the prevalence may seem higher than it really is. A recent study by Leong *et al.* (2006) summarized that low levels of pain in validation studies of behavioural assessment tools in nursing home patients, are a well known "problem" (Leong et al. 2006). We anticipated to find higher levels of pain than we did. One may speculate if this mainly reflects that the published numbers of pain prevalence in elderly are artificially high. Scherder, Sergeant and Swaab (2003) stress the importance of relating neuropathology to pain in patients with dementia. Reviews have demonstrated that pain is experienced differently in patients with different diagnoses. Patients with Alzheimer's disease (AD) are often said to have decreased pain experiences while those with a vascular dementia may have increased pain sensations (Scherder et al. 2003). As previously stated, many patients who were included in Study III and IV have never been properly diagnosed for their dementia and this seems to be a common problem in nursing homes. The internal distribution of subjects with AD and with vascular dementia in a study sample may contribute on the identified pain prevalence in the population.

As a result of the low levels of pain we cannot present evidence regarding the psychometric performance of the Doloplus-2 in patients with high levels of pain. On the contrary, our results provide a comprehensive evaluation of the Doloplus-2 in a heterogeneous group of patients, from five different nursing homes and one geriatric hospital ward, with no to moderate pain.

4.2.3 Limitations related to design

Both studies rely on the assumption that a single expert statement is a valid criterion for pain. In study III, the physicians responsible for the patients' treatment acted as the experts, while we used one expert in all patients in study IV. We tested the inter-rater reliability of this expert's performance (study IV) in a sub-sample (N=15) and it was satisfactory. In the papers (especially in paper IV) we have discussed the pros and cons of this design. Our main argument for using pain experts as criterion was that we wanted to test the performance of the Doloplus-2 in populations with patients unable to self-report. The original French validations were performed in patients who were able to self-report pain and in these patients the Doloplus-2 score was compared to a VAS score given by the patient and the most recent Doloplus-2 study also adopted this design (Wary et al. 2001;Wary et al. 2003;Pautex et al. 2007). Hadjistavropoulos and Craig (2002) argued for a different understanding of pain behaviours performed by those with higher level of mental functioning to those with cognitive impairments (Hadjistavropoulos and Craig 2002). In cognitively intact, pain behaviour will be guided by a communicative intent and the pain stimuli will be cognitively evaluated in front of the pain expression. In cognitively impaired, pain behaviours will lack conscious communicative control. As such, pain behaviours among cognitively impaired are more related to pain reducing behaviour while the cognitively intact also will use pain behaviour to call for help from others. It is therefore important that the testing of behavioural assessment tools are performed in patients who are too cognitively impaired to self-report, as done in our two studies.

The study design could have been strengthened by a Doloplus-2 test-retest with administration of analgesics, in the pain patients, in between the assessments. Such a design would have provided information on the Doloplus-2's responsiveness towards change and it would have contributed with important information regarding pain or not in patients where there was doubt. However, such a design would have demanded substantial additional resources and it was not found feasible to perform at this moment.

The combined experience from studies III and IV indicates that the mode of administration had an important impact on the criterion validity of the Doloplus-2 as concordance between the Doloplus-2 scores and the expert's scores were higher in those cases were the Doloplus-2 was administered by the most experienced and

skilled administrators. Study III indicated criterion validity in the Doloplus-2 and here the Doloplus-2 administration was a co-operation between a nurse/ nurse assistant and a last year medical student with special interest in geriatrics. In study IV we found the same pattern of concordance between domains of the Doloplus-2 and the expert's ratings in a subgroup of 16 patients assessed by a geriatric expert nurse who was the most experienced Doloplus-2 administrator in study IV. The Doloplus-2 would be a more valuable tool if it was valid in the hands of personnel with moderate skills in understanding pain behaviour in those with cognitive impairments, but our results indicate a need for high competence. New studies on the Doloplus-2 should take these considerations into account when recruiting Doloplus-2 administrators.

The lack of data regarding analgesic use in the Doloplus-2 studies may be a weakness. For instance, analgesic efficacy might fluctuate throughout the 24 hour period and could lead to different behavioural expressions (i.e., analgesics may change behaviour independent of pain). Also, comparing across raters who are assessing patients with potentially different levels of analgesia can lead to discordant ratings. Due to recommendations from the regional ethical committee (REK) and the Norwegian Social Science Data Services regarding the anonymity of the patients, the use of analgesics was not recorded. However, the aim of the studies was to assess pain behaviour reflecting the experience of pain. We therefore did not find it necessary to record pain medication since lack of pain behaviour caused by adequate medication or absence of pain would be treated as similar outcomes in the analyses.

Our Doloplus-2 studies differ from several other validation studies of behavioural pain assessment tools in that we found little association between the behavioural assessment tool and the criterion. An explanation for this divergence may be that we also used less educated and experienced Doloplus-2 administrators compared to other similar studies. The intention behind the recruitment of enrolled nurses and assistant nurses was that they are the personnel at Norwegian nursing homes in highest number and with most patient contact. In the validation of the PAINAD (Warden et al. 2003) and the PACSLAC (Fuchs-Lacelle and Hadjistavropoulos 2004), experienced registered nurses participated as administrators, often also in teams of two for each patient. The validation of Pain Assessment for the Dementing Elderly (PADE) (Villanueva et al. 2003) was more similar to our design in that nurse assistants performed most of the administration, though under supervision of a registered nurse.

The authors hypothesized that the demented patients' high agitation in the verbal domain and low in the physical would be an indicator of pain and used this as a pain criterion. Our experience suggests that this is a weak pain criterion as there may be many other causes than pain, effecting upon the level of agitation in this group of demented patients. Further, the authors report correlation coefficients between 0.396 and 0.421 comparing the PADE to the Cohen-Mansfield Agitation Inventory (Cohen-Mansfield 1996;Villanueva et al. 2003). Although significant correlations, these are in our opinion too low to be interpreted as signs of good validity in the PADE as done by the authors (Villanueva et al. 2003).

The French constructors of the Doloplus-2 suggest a cut-off score of five points (scale runs from 0 - 30) as indicative of pain (Collectif Doloplus 2006). In both our studies the Doloplus-2 produced a large number of false positive pain cases (Table 2).

Table 2: Number of pain-free patients (N=132).

Pain scores of 0	Study III, N=59	Study IV, N=73	Sum
Expert score	25 (42%)	26 (36%)	51 (39%)
Doloplus-2	9 (15%)	5 (7%)	14 (11%)
Sensitivity of the Doloplus-2*	91%	96%	
Specificity of the Doloplus-2*	24%	12%	

*Without the cut-off score of five

If we apply the cut-off score of five, the results change. Then 30 patients are rated as pain free by the Doloplus-2 in study III and 27 in study IV (equivalent numbers to the experts). In paper III we argued against this cut-off score since it was not evidence-based. The recommended cut-off would have reduced the seemingly false positive pain cases in our two studies by increasing the specificity of the Doloplus-2. In our data a Doloplus-2 score below five may still indicate pain, especially if a patient displays one of the most valid behaviours. The proportion of false positive and negative pain cases may be a consequence of low levels of pain in our study population. Combining the results from studies III and IV (N=132), 22 patients (10 in study III and 12 in study IV) had a Doloplus-2 score under five and an expert score

above zero and one of these patients had a high expert pain score of five. These patients would have formed a 17% of false negative pain cases if the cut-off score was applied. Our data indicates that some sensitivity in the tool should be sacrificed for higher specificity.

4.2.4 Summary

The assumption behind behavioural pain assessment tools like the Doloplus-2 is that health care personnel can provide valid observations of pain behaviour and express these in a standardized form. Our studies question this assumption.

Taken all discussed limitations with the study designs into account, one should be cautious when interpreting the internal and especially the external validity of our two studies on the Doloplus-2. Issues with the selection of a proper pain criterion are related to the internal validity of the studies and as described the use of a single pain expert is debatable. The external validity is weakened by the fact that we had a homogenous group with regard to pain. However, it is our opinion that our two studies have disclosed some serious problems both with the administration of the Doloplus-2 and with false positive or false negative pain cases as assessed by Doloplus-2. Both issues are closely related to the psychosocial domain and suggest that major revisions should be made to the tool. It is also important to note that some patients with severe levels of pain may have low presence of pain typical behaviours and therefore receive low Doloplus-2 scores (American Geriatrics Society 2002). This may constitute a general challenge against the concept of behavioural pain assessment. Consequently, it will also be of importance to search for other clues of pain in these patients and incorporate this knowledge into future tools.

4.3 Suggestions for future research

Our studies have indicated that both the BPI and the Doloplus-2 are insufficient in their psychometric performance and coverage of the pain problem. Consequently, better assessment tools are needed. For self-reported pain assessment we have, in collaboration with the EAPC research network and with an EU grant, started the development of a new and improved computer based assessment tool. This tool includes pain among other symptoms and it is based upon the recommendations given by the expert panel in study I.

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The future of Doloplus-2 is uncertain. From the beginning of this study in late 2003 the Doloplus group has announced that a Dololus-3 is under development. To our knowledge, this work is still in progress and the results from our studies will constitute important input. Meanwhile the Checklist of Nonverbal Pain Indicators (CNPI) (Feldt 2000) offers an interesting alternative that should be thoroughly evaluated in more patients (Zwakhalen et al. 2006b). The CNPI is brief, with only six items scored for the presence, in rest and in movement, of vocal complaints, facial expressions, bracing, restlessness, rubbing affected areas, and verbal complaints (Feldt 2000). These items cover the same domains that those in the Dololus-2 which had best psychometrical functioning in our studies.

One may also speculate whether the pain indicators repetitively used in all behavioral pain assessment tools are really valid. If not, the whole approach to behavioral pain assessment needs to be re-evaluated before the construction of new and improved assessment tools. Further development of validation methodology is important and it is our opinion that such validation should take place in patients unable to self-report pain. In our two studies on the Doloplus-2 we have suggested a design with expert raters, which should be elaborated on and improved in order to achieve a solid criterion for future testing of behavioural pain assessment tools. The use of a single expert is a criterion with obvious limitations and future research should use at least a combination of two pain experts. Other behavioural pain assessment tools can be used as sub-criterions and a verbal rating scale may be used for self-report in some patients that are communicative. Test-treatment with analgesics may also constitute a valid criterion and could be used in addition to the experts.

An effort should also be made to produce guidelines for when to use self-report based questionnaires and when to use observational tools. Perhaps a short mental screening tool in front of the pain assessment could assign patients to self-report if such is applicable. By now there are no guidelines to advise healthcare personnel as to when self-report is invalid and behaviour observational tools should be used. EAPC and AGS are both in a position to contribute with a much needed guidance on this issue.

5. Conclusions

In response to our three study objectives we have reached the following conclusions:

1. The most relevant pain dimensions for assessment in PC are pain intensity, temporal pattern, treatment and exacerbating / relieving factors, pain location, and pain interference. Intensity is most important while the subsequent four dimensions are recommended for comprehensive assessment.

   a. The 80 reviewed assessment tools contained 11 different pain dimensions (in alphabetic order): Benefits from treatment, Pain affect, Pain beliefs, Pain duration, Pain history, Pain intensity, Pain interference, Pain location, Pain quality, Pain relief (exacerbating/relieving factors), Temporal patterns, Treatment and exacerbating / relieving factors.

   b. The content validity of the existing tools is questionable for assessment in PC as none of the tools meet the experts' recommendations for such assessments.

2. Patients with cancer pain report higher levels of pain's interference with physical functions while patients with NCCP report more interference with psychological functions.

   a. Patients with advanced cancer seem unable to distinguish between pain's interference with functions and impaired functions caused by the disease.

   On this background one might question the recommendation by the expert panel in Study I on the relevance of assessing pain's interference with functions.

3. The Norwegian Doloplus-2 demonstrated satisfactory criterion validity in the pilot study, but these results were weakened by a more thorough study. Valid Doloplus-2 assessment seems to depend on high administration skills.

   a. The Doloplus-2 item for facial expressions explained most of the total variability in the expert score followed by the items for protective body postures adopted at rest, communication, and somatic complaints.

   b. The feasibility of the Doloplus-2 is limited by the need for specific administration and interpretation skills.

c. The inter-rater reliability of the Doloplus-2 seems to be satisfactory, but is of limited value since the tool does not demonstrate satisfactory criterion validity.

d. A comprehensive and promising pain criterion in future studies may consist of a combination of pain ratings from at least two pain experts who have access to relevant information about the patient, pain ratings from other behavioural pain assessment tools, a verbal rating scale for self-report of present pain intensity when applicable, and test-treatment with analgesics.

Errata

In paper II the published paper had been revised by the editorial office after the first author had approved the proofs. This resulted in a new title and the authors' concept of non-malignant chronic pain was changed into noncancer chronic pain.

In the last paragraph at page 220 before the new chapter Measures, the sentence should read: Patients in both groups were 18 years or above and *the cancer patients* were evaluated and found to be cognitively competent to complete…

The patients with NCCP were not screened with regard to cognitive functioning.

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Paper I

Original Article

Pain Assessment Tools: Is the Content Appropriate for Use in Palliative Care?

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Abstract
*Inadequate pain assessment prevents optimal treatment in palliative care. The content of
pain assessment tools might limit their usefulness for proper pain assessment, but data on the
content validity of the tools are scarce. The objective of this study was to examine the content
of the existing pain assessment tools, and to evaluate the appropriateness of different
dimensions and items for pain assessment in palliative care. A systematic search was
performed to find pain assessment tools for patients with advanced cancer who were receiving
palliative care. An ad hoc search with broader search criteria supplemented the systematic
search. The items of the identified tools were allocated to appropriate dimensions. This was
reviewed by an international panel of experts, who also evaluated the relevance of the
different dimensions for pain assessment in palliative care. The systematic literature search
generated 16 assessment tools while the ad hoc search generated 64. Ten pain dimensions
containing 1,011 pain items were identified by the experts. The experts ranked intensity,
temporal pattern, treatment and exacerbating/relieving factors, location, and interference
with health-related quality of life as the most important dimensions. None of the assessment
tools covered these dimensions satisfactorily. Most items were related to interference (231) and
intensity (138). Temporal pattern (which includes breakthrough pain), ranked as the second
most important dimension, was covered by 29 items only. Many tools include dimensions
and items of limited relevance for patients with advanced cancer. This might reduce
compliance and threaten the validity of the assessment. New tools should reflect the clinical*

Introduction

Pain is among the commonest symptoms in cancer patients receiving palliative care.[1,2] Proper pain assessment is generally considered a prerequisite for proper pain treatment, but despite dedicated efforts, studies demonstrate that pain still is not adequately assessed, and as such, not satisfactorily managed.[3–6] In a survey among 897 physicians in the Eastern Cooperative Oncology Group, 76% reported poor pain assessment as the single most important barrier to adequate pain management.[7]

An Expert Working Group of the European Association for Palliative Care (EAPC) reviewed the status of the use of pain measurement tools in palliative care research.[8] Based on the literature and the experts' opinions, the group gave recommendations on pain assessment in palliative care research. The selection of tools should be based on the study population and the specific study design. For adult patients without cognitive impairment, multidimensional pain assessment with the Brief Pain Inventory short form (BPI-sf)[9,10] was recommended.[8] The Short Form McGill Pain Questionnaire (SF-MPQ)[11] was recommended for studies that specifically assess pain quality, such as studies focusing on diagnoses and characterization of various pain syndromes.[8] For simple assessment of changes in pain intensity, Numerical Rating Scales (NRS) were recommended.[8]

Another recent review evaluated the psychometric performance of pain assessment tools in cancer patients in general, both in the clinic and in research.[12] This review demonstrated that single-item unidimensional tools, such as Visual Analogue Scales (VAS) and NRS, were psychometrically satisfactory for assessment of pain intensity in clinical settings. However, these should be used with caution in palliative care patients, particularly because the ability to complete the VAS scales declines with disease progression.[12] In line with the advice of the EAPC Expert Working Group and as emphasized in other studies,[8,12–16] it was recommended that pain assessment in cancer clinical care and research should include dimensions additional to intensity. Fewer than 3% of the studies in the review addressed issues of content validity in pain assessment tools, leading to a recommendation that examination and evaluation of the content should be the focus of future studies.[12]

Both reviews recommended selection of a pain assessment tool on the basis of its psychometric performance. No direct recommendations were given on the basis of the tools' contents, even though both reviews recommended tools for multidimensional pain assessment. However, the literature has shown that many of the present multidimensional tools are burdensome to use for both clinicians and patients, especially in populations with advanced disease.[8,15,17–20] The SF-MPQ was regarded as too demanding to use by the EAPC Expert Working Group and others.[8,17] A study using both the full version of the BPI and the BPI-sf showed that fewer than 58% of the patients completed all questions in the full version, returning partially completed questionnaires.[18] The study concluded that the BPI was too burdensome for both patients and administrators.[18] The BPI-sf, on the other hand, was regarded as not sufficiently comprehensive.[18] Despite the shorter format, two European studies, including more than 400 palliative care cancer patients, demonstrated that 35% and 40% in the two samples, respectively, returned incomplete BPI-sf questionnaires.[19,20]

To our knowledge, evidence-based information regarding the content of pain assessment tools is scarce. At present, we are not aware of any studies that have specifically addressed the content of pain assessment tools with specific relevance for cancer pain assessment in

palliative care. The lack of knowledge on what to assess combined with insufficient performance of the recommended tools made us launch the present study, with the following aims: 1) to examine the content of the existing pain assessment tools for cancer pain in palliative care practice and research, 2) to evaluate the relevance of different dimensions and items for cancer-pain assessment in palliative care practice and research by consulting a panel of international experts, and 3) to explore the need for additional items, dimensions, or assessment tools specific to palliative care.

Methods and Materials

The methodology consisted of two approaches. First, two literature searches were conducted in order to identify the content of existing pain assessment tools. Second, an expert panel was consulted to evaluate and classify the content of the tools identified by the literature searches.

Literature Searches

Two literatures searches were conducted. First, a systematic search on pain assessment tools used in palliative care was performed. This was supplemented by a broader search for pain assessment tools used in other populations. To be included in the *systematic search*, the title or abstract should describe the following: 1) a self-report method used for pain assessment or the name of an assessment tool explicitly used for self-report of pain, and 2) a sample with adult advanced cancer patients receiving palliative care. The search was further restricted to publications in English. Case reports, editorials, letters, and commentaries were excluded.

A systematic, computerized literature search in PubMed (MEDLINE) and Cancerlit (1966 to February 2003), PsychInfo (1972 to February 2003), and Cinahl (1970 to February 2003) was done. The Cochrane Library review group for Pain, Palliative and Supportive Care was also consulted. The following key words and medical subject headings were used: *Pain assessment* or *Pain measurement* combined with *Palliative care* or *Palliative medicine*. All titles and abstracts were examined in relation to

the inclusion criteria. When a tool was named and/or described as a measure for pain, the full paper was examined for further information. If applicable, the original paper describing the construction of the identified tool was examined for further information.

To ensure a more complete coverage of pain assessment tools, we decided to broaden the study with an *ad hoc search* applying wider search areas in the Ovid-MEDLINE journal archive and the BIBSYS book archive. The aim was to identify self-report-based assessment tools for adults including at least one item for pain assessment. This included assessment tools developed for, and used, in patient populations other than palliative care. The aim was to identify supplementary information regarding the pain dimensions being covered by tools developed for other patient populations. The terms in the searches were *Pain assessment* or *Pain measurement*. The Ovid-MEDLINE-bases from 1989 through February 2003 were searched. Because this was a supplementary ad hoc search and because of the vast number of publications on pain assessment in general, the following MEDLINE limitation options were deployed: English language, abstracts available, humans, all adult (19 years or above), and full text. The Norwegian Search Library database BIBSYS (international) was searched for books. The results from the two searches were combined and duplicates were deleted.

The titles and abstracts of the papers were browsed in order to identify those including information about assessment tools. When a tool was named and described as a measure for pain, the full text paper was consulted. Tools especially designed for measurement of back and neck pain and headache/migraine were included, as they are numerous and had the potential to present pain assessment information of general value. We decided not to include ad hoc questionnaires or tailor-made tools for the following specialized areas of interest: ocular pain, ankle and Achilles pain, myofascial pain, mucositis, dental pain, wheelchair user's shoulder pain, and jaw pain, as their potential for adding general cancer pain information for palliative care was evaluated as small. The original papers describing the construction of the identified tools were examined for further information about the

tool. The books were evaluated by the background information provided by the BIBSYS site and by browsing the titles. Only books that seemed to be devoted to pain assessment as the main topic were included. The *Oxford Textbook of Palliative Medicine*,[21] *Quality of Life: Assessment, Analysis and Interpretation*,[22] and *Quality of Life and Pharmacoeconomics in Clinical Trials*[23] were also included because they present relevant assessment tools and were in the first author's possession.

Pain Dimensions and Items

The terms *pain dimensions* and *pain domains* are used interchangeably in the literature on pain. Intensity is typically referred to as a dimension, while location is commonly described as a domain. However, as both concepts refer to aspects of the pain experience, the term dimension is used throughout the present work.

An item is operationalized in the form of a question or a statement.[22] For example, an item conceptualized as "pain intensity" might be operationalized like "How bad is your pain?" or "My pain is as severe as: …". To summarize the numerous items across tools, we defined an item as a question or a statement that requires an answer. A question such as no. 21 from the BPI,[24] "*I believe my pain is due to:*", where the respondent is provided with three choices, was conceptualized, therefore, as three separate items. Body maps for pain were counted as one item (BPI), or one item per question asked in tools that ask about pain in different body parts (Regional Pain Scale[25]). We defined a *pain item* as a question/statement that explicitly refers to pain, is related to pain (headache), or at least includes pain (among other symptoms) in the wording or in the questionnaires' guidelines. Thus, items about psychological distress in a pain assessment tool were not counted unless directly phrased as pain-related distress. Global items about how the present health situation interferes with health-related quality of life (HRQOL) were not defined as pain items, in contrast to items specifically asking about how pain, alone or in combination with other symptoms, interferes with a specific function.

Content Categorization

All the included assessment tools and the papers describing the construction of the tools were examined for information about the content expressed by their pain dimensions and the items covering them. All dimensions that were either described as assessed by the tool developers or that were named in the tool were included in a list of assessed pain dimensions. The tools are presented in Table 1, with their pain dimensions and number of items within each dimension. In some tools, all dimensions were not specified by the constructors, and had to be conceptualized on the basis of the items' content. The items covering the dimensions that were not defined were compared to items from other tools with known dimensionality in order to examine the similarity. Items asking about severity, intensity, and amount of pain were consequently named intensity items, while items asking about where it hurts were classified as location items. This was performed by the first author and later an international expert panel was asked to delete or add other dimensions in order to achieve coverage of all necessary dimensions for palliative care (to be described later). In cases of uncertainty about the actual dimensions within a tool, the dimensions were placed in brackets (Table 1). If only one of the dimensions was obvious, it was decided to label the tool as unidimensional, with the other potential dimensions listed in brackets. In approximately 30% of the tools, we assigned items to dimensions other than those originally suggested by the constructors. This is exemplified by the Oswestry Disability Index,[54] item no. 1: "*Pain killers give complete relief from pain.*" This item was named pain intensity by the developers, but when comparing this wording against similar items in other tools, we classified it as also assessing effects of treatment. In cases with disagreement between tool developers' characterization of included dimensions and our comparisons between tools, dimensions were included in addition to the developers' dimensions (that always were taken into account). The categorization of the dimensions and items was later reviewed by the expert panel.

Expert Panel

In line with the study objectives, an international expert panel was established for the identification and the evaluation of the importance of the different pain dimensions for

Table 1
Assessment Tools

	First Author, Year	Pain Dimensions	Pain Items	Unidimensional
Pain Tools				
24-hour Migraine Quality-of-Life Questionnaire (MQoLQ)	Hartmaier, 1995[26]	Aff, Bel, Inf, Int	15	
Aberdeen Low Back Pain Scale (AB)	Ruta, 1994[27]	Loc, Inf,Int, Rel, Temp	16	
Back Pain Function Scale (BPFS)	Stratford, 2000[28]	Inf	12	X
Borg Category-Ratio 10 Pain Scale (CR10)	Borg, 1998[29]	Int (but depends on wording)	1	X
*Brief Pain Diary for ambulatory cancer care (BPD)	Maunsell, 2000[30]	Inf, Int, Treat	8	
Brief Pain Inventory (BPI)	Cleeland, 1991[10,24]	Bel, Hist, Int, Inf, Loc, Qual, Rel, Treat	49	
*Brief Pain Inventory short form (BPI-sf)	Cleeland, 1991[9,10]	Int, Loc, Inf, Treat (Qual)	15	
Cervical Spine Outcome Questionnaire (CSOQ)	BenDebba, 2002[31]	Inf, Int, Loc, Treat (Aff)	24 (Aff not counted)	
Cognitive Risk Profile (CRP)	DeGood, 2001[32]	Aff, Bel, Inf, Rel	About 58	
Colored Analogue Scale (CAS)	McGrath, 1996[33]	Int (but depends on wording)	1	X
Chronic Pain Coping Inventory (CPCI)	Jensen, 1995[34]	Bel, Treat	65	
Coping Strategies Questionnaire (CSQ)	Rosentiel, 1982[35]	Bel (Rel)	50	X
Dallas Pain Questionnaire (DPQ)	Lawlis, 1989[36]	Bel, Int, Inf	13	
Descriptor Differential Scale (DDS)	Gracely, 1988[37]	Int	12	X
*Faces Pain Scale (FAS)	Bieri, 1990[38]	Int	1	X
Graded Chronic Pain Scale (GCPS)	Von Korff, 1992[39]	Inf, Int	7	
Headache Disability Inventory (HDI)	Jacobson, 1994[40]	Bel, Aff and/or Inf	25	
Initial Pain Assessment Tool (IPAT)	McCaffrey, 1989[41]	Inf, Int, Loc, Qual, Temp	18	
Integrated Pain Score (IPS)	Tamburini, 1987[42]	Dur, Int	6	
Leeds assessment of neuropathic symptoms and signs (LANSS)	Bennett, 2001[43]	Qual, Temp	5	
Low Back Pain Rating scale (LBPR)	Manniche, 1994[44]	Bel, Inf, Int, Loc	21+ tests	
McGill Pain Questionnaire (MPQ)	Melzack, 1975[45,46]	Int, Loc, Qual, Temp	23	
*Short form McGill Pain Questionnaire (SF-MPQ)	Fishman, 1987[47]	Int, Qual	17	
*Memorial Pain Assessment Card (MPAC)	Fishman, 1987[47]	Int, Treat	3	
Migraine Disability Assessment Scale (MIDAS)	Stewart, 2000[48]	Dur, Inf, Int, Loc, Qual, Rel, Treat	20	
Multiperspective Multidimensional Pain Assessment Protocol (MMPAP)–Patient Scale	Rucker, 1996[49]	Aff, Dur, Inf, Temp (Bel)	8 (displayed in paper)	
Neck Pain and Disability Scale (NPAD)	Wheeler, 1999[50]	Aff, Inf, Int, Treat	20	
Neuropathic Pain Scale (NPS)	Galer, 1997[51]	Aff, Int, Qual, Temp	12	
*Numerical rating scales (NRS)	Example in Turk, 2001[52]	Int (but depends on wording)	1	X
Oswestry Disability Index 2 (OSW-2)	Cited in Roland, 2000[53]	Inf, Int (Rel)	10 (2 are different from OSW)	
Oswestry Low-Back Pain Disability Questionnaire (OSW)	Fairbank, 1980[54]	Hist, Inf, Int and/or Treat	10	
*Pain Assessment Questionnaire for a patient with advanced disease (PAQ) (guidelines for assessment)	Perron, 2001[2]	Bel, Dur, Hist, Inf, Int, Loc, Qual, Rel, Temp, Treat	14+ discussion topics on Aff, Bel, Inf Treat	

(Continued)

Table 1
Continued

	First Author, Year	Pain Dimensions	Pain Items	Unidimensional
Pain Beliefs Questionnaire (PBQ)	Edwards, 1992[55]	Bel, (Rel)	20	X
Pain Beliefs and Perceptions Inventory (PBAPI)	Williams, 1989[56]	Bel, Temp	16	X
Pain Catastrophizing Scale (PCS)	Sullivan, 1995[57]	Bel, (Aff)	13	X
Pain Disability Index (PDI)	Tait, 1987[58]	Inf	7	X
Pain and Impairment Relationship Scale (PAIRS)	Riley, 1988[59]	Bel, (Inf)	15	X
Pain Stages of Change Questionnaire (PSOCQ)	Kerns, 1997[60]	Bel	30	
Regional Pain Scale (RPS)	Wolfe, 2003[25]	Int, Loc	38	
Quebec Back Pain Disability Scale (QBPDS)	Kopec, 1996[61]	Inf	20	X
Roland-Morris Disability Questionnaire (RDQ)	Roland, 1983[62]	Inf, Temp, Rel	24	
Survey of Pain Attitudes (SOPA)	Jensen, 1987[63], 1996	Aff, Bel	57–82	
*Verbal Rating Scales (VRS)	Turk, 2001[52]	Int (but depends on wording)	1	X
*Visual Analogue Scales (VAS)	Example in Turk, 2001[52]	Int (but depends on wording)	1	X
*Wisconsin Brief Pain Questionnaire (WBPQ)	Daut, 1983[64]	Bel, Hist, Inf, Int, Loc, Qual, Treat	19	
Vanderbilt Pain Management Inventory (VPMI)	Brown, 1987[65]	Bel	18	X
West Haven-Yale Multidimensional Pain Inventory (MPI)	Kerns, 1985[66]	Aff, Bel, Inf, Int, Rel	34	
World Health Organization Quality of Life Assessment Instrument –Pain Module (WHQOL-Pain)	Mason, 2004[67]	Aff, Bel, Dur, Inf, Int, Loc, Temp, Treat	28	
General Symptom/HRQoL Tools				
Arthritis Impact Measurement Scale (AIMS)	Meenan, 1980[68]	Int and/or Temp, Qual, (Loc)	4 (+1 about morning stiffness)	
Assessment of Quality of Life Instrument (AQoL)	Hawthorne, 1999[69]	Int	1	X
Breast Cancer Treatment Outcomes Scale (BCTOS)	Stanton, 2001[70]	Int, (Aff)	3	X
Coping with Health, Injuries, and Problems Scale (CHIP)	Found in Hadjistavropoulos, 1999[71]	Unavailable	32	
Dartmouth COOP Functional Health Assessment Charts (COOP)	Presented in Nelson, 1996[72]	Int	1	X
*Edmonton Functional Assessment Tool-2 (EFAT-2)	Kaasa, 2001[73]	Inf	1	X
*Edmonton Symptom Assessment Scale (ESAS)	Bruera, 1991[74]	Int	1	X
*European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ-C30)	Aaronson, 1993[75]	Inf, Int	2	
EORTC Head and Neck Cancer Module QLQ-H&N37	Bjordal, 1994[76]	Int, Loc, Treat	4	
Euro QOL Group (EQ-5D)	Rabin, 2001[77]	Int	1	X
Expanded Prostate Cancer Index Composite (EPIC)	Wei, 2000[78]	Inf, Temp, Loc	5	
*Functional Assessment of Cancer Therapy Scale (FACT-G)	Cella, 1993[79]	Int	1	X
Functional Living Index-Cancer (FLIC)	Schipper, 1984[80]	Bel, Inf	2	
Fibromyalgia Impact Questionnaire (FIQ)	Burckhardt, 1991[81]	Inf, Int	2	
Head and Neck Cancer-Specific Quality of Life (HNQOL)	Terrell, 1997[82]	Aff, Loc, Treat	3	
Health Assessment Questionnaire (HAQ)	Fries, 1980[83]	Int	1	X
HRQoL Questionnaire for Advanced Prostate Cancer Patients (QAPC)	Cleary, 1995[84]	Inf, Int	4	
Health Utilities Index Mark 3 (HUI3)	Feeny, 1996[85]	Int (Inf)	1	X
Hospice Quality of Life Index (HQLI)	McMillan, 1994[86]	Treat	1	X

Tool	Reference	No.	Dimensions	
Illness Behavior Questionnaire (IBQ)	Pilowsky, 1984[87]	3	Bel, Int	X
M. D. Anderson Symptom Inventory (MDASI)	Cleeland, 2000[88]	1	Int	
Medical Outcome Study 116 item core set (MOS-116)	RAND, 2003[89]	15	Inf, Int, Temp	
Nottingham Health Profile (NHP)	Hunt, 1985[90]	8	Int, Temp, Rel	X
Pain and Distress Scale (PAD)	Zung, 1983[91]	1	Int	X
Palliative Care Outcome Scale (POS)	Hearn, 1999,[92] proxy and self-report	1	Inf (Aff)	X
Quality of Life Index (QLI)	Padilla, 1983[93]	1	Int	X
Rotterdam Symptom Checklist (RSCL)	Presented in de Haes, 1990[94]	4	Int, Loc	
*Medical Outcome Study 36-item short form health survey (SF36)	Ware, 1992[95]; McHomey, 1993[96]	2	Inf, Int	
Short Musculoskeletal Function Assessment Questionnaire (SMFA)	Swiontkowski, 1999[97]	2	Inf, Int	
Therapy Impact Questionnaire (TIQ)	Tamburini, 1992[98]	2	Int, (Loc, Int of headache)	X
Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)	Consky, 1994[99]	3	Dur, Inf, Int	
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	Bellamy, 1988[100]	5	Inf, (Int)	X

Treat = Effects of treatment, Aff = Pain affect, Bel = Pain beliefs, Dur = Duration, Hist = Pain history, Inf = Pain interference, Int = Pain intensity, Loc = Pain location, Qual = Pain quality, Rel = Pain relief—exacerbating/relieving factors, Temp = Temporal pattern.
Tools marked with * are from the systematic literature search. Tools are presented alphabetically.
Dimensions are placed in brackets when it is unclear if the dimension is assessed or not, or when it is only partly assessed.

palliative care pain assessment. This panel consisted of six physicians who are experienced pain and palliative care specialists in both clinical practice and research from five European countries and members of the EAPC Research Network. The expert panel was involved in two steps.

First, the identified pain dimensions were alphabetically listed and mailed to the experts together with an instruction sheet. They were asked to consider both clinical and research objectives combined, and to provide one rank of the dimensions for relevance and importance for pain assessment (clinical + research) in palliative care. The experts were instructed to add new dimensions if they considered any to be missing, and to delete those that they found inappropriate or unnecessary to assess in palliative care. Thus, the most important dimension was to be ranked as number one, the second most important as two, and so on. The overall importance of each dimension was calculated as the average of the expert rankings. Thus, the lowest total score signified the most important dimension. Dimensions that were deleted were all given the highest score for the purpose of analyses. The five top-ranked dimensions were retained for the next phase of this study.

Based on the experts' definitions and selection of pain dimensions, the first author assigned items to the appropriate dimensions. As the second expert task, the list with all the appropriate items assigned to the five highest-ranked dimensions was mailed to the experts. This time they were asked to evaluate the assignments, to move items to the appropriate dimension if they disagreed with our suggestions, and to delete items that they deemed inappropriate for palliative care.

Results

Literature Search

A total of 412 citations were retrieved from the systematic search, with 10 being duplicates. Examination of the titles and the abstracts identified 48 papers that met our inclusion criteria. The majority of the excluded studies failed to meet the criterion regarding advanced cancer patients receiving palliative care. The search disclosed 16 different tools for pain assessment

used in palliative care studies. The most popular pain assessment tool was the VAS, used in 21 (44%) of the included studies, followed by NRS with 8 (17%), and the MPQ and the BPI with 6 (13%) each (the tools that were found in the systematic literature search are marked with an * in Table 1).

The ad hoc search in the Ovid-MEDLINE databases resulted in a total of 18,021 hits as follows: *pain assessment* produced 919 hits, while *pain measurement* identified 17,102 papers. When the searches were limited according to our criteria, the numbers were reduced to 48 and 1,343, respectively. The full text limitation that was applied to this search only, reduced the number of hits in the ad hoc search by 85%. After duplicates were deleted, 1,359 papers were eligible for this report. The BIBSYS search identified 100 books.

The entire literature search generated 80 different assessment tools containing at least one pain item. The tools were categorized into Pain Tools ($n = 48$) and General Symptom/HRQOL Tools ($n = 32$). The tools can be separated into those that assess pain with a unidimensional approach usually measuring pain intensity, and the multidimensional tools that include more than one pain dimension.

Among the 48 Pain Tools, 16 (33%) tools were unidimensional, and of 32 General Symptom/HRQOL Tools, 16 (50%) were unidimensional with regard to pain. The majority of the unidimensional tools (58%) were single-item scales such as VAS, Verbal Rating Scales (VRS), and NRS. Pain intensity was the most common dimension, targeted in 60% of the tools.

Forty-eight (60%) of the tools assessed pain multidimensionally. Sixty-seven percent of the Pain Tools were multidimensional, compared with 50% of the General Symptom/HRQOL tools. Of the multidimensional tools, 38% were two-dimensional. The most frequently appearing dimension was intensity, included in 75% of the multidimensional tools. Other frequently occurring dimensions were interference, location, and beliefs. These dimensions were particularly targeted by two kinds of specialized tools: disease-specific tools (with a majority of low back Pain Tools), and tools that measure pain affect, beliefs, and coping-related issues in nonmalignant chronic pain patients.

Pain Dimensions and Items

The search identified 11 different pain dimensions (Table 1). These were, in alphabetical order: Effects of treatment, Pain affect, Pain beliefs, Pain duration, Pain history, Pain intensity, Pain interference with HRQOL, Pain location, Pain quality, Pain relief (exacerbating/relieving factors), and Temporal pattern (dimension descriptions are offered in Table 2). The three most frequently assessed dimensions were: intensity in 55 tools, interference in 37, and beliefs in 22, while duration and history were assessed in six and four tools, respectively.

The tools contained 1,011 pain items. There were 893 items in the Pain Tools (88%) and 118 items in the General Symptom/HRQOL Tools. Most items were formulated as statements or as questions followed by an NRS, VAS, or VRS.

Expert Panel Evaluation

The expert panel suggested that the dimensions for "pain relief (exacerbating/relieving factors)" and "effects of treatment" be collapsed into one dimension named *treatment and exacerbating/relieving factors*, after the initial suggestion of one expert and the approval by the others. The rationale was to make one dimension that includes all nontreatment and

Table 2
Pain Dimensions Ranked by Experts According to Importance for Pain Assessment in Palliative Care

	Pain Dimensions	Descriptions
1	Pain intensity	How much it hurts, sensory component
2	Temporal pattern	Pain fluctuations, variations in intensity and occurrence
3	Treatment and exacerbating/ relieving factors	Medical and nonmedical
4	Pain location	Where it hurts
5	Pain interference	How much components of HRQOL are reduced by pain
6	Pain quality	The specific physical sensation associated with the pain
7	Pain affect	Emotional component of pain, the unpleasantness and significance of pain
8	Pain duration	How long pain has lasted
9	Pain beliefs	Attitudes, coping strategies and beliefs about causes and consequences
10	Pain history	Previous pain experiences

treatment factors (medical and nonmedical) that influence pain. The experts thereby reduced the number of pain dimensions from 11 to 10 and ranked them, according to the perceived importance for pain assessment in palliative care (Table 2).

Pain intensity was rated as the most important dimension by four of the experts and as the second most important by the two others. All experts agreed that the first five dimensions were important for pain assessment in palliative care. The other five were ranked as less important. Furthermore, by at least one expert, each of the last five dimensions was regarded as not important enough to be assessed in palliative care patients, weighed against the assessment burden. No additional dimensions were suggested.

The item distribution for the five highest-ranked dimensions, according to the expert evaluation, is presented in Table 3. The experts rearranged three items from our original dimension assignment. All of these were moved from the intensity dimension to the treatment and exacerbating/relieving factors dimension, due to the focus on pain intensity after medication with painkillers. Four items, among them the item, "*My life is hardly worth living with all of this pain*,"[32] were deleted because they were regarded by at least one expert as inappropriate (unnecessarily offensive) for use in palliative care.

Pain intensity items could be categorized into two groups: statements about pain and questions about pain. The statements include descriptions of pain sensations, experiences of intensity level, and items relating intensity to the need for analgesics. The intensity questions approached pain intensity in four ways (according to the tool constructors dimension definitions): suffering caused by pain, intensity of the pain, dependency on analgesics, and how bad pain has been. Most tools did not include "intensity" in the wording of the item. The majority asked about *pain*, when addressing *pain intensity*.

Tool Content Compared to Expert Recommendations

Three of the reviewed tools covered all of the five highest-ranked dimensions: the Aberdeen Low Back Pain Scale (AB),[27] the World Health Organization Quality of Life Assessment Tool-Pain Module (WHQOL-Pain),[68] and the Pain Assessment Questionnaire for a patient with advanced disease (PAQ).[2] The latter is not an ordinary questionnaire, but a pain assessment protocol based on the guidelines presented in *Management of Cancer Pain: Clinical Practice Guidelines*. The dimensions for pain quality, beliefs, and pain history (ranked 6, 9, and 10, Table 2) were also covered by the PAQ guidelines. The WHQOL-Pain tool included pain affect, duration, and beliefs (respectively ranked 7, 8, and 9), in addition to the five that were recommended.

Discussion

A number of different tools for pain assessment is available. Pain is a complex phenomenon, however, and evaluation of the content of the existing tools revealed great diversity of dimensions and items. This variety might affect the validity of pain assessment in general. It also makes comparisons between studies difficult,[3,12] as recently noted in two Cochrane reviews that concluded that meta-analyses were impossible to perform due to the use of different pain assessment tools.[101,102] Among the studies that were included in the systematic review, the VAS was the most frequently used

Table 3
Number of Items per Dimension

	Intensity	Temporal pattern	Treatment	Location	Interference
Pain tools	103	18	67	76	206
General symptom/HRQOL tools	35	11	18	17	25
Total	138	29	85	93	231

Items that measure several dimensions are counted once for each dimension. Example: the RPS instructs the patients to rate intensity for a list of joints and body parts. All 38 items are counted as one item on intensity and one on location. Items in dimensions in brackets (Table 1) were counted when summarizing the total item number.

(44%). According to two recent reviews on pain assessment,[8,12] this is suboptimal.

Ten pain dimensions were identified and confirmed by the expert panel. The expert panel regarded five dimensions as appropriate for comprehensive pain assessment in both palliative care practice and research. Although these five were considered optimal, the present results do not state that all five dimensions should be included in all situations. The response burden must be weighed against the need for information, as emphasized in the EAPC review.[8] Intensity was ranked as the most important dimension, in line with results from the literature. Thus, it should be included in most assessments. The subsequent four dimensions are recommended for comprehensive assessment, but optional. Temporal pattern was regarded as the second most important dimension. However, only 16% of the tools assessed this dimension, providing the lowest number of items (29 items, Table 3). A recent review supports this lack of focus by demonstrating that fewer than 2% of the cancer pain tools measured temporal aspects of pain.[12] Temporal patterns are of special interest for palliative care, because of high prevalence of breakthrough pain.[103] As most tools were developed for other patient populations, this may explain why temporal aspects were omitted. The five dimensions that were recommended by the expert panel are covered by three tools only. The AB includes the suggested dimensions, and contains items that may be suitable if the word "back" is removed. The WHQOL-Pain includes the essential dimensions with 149 items covering both pain and other issues of HRQOL (+ items about background information), but is too lengthy for use in palliative care. The PAQ covers the recommended content, as well as additional dimensions, but in its present form it is just an assessment guide and not a tool.[2] Assessment in palliative care should be guided by a fine line between the need for full information and the patients' limited capacity for providing it. Tool brevity is of great importance for valid and usable assessment. Many tools include dimensions of limited relevance to patients with advanced disease. Patients with advanced cancer are the target group for only a few of the multidimensional Pain Tools, such as the Brief Pain Diary (BPD),[30] the BPI-sf, and the PAQ. The BPD and the BPI-sf are not as comprehensive as

recommended by the experts and the PAQ needs further development. Many General Symptom/HRQOL tools contain only one or two pain dimensions and the number of items is too few to provide comprehensive pain information (Table 1). Consequently, they are inadequate as stand-alone pain tools. In addition, as many as 38% of the multidimensional tools are only two-dimensional, and do not allow for comprehensive pain assessment. At the moment there is no suitable pain assessment tool that covers the most important dimensions for pain assessment in palliative care patients according to the experts' recommendations.

Among the 1,011 items, there is great overlap, often with minor wording differences across tools. One example is that most disease-specific tools ask about pain intensity in all the areas of interest, leading to a large number of items relating to intensity in different body parts (Table 3). The finding that most tools only ask about pain when assessing intensity might highlight a problem. Multidimensional tools, asking about pain interference with functions, pain quality, and temporal pattern, suddenly shift to a plain "how bad is your pain" item. Such wording might confuse the patients to summarize the total pain or to give pain affect information instead of rating intensity.

We recognize some limitations in this study. Due to the vast number of publications in the field, certain limitations were applied to the literature searches. Consequently, some assessment tools have been missed. The literature search aimed at covering the range of different pain dimensions and items with specific focus on their content rather than identifying all existing pain tools. We believe this strategy identified a sufficient number of relevant tools for the purpose of content evaluation. It was challenging to distinguish the different dimensions, as some were overlapping and strongly associated with each other. However, the intention of this study was to give an overview of the content of pain tools, not to provide an examination of their psychometric properties. Some dimension assignments might, therefore, be debatable. Only physicians participated in the expert panel and this may limit the generalizability of the results. However, nurses, psychologists, and physiotherapists evaluated the process and they reviewed and approved the

results from the expert panel. The rationale behind this choice of experts was that we wanted an evaluation of the content that was directly based on experience from palliative care clinical work and palliative care research. Thus, within the EAPC research network, physicians experienced in both the clinic and research were asked to participate.

In conclusion, a large number of pain assessment tools exist, but there is no agreement on what they should assess. This study offers an original recommendation on the appropriateness of the content for pain assessment in palliative care. It is our opinion that there is a need to improve and/or develop an international standard for pain assessment in palliative care in the clinic and in research. A consensus on these matters might make future meta-analyses possible. The ideal assessment tool for patients in palliative care should be precise (high validity and reliability) and short. It should be flexible in such a way that it could be used in different patient populations and various situations, for example, by assessing different combinations of dimensions. These aims can probably be achieved most efficiently by using dynamic computerized tools[104,105] rather than paper-based questionnaires. Such tools can also be integrated with other electronic data from the hospital's database and thereby be suitable for use both in the clinic and in research.

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Paper II

Paper III

Paper IV

BMC Geriatrics

Doloplus-2, a valid tool for behavioural pain assessment?

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Abstract

Background: The Doloplus-2 is used for behavioural pain assessment in cognitively impaired patients. Little data exists on the psychometric properties of the Doloplus-2. Our objectives were to test the criterion validity and inter-rater reliability of the Doloplus-2, and to explore a design for validations of behavioural pain assessment tools.

Methods: Fifty-one nursing home patients and 22 patients admitted to a geriatric hospital ward were included. All were cognitively impaired and unable to self-report pain. Each patient was examined by an expert in pain evaluation and treatment, who rated the pain on a numerical rating scale. The ratings were based on information from the medical record, reports from nurses and patients (if possible) about pain during the past 24 hours, and a clinical examination. These ratings were used as pain criterion. The Doloplus-2 was administered by the attending nurse. Regression analyses were used to estimate the ability of the Doloplus-2 to explain the expert's ratings. The inter-rater reliability of the Doloplus-2 was evaluated in 16 patients by comparing the ratings of two nurses administrating the Doloplus-2.

Results: There was no association between the Doloplus-2 and the expert's pain ratings (R^2 = 0.02). There was an association (R^2 = 0.54) between the expert's ratings and the Doloplus-2 scores in a subgroup of 16 patients assessed by a geriatric expert nurse (the most experienced Doloplus-2 administrator). The inter-rater reliability between the Doloplus-2 administrators assessed by the intra-class coefficient was 0.77. The pain expert's ratings were compared with ratings of two independent geriatricians in a sub sample of 15, and were found satisfactory (intra-class correlation 0.74).

Conclusion: It was challenging to conduct such a study in patients with cognitive impairment and the study has several limitations. The results do not support the validity of the Doloplus-2 in its present version and they indicate that it demands specific administration skills.

Background

Pain is common in elderly institutionalized patients, and prevalence rates ranging from 45% to 84% have been reported [1,2]. Cognitive impairment is also common in the same group, and more than 50% of nursing home residents have been found to be cognitively impaired [3,4]. A recent review reported prevalence rates in palliative care patients ranging from 14% to 44%, rising to 90% prior to death [5].

Proper pain assessment is a prerequisite for optimal pain treatment [6], but pain assessment is challenging in cognitively impaired patients. Pain is therefore often overlooked in these patients [3,7-10], leaving them at risk for sub-optimal pain treatment [7,11,12]. When feasible, self-report assessment of pain is regarded as the standard method [9,13]. In patients with mild to moderate cognitive impairment, studies have reported completion rates ranging from 47% to 100% for simple self-report tools such as numerical rating scales and verbal rating scales [3,10]. Ratings of present pain intensity have the highest completion rates, while self-report of other pain dimensions, like location, interference and temporal patterns, is more challenging [10].

Cognitive impairment can make self-report tools for pain assessment invalid and consequently limits their usefulness. Observational assessment of behaviour is an alternative. While self-report tools primarily assess communicative pain behaviours that are under the subject's control, observational tools assess behaviours that are more unconscious or automatic [14]. Behavioural assessment tools are therefore appropriate in subjects with impaired higher mental processes. However, thoroughly validated tools for behavioural assessment are scarce [10,15], and several reviewers have noted the lack of validation of the tools for behavioural pain ratings in the cognitively impaired [2,7,10,15-17]. Although data are limited, a recent review rated the psychometric aspects of 12 behavioural assessment tools according to several quality judgement criteria. Five tools (in English versions) received a satisfactory evaluation of validity and reliability [17]: the Abbey Scale [18], the Pain Assessment for the Dementing Elderly (PADE) [19], the Pain Assessment in Advanced Dementia Scale (PAINAD) [20], the Pain Assessment Checklist for Seniors With Limited Ability to Communicate (PACSLAC) [21], and the Doloplus-2 [22]. The review concluded by recommending the PACSLAC and the Doloplus-2, stating that they seem promising but required further testing [17].

The Doloplus, launched by Bernard Wary in 1992/93, was originally a 15-item clinical tool for proxy rating of pain in elderly patients with cognitive failure [22,23]. It was based on a tool for behavioural assessment of pain in children with neoplastic disease (Douleur Enfant Gustave Roussy scale) [22,23]. In 1995, the Doloplus was refined by a French/Swiss network of geriatricians, resulting in the present ten-item version (Doloplus-2 [22]). A Doloplus-2 assessment is performed by a proxy-rater who observes the subject and evaluates the presence of ten pain-related behaviours from 0 to 3 – representing increasing presence of the behaviour [22,24]. These include: verbal complaints, facial expressions, protective body postures, protection of sore areas, disturbed sleep, functional impairment in activities of daily living (washing and dressing, and general mobility), psychosocial reactions such as behavioural problems, and changes in communication or social life. Authors of the Doloplus-2 suggest a cut-off score of 5 out of 30, representing possible pain being present [22,23], but this has not been empirically validated.

Despite a shortage of validation studies published in international journals and despite a call for thorough validation [25], including information on inter-rater reliability [17], the French version of the Doloplus-2 is in widespread clinical use in France and Switzerland [23]. This prompted us to undertake a Norwegian pilot validation study in 2004, in which we evaluated 59 patients who were institutionalized in nursing home units for the demented [24]. While well established protocols are available for the validation of self-report based assessment tools there is no consensus on how to validate tools for observational assessment. The objective of this pilot study was to translate the Doloplus-2 from French into Norwegian, to test the translation, explore the user-experiences, and evaluate the criterion validity of the Doloplus-2. The aim was to test the Doloplus-2 in patients who were unable to self-report and therefore we compared nurses' Doloplus-2 scores to pain scores (pain criterion) given by pain experts who examined these patients ($R^2 = 62\%$). The results demonstrated satisfactory criterion validity in some domains. The Doloplus-2 item for *facial expressions* was the most informative, while the item for *social life* contributed least. All the three items forming the psychosocial domain (Communication, Social life, and Behavioural problems) were reported as problematic to conceptualize and contributed marginally to explain the expert pain score [24]. These results were supported by a recent study that evaluated the psychometric properties of the Doloplus-2, and two other tools for behavioural pain assessment, by comparing observer based pain scores from two independent raters [26]. This study found low congruent validity in the Doloplus-2, it questioned the validity of the psychosocial domain, and its clinical usefulness was evaluated as moderate by the participating nurses. The authors acknowledged that the study design was less adequate for exploring the psychometric properties of the Dololplus-2 compared to the other tools and they requested more

studies on the validity and intra- and inter-reliability of the Doloplus-2 [26].

Based on the previous results and our experiences with the use of a pain expert as a criterion for pain, a new study was launched in order to further study the psychometric performance of the Doloplus-2. The objectives of the present study were to:

1. Assess the criterion validity of the Doloplus-2 in patients who are unable to self-report pain due to cognitive failure.

2. Test the inter-rater reliability of a pain expert's ratings (used as criterion).

3. Evaluate the inter-rater reliability of the Doloplus-2 by comparing the results from different and independent administrators.

Methods
Subjects
The subjects were a convenience sample of 73 consecutively recruited patients from two nursing homes (N = 51) and from the Section of Geriatrics at St. Olav's University Hospital (N = 22) in Trondheim, Norway. As previous publications had demonstrated pain to be prevalent in regular nursing homes and in geriatric hospital units [3,27], these were approached under the assumption that painful somatic conditions would be prevalent. The patients should be unable to self-report pain due to cognitive impairment based upon the nurses' clinical evaluation of the patients. Pain was defined as and limited to somatic pain, i.e. a symptom generally relieved by analgesics, and consequently excluding what the pain expert interpreted as existential pain.

Baseline characteristics
Cognitive function was assessed by the Mini Mental State Examination (MMSE) [28,29] administered by either a ward nurse or a medical student. The MMSE rates the level of cognitive function on a scale from 0–30. Patients with scores from 30-21 are regarded as normal to mildly cognitively impaired, scores from 20-11 denote moderate cognitive impairment, and patients scoring 10-0 are severely cognitively impaired [30]. The MMSE was performed within the same week as the main data collection. At one nursing home ward the MMSE was performed within a month (N = 10). Due to the patients' stabile conditions this was regarded as appropriate. Ability to perform activities of daily living (ADL) was evaluated by a nurse familiar with the patient, using the Barthel Index [31]. This tool describes the ability to perform ADL on a scale from 0–20. Barthel index scores from 20-15 indicate independence to mildly disabled ADL function, 14-10 indicate moderate

disability, while a score of 9-0 indicate that the patient is severely to very severely disabled [32]. The Barthel Index was completed within a week of the Doloplus-2. The MMSE and Barthel Index measures were used to provide a baseline characteristic of the patients' status. Information regarding patients' use of analgesics was not recorded. Because our aim was to test if the Doloplus-2 could assess pain in those who experienced pain, it was not regarded necessary to know if a low level of pain behaviours were caused by adequate treatment or lack of pain.

Criterion validity of the Doloplus-2
The Doloplus-2 [22,24] is composed of ten items distributed on three domains: somatic, psychomotor and psychosocial. The somatic domain has five items, while the psychomotor and psychosocial domains have two and three items, respectively. Each item has four response alternatives, and is scored 0 for normal behaviour, through to 3 for high levels of pain-related behaviour. Thus the total Doloplus-2 score ranges from 0–30.

The Doloplus-2 was administered by trained enrolled nurses, or registered nurses who were familiar with the patient. The attending daytime nurse completed the Doloplus-2 registration after consulting with the other personnel who had been involved with the patient during the past 24 hour period. Pain in the Doloplus-2 was registered according to the instructions for Doloplus-2 and recorded once for each patient, usually between noon and 3 p.m. [22].

In line with psychiatric methods for observational assessment and diagnoses in cases where an objective measure is inaccessible a clinical expert statement was used as the criterion for pain [33-35]. A pain specialist nurse (pain expert) from the National Centre of Expertise for Pain and Complex Disorders at St. Olav's University Hospital of Trondheim made a single evaluation of each patient's pain level on an eleven point Numerical Rating Scale (NRS-11) from zero (no pain) to ten (worst imaginable pain). Each patient was ascribed two pain intensity scores, one for pain in movement and one for pain at rest. These scores were used as the pain criterion. The pain evaluation was performed the same day as the Doloplus-2 assessment, usually between noon and 4 p.m. The expert's evaluation made use of information from the medical record, reports from nurses and patients (if possible) about pain during the past 24 hours, and a clinical examination. The clinical examination comprised observation of the patient during rest and activity, and examination of common trigger points for pain. Both the expert's pain score and the nurses' Doloplus-2 scores were based upon the same time interval and all assessors had access to information about the patient's medical condition during the past 24 hours.

The expert was blinded from the Doloplus-2 administrators' assessment, and vice versa.

As a validation of the evaluations performed by the pain expert, two geriatricians with expertise in pain presentation in demented patients observed the pain expert while he evaluated 15 consecutive patients. Without discussing the patients with the pain expert, the two geriatricians independently rated the patients' pain using NRS-11. Their ratings were later examined for degree of association with the expert's ratings.

Inter-rater reliability
Inter-rater reliability of the Doloplus-2 was assessed in 16 patients consecutively included at the Section of Geriatrics at St Olav's University Hospital. A geriatric specialist nurse (GN) and an enrolled nurse evaluated each patient at the same day and blinded from each other. The GN assessed all patients, while a team of six different enrolled nurses made the second assessment.

See Figure 1 for overview of the study procedure.

Analyses
Univariate regression analyses were performed in order to analyse how well the Doloplus-2 predicted the expert pain score (R-squared), and to analyse the contributions of each of the ten items. Since the Doloplus-2 score maximizes pain by adding the scores of all items, we chose to compare with the highest of the pain expert's scores. The pain-in-movement score was higher than the pain-at-rest score in all patients and consequently used as the pain criterion.

Association between the expert's pain ratings and the two geriatricians' ratings and the inter-rater reliability of the Doloplus-2 were evaluated with intra-class correlation coefficients. All analyses were performed by the SPSS statistical software version 13.0 (SPSS Inc., Chicago, USA).

Ethics
The Regional Committee for Medical Research Ethics approved the study. As recommended by the committee, written informed consent was not obtained from the patients due to their cognitive impairment. Instead, the patient's nearest relative was informed, both in writing and orally, and asked to give consent. Eligible patients were informed orally and asked if they would participate before the administration of the MMSE and the pain expert evaluation. Patients were not to be included if they or their relative declined participation, but no one did.

The constructors of the Doloplus-2 have approved our use of the tool.

Results
Baseline characteristics
Seventy-three patients were approached and all were included. The mean age of the sample was 84 years (Table 1), and 74% were female. The median MMSE score was 10 (Table 1). Two subjects died before the MMSE assessment, and seven were not assessed as they moved to another nursing home before the MMSE assessment. These patients were included in the pain analyses, but excluded from the MMSE calculations. The Barthel Index scores had a median value of 9 (Table 1).
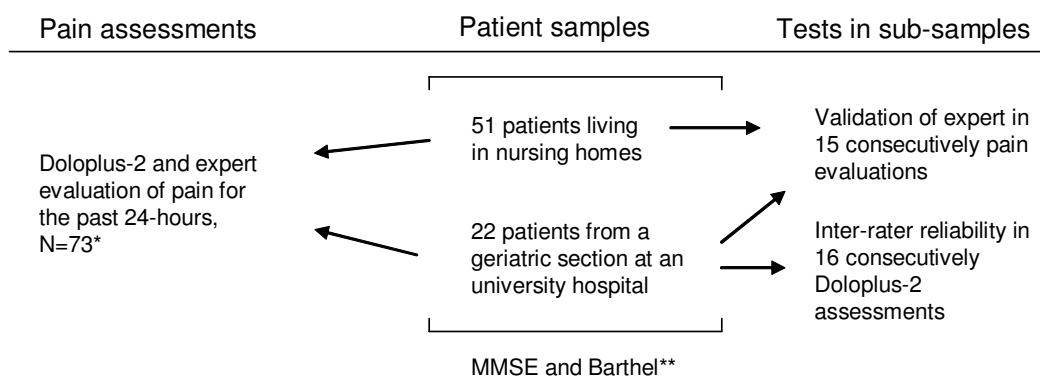
Figure 1
Study procedure. *Performed the same day, usually performed between noon – 3 p.m. **The MMSE and Barthel were performed within the same week as the pain assessments except from ten MMSE that was performed within a month.

Table 1: Distribution frequencies of background variables

Age (mean 84)		Numbers (N = 73)
	69–79 years	19 (26%)
	80–90 years	37 (51%)
	> 90 years	17 (23%)
MMSE-Score (median 10)*		
Severely cognitively impaired (CI)	0–10	32 (50%)
Moderately CI	11–20	23 (36%)
Mildly CI to normal	21–30	9 (14%)
Barthel Index-Score (median 9)		
Very severely to severely disabled	0–9	41 (56%)
Moderately disabled	10–14	18 (25%)
Mildly disabled to independent in ADL	15–20	14 (19%)

*9-missing

Validity of the Doloplus-2

The expert rated seven patients ≥ 4 for pain-in-movement (moderate-to-severe pain), 40 were rated 1–3, and 26 were rated as without pain. In all patients, the pain-in-movement score was equal to or higher than the pain-at-rest score. The association between the pain expert's ratings and the two geriatricians' ratings (N = 15) was estimated with an intra-class correlation of 0.74 with a 95% confidence interval from 0.5 to 0.89.

The mean Doloplus-2 score was 7.47 (SD = 5.08) with a range from 0–22. Five patients received a Doloplus-2 score of zero. Among these, three were also rated with no pain by the expert, while the other two received a score of zero at rest and two in movement.

The regression analysis of the Doloplus-2 scores against the expert scores produced an R^2 of 0.023, implying poor criterion validity of the Doloplus-2 in this data set (Figure 2).

To explore the data more closely we analysed each study site separately. No significant results were obtained while looking at the complete data from the three sites; however, association was found between the pain expert and the geriatric expert nurse (GN) who administered the Doloplus-2 in 16 patients in the Section of Geriatrics, with an R^2 of 0.54.

Univariate regression analyses of the different Doloplus-2 items (full sample) showed small but significant relationships between the Doloplus-2 item for *protective body pos-*

tures at rest and the expert's pain-in-movement score (R^2 = 0.12, p = 0.003) and for the Doloplus-2 item *pain complaints* and the expert's pain-at-rest score (R^2 = 0.13, p = 0.002).

Inter-rater reliability

The intra-class correlation for inter-rater reliability of the Doloplus-2 administrators was 0.77, with a 95% confidence interval of 0.47 – 0.92.

Discussion

Herr *et al.* (2004) called for extensive testing of the Doloplus-2 to provide sufficient details on which to base sound judgment of the tool, and a recent review questioned both the specificity of the Doloplus-2 and the nurses' competence for scoring and interpreting the results [17]. The present study failed to confirm a valid relationship between the expert's ratings of pain and the Doloplus-2 scores in a sample of 73 cognitively impaired patients, even though the inter-rater reliability of the Doloplus-2 seemed to be satisfactory. These results differ from those of our previous pilot validation study [24], in which acceptable criterion validity was demonstrated when comparing Doloplus-2 against expert ratings.

We acknowledge several limitations in the present study. The samples sizes were small as indicated by the confidence intervals for the inter-rater analyses and the majority of the subjects were female (74%). Use of analgesics was not recorded. Analgesic efficacy might fluctuate throughout the day and information on the use of analgesics could have provided valuable baseline information. However, since all patients were evaluated on the basis of the full 24-hour period any potential bias from analgesics should be equivalent in both the expert and in the Doloplus-2 assessments.

The use of a pain expert's rating as a pain criterion is disputable as it may be questioned whether this represents a valid criterion. In line with psychiatric methodology for cases where no obvious gold standard exists, we used an expert-evaluation of the patients as the pain criterion. We tested the expert's performance in a sub-sample (N = 15) and found satisfactory inter-rater reliability between the expert and the two geriatricians. The low end of the confidence interval for the inter-rater reliability indicates that despite the small sample size of 15 evaluations the agreement is satisfactory.

It is probably an advantage for an expert-rater to know the patients. In the pilot study, the physicians responsible for the patients' treatment acted as the expert [24]. It is possible that the lack of association between Doloplus-2 and the expert's rating in the present study may partly be due to the use of an external pain expert who was unfamiliar
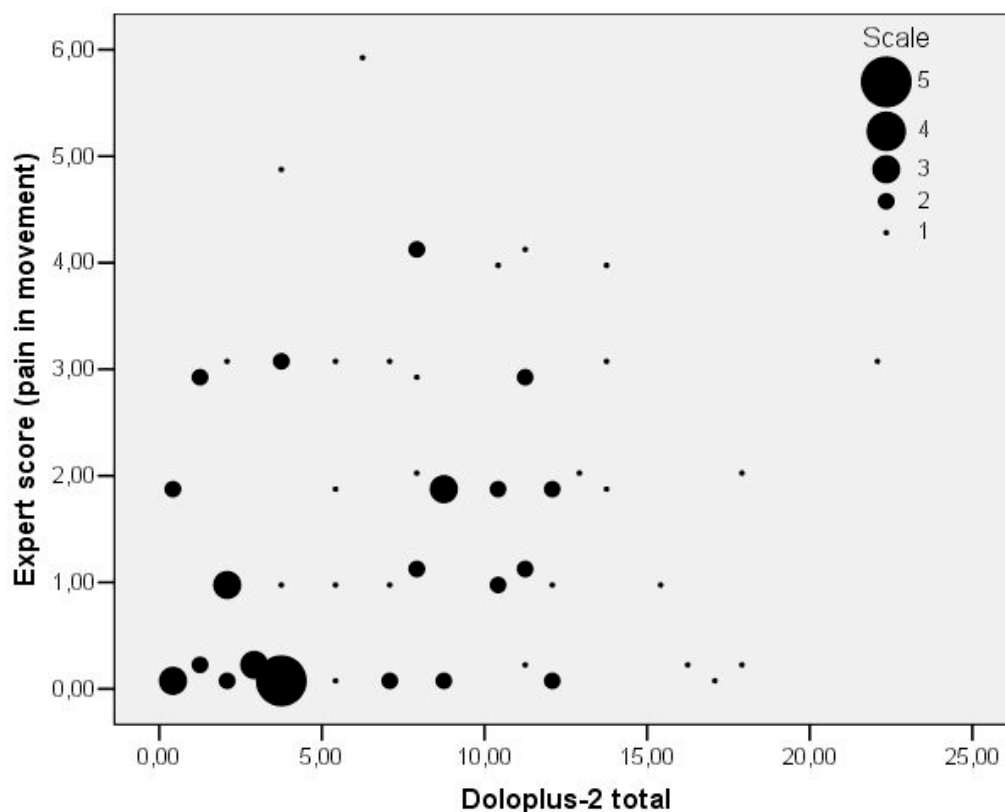
Figure 2
The relationship between expert ratings and Doloplus-2. The scatter plot demonstrates the relationship between the expert's pain score (NRS-11) and the Doloplus-2 score (0–30) in all 73 patients.

with the patients instead of one who was familiar with the patients and the staff. The expert evaluated the presence of pain at rest and in movement. The Doloplus-2 does not distinguish between rest and movement, but adds all scores together. We decided to use the higher obtained of the two expert scores. This was without exception the pain-in-movement score. We do not suggest that the Doloplus-2 is designed to measure only pain in movement, but we believe that the expert's pain-in-movement score is the best indicator of pain in these patients.

Five patients were rated with a Doloplus-2 score of zero, as opposed to 26 in the expert's ratings. In order to discuss the discrepancy between Doloplus-2 and expert score, the pain expert, the GN and the Doloplus-2 administrators at one nursing home were consulted. It was impossible to

know whether the pain expert identified false negative pain cases or whether the Doloplus-2 identified false positives. A general conclusion was that Doloplus-2 assessment in many of these patients was perceived as difficult. In patients who had high Doloplus-2 scores and low expert scores, clinical examinations revealed that the patients' discomfort seemed frequently related to grief, depression, anxiety and/or agitation rather than to somatic pain. This might suggest that the Doloplus-2 identifies patients with pain who may not have somatic pain (i.e. false positives), on the other side we can not out rule that this is a result from the pain expert underrating pain. The Doloplus-2 administrators were instructed to give positive scores on items only if changes in behaviour were suspected to be pain-related. In practice however, they were not able to evaluate this. As a result, they may

have given positive scores on behavioural changes probably related to other causes than pain. This illustrates some well-known difficulties in pain assessment among patients with Behavioural and Psychological Symptoms of Dementia (BPSD) who are not able to describe their problems thoroughly and who may also have atypical symptom presentation [17,36]. The expert performed a comprehensive evaluation of the patient, but his pain ratings focused on what he judged as somatic pain intensity. The Doloplus-2 approaches pain multidimensional and this difference can partly explain some of the disagreement between expert and Doloplus-2. A concern for the validity of the expert judgments could be the use of patient charts information to inform their judgments. Presumably, this would allow access to information about physical pathology. There is only a marginal correlation between physical pathology and self-report of pain in people able to self-report. Inferring pain from this information can be questionable. However, the pain expert has several years experience from work at the National Centre of Expertise for Pain and Complex Disorders at St. Olav's University Hospital of Trondheim. A majority of the patients coming to this clinic has pain that does not have an identifiable basis in physical pathology. In the study design we wanted to give the expert access to all available information to minimize the chances of underestimating pain. He evaluated the different sources of information towards each other and we are confident in that he did not underrate pain due to lack of information on physical pathology in the charts. Instead, it may strengthen the expert evaluation that the expert was informed about the patients' diagnoses of possible painful chronic conditions.

Analyses indicated that competence in geriatrics improved the validity of the Doloplus-2 assessment. The Doloplus-2 scores had higher correlations with the expert's pain ratings in a small sub-group in which the Doloplus-2 was administered by a specialist GN. This finding was in concordance with the pilot study, where the Doloplus-2 administrators had higher skills than the administrators in the present study, as all assessments were made jointly by an enrolled nurse/registered nurse in cooperation with a fully trained final-year medical student [24]. Thus, it may be hypothesized that valid Doloplus-2 administration and interpretation demand training in geriatrics and knowledge of pain presentation in cognitively impaired patients. Analyses of the sub-group with the GN resulted in a similar pattern of items contributing in explaining the expert's pain score to that found in the pilot study [24]. The items for complaints, disturbed sleep, functionality during washing/dressing, and facial expressions explained most of the expert score, while the three psychosocial items explained close to nothing. The Doloplus-2 was originally developed for pain assessment in children and

the inclusion of the psychosocial items may come from this origin. Based on results from Zwakhalen et al. (2007) and our two studies we suggest that the psychosocial domain could be removed from the Doloplus-2.

Some of the patients could provide limited information about pain at the moment and this was demonstrated during the expert's clinical examination and during the morning sessions, while the nurses wash and dress the patients, which caused some patients to express pain complaints, which then again lead to positive expert pain score and positive score on the Doloplus-2 item about pain complaints. The subjects' self-report was consequently taken into account when it was available. Future studies could try a simple verbal rating scale for self-report of pain intensity in some patients and use this in a combination with other criterions.

Reports have shown that pain is frequent, under-recognised and under-treated in nursing homes. Therefore we approached patients at regular nursing home units and at a geriatric department in order to include patients with higher levels of pain than in the pilot study [24]. As expected the MMSE scores and the Barthel Index demonstrated that the study population was cognitively impaired and dependent on care. However, unexpectedly it turned out that the sample had lower average levels of pain, as rated by the experts than, the sample in the pilot study. Low levels of pain have surprised other researchers in the field [36]. Thus, the present study also failed to provide data about the performance of Doloplus-2 in patients with severe pain.

To validate a tool is a long process and solid conclusions regarding the validity of the Doloplus-2 cannot be reached on the basis of our two studies. Through our studies we have established some experience in the design of studies for such validations. Future studies should include some patients with known painful diagnoses like patients with post operative hip-fractures. It will also be most valuable to have more than one pain criterion to test for agreement, in those where self-report is invalid. Pain experts could be used to establish a criterion. The use of more than one expert, blinded or unblinded, in each patient will strengthen the study. Test treatment with analgesics in patients with suspected pain and use of other behavioural tools and a verbal rating scale for present pain intensity may be valuable amendments.

The lack of agreement between expert and Doloplus-2 might reflect a common challenge for pain measurement in cognitively impaired by the use of behavioural assessment tools. Other tools recommended for use in these patients Abbey Scale [18], PADE [19], PAINAD [20], and PACSLAC [21] have obvious similarities to the Doloplus-

2. All tools cover facial expressions, abnormalities in body postures/movements like guarding sore areas, impaired movement and verbal expressions. These tools are constructed for administration by health care providers, but to our knowledge none of them claim any criteria with regard to the administrators' competence. All tools include domains that are not only affected by pain. The inclusion of BPSD increases the pain sensitivity in these tools, but the specificity decreases. The consequence may be that comprehensive training of administrators and high administration skills is needed. The brief Checklist of Nonverbal Pain Indicators (CNPI) [37] is another interesting behavioural pain assessment tool, as it covers those parts of the Doloplus-2 that performed most successfully in our studies, but it needs further validation [17]. The CNPI may be an alternative that should be thoroughly tested before finally judged.

Conclusion

Based on the results from our two studies combined, we recommend the use of more than one pain criterion. Pain experts can be used as one of these, especially in patients that have no or limited ability to self-report. A combination of pain experts, other behavioral pain assessment tools, a verbal rating scale for self-report of present pain intensity and test-treatment with analgesics could constitute a promising pain criterion in future studies. The present study does not support the criterion validity of the Doloplus-2 as a clinical pain assessment tool in its present version. The results indicate that there seems to be a need for systematic training of the administrators before the instrument can be of clinical use.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

JCH, IS, PMF and SK contributed to the design of this study. JCH and IS organized and performed the data-collection. JCH, PMF and JHL performed the statistical analysis. All authors participated in interpretation of the data, drafting the manuscript and all read and approved the final manuscript.

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7. Appendices

1. Barthel index

2. Brief pain inventory

3. Doloplus-2

4. EORTC QLQ-C30

5. Karnofsky performance status scale

6. Mini mental status exam

7. NRS for pain assessment by pain experts in study III and IV

8. Questionnaire for debriefing of Doloplus-2 administrators in study III

Barthel's index of activities of daily living (BAI)

1. Bowel status (Question 1 of 10)

> 0 points - Incontinent (or needs to be given enema)
> 1 point - Occasional accident (once a week)
> 2 points - Fully Continent

2. Bladder status (Question 2 of 10)

> 0 points - Incontinent or catheterized and unable to manage
> 1 point - Occasional accident (max once per 24 hours
> 2 points - Continent (for more than seven days)

3. Grooming (Question 3 of 10)

> 0 points - Needs help with personal care: face/ hair/ teeth / shaving
> 1 point - Independent (implements provided)

4. Toilet Use (Question 4 of 10)

> 0 points - Dependent
> 1 point - Needs some help but can do something alone
> 2 points - Independent (on and off/ wiping/ dressing)

5. Feeding (Question 5 of 10)

> 0 points - Unable
> 1 point - Needs help in cutting / spreading butter/ etc.
> 2 points - Independent (food provided within reach)

6. Transfer (Question 6 of 10)

> 0 points - Unable (as no sitting balance)
> 1 point - Major help (physical/ one or two people)
> 2 points - Can sit minor help (verbal or physical)
> 3 points - Independent

7. Mobility (Question 7 of 10)

> 0 points - Immobile
> 1 point - Wheelchair-independent (including corners etc)
> 2 points - Walks with help of one person (verbal or physical)
> 3 points - Independent

8. Dressing (Question 8 of 10)

> 0 points - Dependent
> 1 point - Needs help but can do about half unaided
> 2 points - Independent (including buttons/ zips/ laces/ etc.)

9. Stairs (Question 9 of 10)

> 0 points - Unable
> 1 point - Needs help (verbal/ physical/ carrying aid)
> 2 points - Independent up and down

10. Bathing (Question 10 of 10)

> 0 points - Dependent
> 1 point - Independent bathing or showering

Reset

Barthel Score (max 20):

Brief Pain Inventory (Short Form)

Date: _____/_____/_____   Time: _____

Name: _____   _____   _____
                Last   First   Middle Initial

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

        1.   Yes   2.   No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.
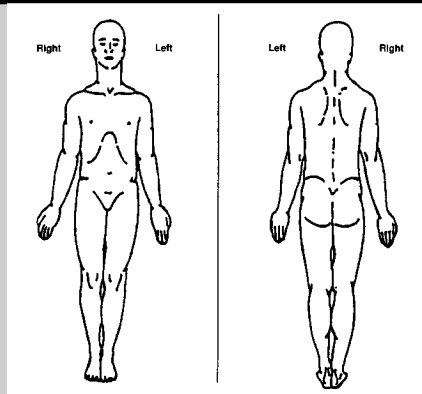
3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

DOLOPLUS-2 SCALE

BEHAVIOURAL PAIN ASSESSMENT IN THE ELDERLY

NAME : Christian Name : Unit :	DATES			
Behavioural Records				

SOMATIC REACTIONS

1• Somatic complaints	• no complaints	0	0	0	0
	• complaints expressed upon inquiry only	1	1	1	1
	• occasionnal involuntary complaints	2	2	2	2
	• continuous involontary complaints	3	3	3	3
2• Protective body postures adopted at rest	• no protective body posture	0	0	0	0
	• the patient occasionally avoids certain positions	1	1	1	1
	• protective postures continuously and effectively sought	2	2	2	2
	• protective postures continuously sought, without success	3	3	3	3
3• Protection of sore areas	• no protective action taken	0	0	0	0
	• protective actions attempted without interfering against any investigation or nursing	1	1	1	1
	• protective actions against any investigation or nursing	2	2	2	2
	• protective actions taken at rest, even when not approached	3	3	3	3
4• Expression	• usual expression	0	0	0	0
	• expression showing pain when approached	1	1	1	1
	• expression showing pain even without being approached	2	2	2	2
	• permanent and unusually blank look (voiceless,staring, looking blank)	3	3	3	3
5• Sleep pattern	• normal sleep	0	0	0	0
	• difficult to go to sleep	1	1	1	1
	• frequent waking (restlessness)	2	2	2	2
	• insomnia affecting waking times	3	3	3	3

PSYCHOMOTOR REACTIONS

6• washing &/or dressing	• usual abilities unaffected	0	0	0	0
	• usual abilities slightly affected (careful but thorough)	1	1	1	1
	• usual abilities highly impaired, washing &/or dressing is laborious and incomplete	2	2	2	2
	• washing &/or dressing rendered impossible as the patient resists any attempt	3	3	3	3
7• Mobility	• usual abilities & activities remain unaffected	0	0	0	0
	• usual activities are reduced (the patient avoids certain movements and reduces his/her walking distance) .	1	1	1	1
	• usual activities and abilities reduced (even with help, the patient cuts down on his/her movements)	2	2	2	2
	• any movement is impossible, the patient resists all persuasion	3	3	3	3

PSYCHOSOCIAL REACTIONS

8• Communication	• unchanged	0	0	0	0
	• heightened (the patient demands attention in an unusual manner)	1	1	1	1
	• lessened (the patient cuts him/herself off)	2	2	2	2
	• absence or refusal of any form of communication	3	3	3	3
9• Social life	• participates normally in every activity (meals, entertainment, therapy workshop)	0	0	0	0
	• participates in activities when asked to do so only	1	1	1	1
	• sometimes refuses to participate in any activity	2	2	2	2
	• refuses to participate in anything	3	3	3	3
10• Problems of behaviour	• normal behaviour	0	0	0	0
	• problems of repetitive reactive behaviour	1	1	1	1
	• problems of permanent reactive behaviour	2	2	2	2
	• permanent behaviour problems (without any external stimulus)	3	3	3	3

SCORE				

DOLOPLUS-2 SCALE : LEXICON

Somatic complaints
The patients expresses pain by word, gesture, cries, tears or moans.

Protective body postures adopted at rest
Unusual body positions intended to avoid or relieve pain.

Protection of sore areas
The patient protects one or several areas of his/her body by a defensive attitude or gestures.

Expression
The facial expression appears to express pain (grimaces, drawn, atonic) as does the gaze (fixed gaze, empty gaze, absent, tears).

Investigation
Any investigation whatsoever (approach of a caregiver, mobilization, care procedure, etc.).

Washing/dressing
Pain assessment during washing and/or dressing, alone or with assistance.

Mobility
Evaluation of pain in movement: change of position, transfer, walking alone or with assistance.

Communication
Verbal or non-verbal.

Social life
Meals, events, activities, therapeutic workshops, visits, etc.

Problems of behaviour
Aggressiveness, agitation, confusion, indifference, lapsing, regression, asking for euthanasia, etc.

DOLOPLUS-2 SCALE : INSTRUCTIONS FOR USE

1 • Scale use requires learning
As is the case with any new instrument, it is judicious to test it before circulating it. Scale scoring time decreases with experience (at most a few minutes). Where possible, it is of value to appoint a reference person in a given care structure.

2 • Pluridisciplinary team scoring
Irrespective of the health-care, social-care or home structure, scoring by several caregivers is preferable (physician, nurse, nursing assistant, etc.). At home, the family and other persons can contribute using a liaison notebook, telephone or even a bedside meeting. The scale should be included in the 'care' or 'liaison notebook' file.

3 • Do not score if the item is inappropriate
It is not necessary to have a response for all the items on the scale, particularly given an unknown patient on whom one does not yet have all the data, particularly at psychosocial level. Similarly, in the event of coma, scoring will be mainly based on the somatic items.

4 • Compile score kinetics
Re-assessment should be twice daily until the pain is sedated, then at longer intervals, depending on the situation. Compile score kinetics and show the kinetics on the care chart (like temperature or blood pressure). The scale will thus become an essential argument in the management of the symptom and in treatment initiation.

5 • Do not compare scores on different patients
Pain is a subjective and personal sensation and emotion. It is therefore of no value to compare scores between patients. Only the time course of the scores in a given patient is of interest.

6 • If in doubt, do not hesitate to conduct a test treatment with an appropriate analgesic
It is now accepted that a score greater than or equal to 5/30 is a sign of pain. However, for borderline scores, the patient should be given the benefit of the doubt. If the patient's behavior changes following analgesic administration, pain is indeed involved.

7 • The scale scores pain and not depression, dependence or cognitive functions
Numerous instruments are available for each situation. It is of primary importance to understand that the scale is used to detect changes in behavior related to potential pain.
Thus, for items 6 and 7, we are not evaluating dependence or independence but pain.

8 • Do not use the DOLOPLUS 2 scale systematically
When the elderly patient is communicative and cooperative, it is logical to use the self-assessment instruments. When pain is patent, it is more urgent to relieve it than to assess it … However, if there is the slightest doubt, hetero-assessment will avoid underestimation.

DOLOPLUS - 2   Observasjonsbasert smerteskala for eldre

Etternavn:	Fornavn:	Avdeling:				
Senternummer:	Pasientnummer:	Dato:				

SOMATISKE REAKSJONER

1. Klager på smerte	- ingen klager	0	0	0	0
	- klager bare ved forespørsel/kontakt/undersøkelse	1	1	1	1
	- spontane klager av og til	2	2	2	2
	- vedvarende klager	3	3	3	3
2. Smertelindrende hvilestillinger	- benytter ingen smertelindrende hvilestillinger	0	0	0	0
	- unngår av og til enkelte hvilestillinger	1	1	1	1
	- benytter vedvarende og effektive smertelindrende stillinger	2	2	2	2
	- stadige virkningsløse posisjonskift (finner ikke ro)	3	3	3	3
3. Beskytter smertefulle områder	- ingen beskyttelse	0	0	0	0
	- beskytter seg, men tillater stell/undersøkelse	1	1	1	1
	- beskyttelse som hindrer stell/undersøkelse	2	2	2	2
	- beskytter seg også i fravær av kontakt	3	3	3	3
4. Ansiktsuttrykk	- normalt ansiktsuttrykk	0	0	0	0
	- ansiktsuttrykk som uttrykker smerte ved forespørsel/kontakt/undersøkelse	1	1	1	1
	- ansiktsuttrykk som uttrykker smerte spontant	2	2	2	2
	- vedvarende uttrykksløst ansikt (matthet, stivhet, tomt blikk)	3	3	3	3
5. Søvn	- normal søvn	0	0	0	0
	- problemer med innsovning	1	1	1	1
	- hyppige oppvåkninger (urolig søvn)	2	2	2	2
	- søvnløshet som påvirker våken tilstand	3	3	3	3

PSYKOMOTORISKE REAKSJONER

6. Stell og/eller påkledning	- aktivitet/bevegelighet er uendret (normalt)	0	0	0	0
	- aktivitet/bevegelighet er litt hemmet, men lar seg gjennomføre	1	1	1	1
	- aktivitet/bevegelighet er betydelig hemmet (vanskelig å gjennomføre)	2	2	2	2
	- umulig, pasienten motsetter seg ethvert forsøk	3	3	3	3
7. Forflytning	- forflytter seg som vanlig	0	0	0	0
	- lett redusert (unngår enkelte bevegelser, begrenset gå-radius)	1	1	1	1
	- sterkt redusert (selv med hjelp er forflytning vanskelig)	2	2	2	2
	- forflytning er umulig, pasienten lar seg ikke overtale	3	3	3	3

PSYKOSOSIALE REAKSJONER

8. Kommunikasjon	- normal kommunikasjon	0	0	0	0
	- intensivert kommunikasjon, søker oppmerksomhet på uvanlige måter	1	1	1	1
	- redusert kommunikasjon (vil være alene)	2	2	2	2
	- fravær eller avvisning av all kommunikasjon	3	3	3	3
9. Sosialt aktivitet	- normal deltakelse i aktiviteter (måltider, tilstelninger osv.)	0	0	0	0
	- deltar i aktiviteter, men kun etter overtalelse	1	1	1	1
	- nekter av og til å delta i aktiviteter	2	2	2	2
	- avstår fra all sosial aktivitet	3	3	3	3
10. Atferdsproblemer	- normal atferd	0	0	0	0
	- gjentatte atferdsproblemer	1	1	1	1
	- permanente atferdsproblemer i kontakt med andre	2	2	2	2
	- permanente atferdsproblemer (selv uten ekstern stimulans/kontakt)	3	3	3	3
	TOTALT				

DOLOPLUS SKALA NØKKELORD

Klager
Pasienten uttrykker smerte ved tale, kroppsspråk (tegn/mimikk), utrop, gråt, stønning og/eller jamring.

Smertelindrende stillinger
Uvanlig kroppsstilling for å unngå eller lindre smerte.

Beskyttelse av smertefulle områder
Pasienten beskytter én eller flere deler av kroppen ved å innta en forsvarsposisjon og/eller ved beskyttende/avvergende bevegelser. Ikke skår hvis du mistenker at det er angst som utløser atferden. Mange demente vil beskytte seg når de ikke forstår hva som skal skje og dette skal ikke skåres.

Ansiktsuttrykk
Ansiktet uttrykker smerte ved grimaser, mimikk (stram, sammenbitt eller uttrykksløst) og ved blikk (stirrende, fraværende, tårefylt, bedende, sint, desperat, engstelig eller fortvilet). Noen demente har vedvarende uttrykksløst ansikt som en konsekvens av sin demens, se derfor etter forandringer i forhold til det normale for pasienten når du skårer.

Forespørsel/Kontakt/Undersøkelse
Alle former for konfrontasjoner; undersøkelse, tilnærming (innblanding), henvendelser, omtanke, behandling og stell.

Stell/påkledning
Vurdering av smerte under stell (eventuelt toalettbesøk) og/eller påkledning alene eller ved hjelp.

Bevegelser
Vurdering av smerte ved bevegelser; endring av stilling/posisjon, forflytning, gange; alene eller ved hjelp.

Kommunikasjon
Verbal eller nonverbal. Se etter forandringer fra pasientens normale kommunikasjonsmønstre.

Sosial aktivitet
Måltider, tilstelninger, aktiviteter, terapeutisk behandling og besøk.

Atferdsproblemer
Aggressivitet, uro (rastløshet), forvirring, likegyldighet, regresjon, spørsmål om aktiv dødshjelp osv. Se spesielt etter forandringer i normale atferdsmønstre som kan skylles smerte.

DOLOPLUS SKALA: BRUKERVEILEDNING

1. Bruk forutsetter opplæring
Som ved et hvilket som helst nytt instrument, er det klokt å prøve det ut før man setter i gang. Noteringstiden reduseres ved erfaring (maks. noen få minutter.) Hvis det er mulig, er det lurt å øve seg på pasienter som allerede er henvist til et behandlingsopplegg.

2. Registrering i tverrfaglige grupper
Registrering fra flere pleiere (lege, sykepleier, hjelpepleier) er å foretrekke, uansett behandlingssted (offentlig, privat, hjemme). I hjemmet kan familien og andre pårørende delta. Skalaen integreres i pleiejournalen.

3. Ikke kryss av ved tvil eller hvis spørsmålet er uegnet
Det er ikke nødvendig å finne svar på alle deler av skalaen, særlig ikke overfor en ukjent pasient hvor man ikke kjenner alle data (spesielt på det psykososiale plan.) Ved for eksempel koma, registreres bare legemlige fakta.

4. Rutiner
Re-evalueringen bør finne sted to ganger daglig inntil lindring av smertene; videre registrering er avhengig av den enkeltes situasjon. I forkant av behandling er det viktig å ha resultatene fra DOLOPLUS i pleiejournalen (på lik linje med temperatur og blodtrykk) dermed kan man kartlegge plagene og igangsette egnet behandling.

5. Ikke sammenlign resultatene til ulike pasienter
Smerte er subjektivt. Sammenlikning av poengsum pasienter imellom har derfor ingen hensikt. Kun pasientens individuelle utvikling er av interesse.

6. Ved tvil; ikke nøl med å sette i gang en testbehandling med smertestillende tiltak
En skåre lik eller over 5 av 30, antyder smerte. I tilfeller med nærliggende poengsummer, bør man la tvilen komme pasienten til gode. (Hvis situasjonen forandres ved smertestillende tiltak, vil smerte være påvist).

7. Skalaen avdekker smerte; ikke depresjon, uselvstendighet eller kognitiv funksjon
Det finnes passende måleinstrumenter for alle symptomer, men det er viktig å forstå at man her prøver å fange opp atferdsforandringer knyttet til eventuell smerte; punkt 6 og 7 evaluerer bare smerte, ikke grad av selvstendighet.

8. Ikke bruk DOLOPLUS 2 - skalaen i alle tilfeller
Hvis pasienten er kommunikativ og samarbeidsvillig, er det naturlig å bruke instrumenter for selvrapportering. Dersom smerte er innlysende, er det viktigere å lindre enn å evaluere. Likevel, hvis det er noen som helst tvil, er det bedre med en DOLOPLUS evaluering enn en undervurdering av pasientens smertetilstand.

EORTC QLQ C30

We are interested in some things about you and your health. Please answer all of these questions yourself by ticking the alternative that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	Not at all	A little	Quite a bit	Very much
1. Do tou have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	☐	☐	☐	☐
2. Do you have any trouble taking a long walk?	☐	☐	☐	☐
3. Do you have any trouble taking a short walk outside of the house?	☐	☐	☐	☐
4. Do you need to stay in bed or a chair during the day?	☐	☐	☐	☐
5. Do you need help with eating, dressing, washing yourself or using the toilet?	☐	☐	☐	☐

During the past week:	Not at all	A little	Quite a bit	Very much
6. Were you limited in doing either your work or other daily activities?	☐	☐	☐	☐
7. Were you limited in pursuing your hobbies or other leisure time activities?	☐	☐	☐	☐
8. Were you short of breath?	☐	☐	☐	☐
9. Have you had pain?	☐	☐	☐	☐
10. Did you need to rest?	☐	☐	☐	☐
11. Have you had trouble sleeping?	☐	☐	☐	☐
12. Have you felt weak?	☐	☐	☐	☐
13. Have you lacked appetite?	☐	☐	☐	☐
14. Have you felt nauseated?	☐	☐	☐	☐

Please go to the next page

Draft

During the past week:

	Not at all	A little	Quite a bit	Very much
15. Have you vomited?	☐	☐	☐	☐
16. Have you been constipated?	☐	☐	☐	☐
17. Have you had diarrhea?	☐	☐	☐	☐
18. Were you tired?	☐	☐	☐	☐
19. Did pain interfere with your daily activities?	☐	☐	☐	☐
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching TV?	☐	☐	☐	☐
21. Did you feel tense?	☐	☐	☐	☐
22. Did you worry?	☐	☐	☐	☐
23. Did you feel irritable?	☐	☐	☐	☐
24. Did you feel depressed?	☐	☐	☐	☐
25. Have you had difficulty remembering things?	☐	☐	☐	☐
26. Has your physical condition or medical treatment interferred with your family life?	☐	☐	☐	☐
27. Has your physical condition or medical treatment interferred with your social activities?	☐	☐	☐	☐
28. Has your physical condition or medical treatment caused you financial difficulties?	☐	☐	☐	☐

For the following question please tick the number between 1 and 7 that best applies to you.

29. How would you rate your overall health during the past week?

☐ 1　☐ 2　☐ 3　☐ 4　☐ 5　☐ 6　☐ 7

Very poor　　　　　　　　　　Excellent

30. How would you rate your overall quality of life during the past week?

☐ 1　☐ 2　☐ 3　☐ 4　☐ 5　☐ 6　☐ 7

Very poor　　　　　　　　　　Excellent

Draft

The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.

KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

MINI MENTAL STATE EXAMINATION (MMSE)

Patient's name:
Hospital number:

ONE POINT FOR EACH ANSWER

	DATE			
ORIENTATION				
Year Month Day Date Time	____/5	____/5	____/5	____/5
Country Town District Hospital Ward	____/5	____/5	____/5	____/5
REGISTRATION				
Examiner names 3 objects (eg apple, table, penny) Patient asked to repeat (1 point for each correct). THEN patient to learn the 3 names repeating until correct.	____/3	____/3	____/3	____/3
ATTENTION AND CALCULATION				
Subtract 7 from 100, then repeat from result. Continue 5 times: 100 93 86 79 65 Alternative: spell "WORLD" backwards - dlrow.	____/5	____/5	____/5	____/5
RECALL				
Ask for names of 3 objects learned earlier.	____/3	____/3	____/3	____/3
LANGUAGE				
Name a pencil and watch.	____/2	____/2	____/2	____/2
Repeat "No ifs, ands, or buts".	____/1	____/1	____/1	____/1
Give a 3 stage command. Score 1 for each stage. Eg. "Place index finger of right hand on your nose and then on your left ear".	____/3	____/3	____/3	____/3
Ask patient to read and obey a written command on a piece of paper stating "Close your eyes".	____/1	____/1	____/1	____/1
Ask the patient to write a sentence. Score if it is sensible and has a subject and a verb.	____/1	____/1	____/1	____/1
COPYING				
Ask the patient to copy a pair of intersecting pentagons:	____/1	____/1	____/1	____/1
TOTAL	____/30	____/30	____/30	____/30

Ekspertvurdering DOLOPLUS-studien

Pasientnummer: Senternummer:

Senternummer: Bromstad = 1   Furuveien = 2   Persaunet D2 = 3   Persaunet D3 = 4

Vennligst sett ring rundt det tallet som best beskriver pasientens smerteintensitet **i ro**

$$0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10$$

Ingen smerter   Verst tenkelige smerter

Vennligst sett ring rundt det tallet som best beskriver pasientens smerteintensitet **i bevegelse**

$$0 \quad 1 \quad 2 \quad 3 \quad 4 \quad 5 \quad 6 \quad 7 \quad 8 \quad 9 \quad 10$$

Ingen smerter   Verst tenkelige smerter

Eventuelle kommentarer:

Responses of the assessor to the DOLOPLUS questionnaire.

Please fill in how you experienced using the DOLOPLUS questionnaire. By "difficulty" we mean any practical problems you encountered with this item. Confusing is about the wording of the item, and whether it could be ambiguous. Tick the box for "difficult words" if you think it was difficult to understand the content of the item. Please let us know how you would have asked the question if you don't like the suggested wording.
Thanks a lot for your contribution!

Comments

Question 1: Somatic complaints

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Question 2: Protective body postures adopted at rest

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____
                                          Comments

Question 3: Protection of sore areas

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Question 4: Expression

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Comments

Question 5: Sleep pattern

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Question 6: Washing and/or dressing

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____
Comments

Question 7: Mobility

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Question 8: Communication

a. Difficulty?   Yes   ☐   _____

_____

b. Confusing?   Yes   ☐   _____

_____

c. Difficult words?   Yes   ☐   _____

_____

d. How would you ask this question ?   _____

_____

_____

Comments

Question 9: Social life

a. Difficulty?   Yes   ☐

_____

_____

b. Confusing?   Yes   ☐

_____

_____

c. Difficult words?   Yes   ☐

_____

_____

d. How would you ask this question ?

_____

_____

_____

Question 10: Problems of behaviour

a. Difficulty?   Yes   ☐

_____

_____

b. Confusing?   Yes   ☐

_____

_____

c. Difficult words?   Yes   ☐

_____

_____

d. How would you ask this question ?   _____

Do you have general comments to the questionnaire?
(Is it relevant for pain assessment? Was it relevant for your patients? Was
it easy to implement in routine practice? Etc etc …)

_____

_____

_____

_____

_____

_____

Dissertations at the Faculty of Medicine, NTNU

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1. Knut Joachim Berg: EFFECT OF ACETYLSALICYLIC ACID ON RENAL FUNCTION
2. Karl Erik Viken and Arne Ødegaard: STUDIES ON HUMAN MONOCYTES CULTURED *IN VITRO*

1978
3. Karel Bjørn Cyvin: CONGENITAL DISLOCATION OF THE HIP JOINT.
4. Alf O. Brubakk: METHODS FOR STUDYING FLOW DYNAMICS IN THE LEFT VENTRICLE AND THE AORTA IN MAN.

1979
5. Geirmund Unsgaard: CYTOSTATIC AND IMMUNOREGULATORY ABILITIES OF HUMAN   BLOOD MONOCYTES CULTURED IN VITRO

1980
6. Størker Jørstad: URAEMIC TOXINS
7. Arne Olav Jenssen: SOME RHEOLOGICAL, CHEMICAL AND STRUCTURAL PROPERTIES   OF MUCOID SPUTUM FROM PATIENTS WITH CHRONIC OBSTRUCTIVE BRONCHITIS

1981
8. Jens Hammerstrøm: CYTOSTATIC AND CYTOLYTIC ACTIVITY OF HUMAN MONOCYTES AND EFFUSION MACROPHAGES AGAINST TUMOR CELLS *IN VITRO*

1983
9. Tore Syversen: EFFECTS OF METHYLMERCURY ON RAT BRAIN PROTEIN.
10. Torbjørn Iversen: SQUAMOUS CELL CARCINOMA OF THE VULVA.

1984
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