Development of a Breast Cancer Specific Patients Concerns Inventory (PCI)

THESIS SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE UNIVERSITY OF LIVERPOOL FOR THE DEGREE OF MEDICAL DOCTORATE

By

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"The quality of a person's life is in direct proportion to their commitment to excellence, regardless of their chosen field of endeavour."

Vincent Thomas "Vince" Lombardi (1913-1970)

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ABSTRACT. Development of a Breast Cancer Specific Patients Concerns Inventory (PCI). By A. Kanatas.

Introduction

Treating breast cancer is based on a combination of therapies: surgery, radiotherapy, chemotherapy, as well as hormonal and biological agents. The full impact of the disease and its treatment at a human level is often underestimated, and the benefits of holistic cancer care are increasingly recognised. Furthermore, patients often face a frightening and uncertain journey that presents a variety of needs. Moreover, recovery is not necessarily the end-point of the cancer experience. The many complexities and challenges in the identification of patient issues along this journey can lead to unmet needs. This can be particularly difficult in the confines of a busy clinic, where time constraints, together with an over-reliance on verbal communication, can pose significant barriers to effective consultations.

A novel tool, known as the patient concerns inventory (PCI), has been successfully developed and introduced for use in patients with head and neck cancer. In this setting, it has helped to formulate an individualized record of patient concerns, needs, and priorities, thereby structuring outpatient consultations, and promoting and facilitating a multidisciplinary approach. This study aimed to develop and assess a PCI specific to breast cancer and to evaluate its impact on patient care; that is, to provide a "proof of concept" for a breast cancer PCI.

Methods

This was a four-phase study, as follows. (1) Item generation through a literature review, input from clinicians (n = 10), four patient focus groups (n = 24), and national breast cancer charities (n = 3). (2) A survey of breast cancer patients (n = 200) for cross-sectional validation, to compare the PCI with an established quality of life tool and to look at the relative frequency of items and any associations. (3) A pilot, before and after study, assessing the PCI in a clinical setting with breast cancer patients (n = 53). (4) Semi-structured interviews with a breast surgeon (n = 1) and specialist nurses (n = 2) who used the PCI during clinics, to identify the perceived benefits of using the PCI.

Results

In total 277 patients responded and participated in this work. The literature review identified 164 items; following input from clinicians, focus groups, and national charities, 56 items remained. The cross sectional study (phase 2; n=200, 80 % response rate) revealed that patients wanted to discuss the following: breast sensitivity or pain (46 %), fatigue (46 %), hot flushes (44 %), sleep (34 %); breast appearance (30 %), unable to control weight (28 %), mastectomy appearance (19 %), overall physical appearance (17 %); fear of recurrence (62 %), fear of cancer spreading (39 %), fear about the future (32 %), or one or more of these (72 %); 'mood' (15 %), 'anxiety' (21 %), 'depression' (17 %), or one or more of these (35 %); Phase 3 found that the PCI resulted in a focused consultation and no increase in consultation time. All the patients from phase 3 wanted to see a breast surgeon. Phase 4 revealed that clinicians involved with the PCI supported its use, and stated several advantages. In its final format, the breast cancer specific PCI had 57 items over several domains, with 16 referral options.

Conclusions

The PCI could identify issues that patients would like to discuss in the breast oncology clinic. The routine use of the PCI in follow-up clinics could ultimately improve care for women with breast cancer; however, the clinical environment continues to make it difficult to screen for issues related to intimacy, relationship, and sex.

Further research is essential to evaluate the breast cancer specific PCI. A larger patient cohort, a longitudinal approach, qualitative input, and a link to possible interventions, would each improve our understanding of the issues faced by breast cancer patients.

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PREFACE: Thesis Overview

The chapters in this thesis present a stepwise sequence of the process necessary for the development of the breast cancer specific patient concerns inventory (PCI). The hypothesis was *that 'using a specifically developed PCI in clinical practice will help to identify patient concerns, improve consultations between professionals and patients, and help inform pathways for patients to follow so that their concerns are addressed.'* Specific objectives identified from this, were: (1) to develop a PCI specific to breast cancer; (2) To pilot the use of the developed PCI; and (3) to gain feedback on the merit of the PCI from members of the multidisciplinary team. The following provides an overview of the contents of this thesis.

Chapter 1 reviews the treatment of breast cancer and its effects on patients' health-related quality-of-life.

Chapter 2 looks at the assessment of need in breast cancer patients and the potential role of a breast cancer specific PCI in this context.

Chapter 3 presents the methodology used in all of the phases in this thesis to ensure reproducibility.

Chapter 4 identifies the issues assessed by the current, validated outcome instruments, used with breast cancer patients. Data from this review forms the basis of the PCI development.

Chapters 5 and 6 present the progression of the item generation process, together with their further reduction into a preliminary PCI. Also, the roles of focus groups and National breast cancer charities are outlined.

Chapter 7 details and assesses the results of a cross-sectional survey of breast cancer patients within two National Health Service hospitals. At this stage, a relatively stable form of the PCI was produced that was considered suitable for clinical introduction.

Chapter 8 reviews a pilot study -before and after study- evaluating the introduction of the PCI in a consultant breast surgeon's clinic.

Chapter 9 is an evaluation of the PCI from the breast cancer specialist and the breast cancer nurses

Chapter 10 concludes on the scope and potential use of the PCI. Future directions for this research are considered.

Chapter 11 outlines all the publications that were produced during this thesis, as well as both the poster and oral presentations made at National and International meetings.

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DECLARATION OF ORIGINALITY

This thesis is submitted in accordance with the requirements of the University of Liverpool for the degree of Medical Doctorate. The research work reported herein was carried out by the author in the Departments of Breast Surgery in Leeds Teaching Hospitals (Leeds General Infirmary, Pinderfields Hospital and St James Institute of Oncology).

No part of this thesis has been submitted in support of an application for a degree or qualification of this or any other university or educational establishment. However, some parts of this thesis have been previously published, or are under consideration for publication in peer review journals, with the supervisors of these works as named co-authors.

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CHAPTER 1. Breast Cancer – An Overview of Treatment and its Effect on Health Related Quality of Life (HRQOL)

Breast cancer is the third most common cause of cancer death in the UK, accounting for 7% of all cases. In 2010, there were 49,564 women and 397 men in the UK diagnosed with invasive breast cancer [Office for National statistics (2012), Northern Ireland Registry (2012), Welsh Cancer Intelligence and Surveillance (2012)]. It is known that women previously treated with curative intent can develop local recurrence or metastases many years after their original treatment, making this a significant issue worthy of investigation (NICE, 2009). In addition, a small proportion of women are diagnosed with advanced disease where the tumour has spread exensively within the breast or to other organs (NICE, 2009). However, before we move on to consider the minutiae of this thesis, it is important to place it in context. Here, a brief overview of the current breast cancer research is presented. This includes a review of the risk factors as well as the diagnostic and treatment options. Ultimately, we consider the increasing survival rates and the impact this is likely to have on future health needs.

Risk factors

Age related factors:

After gender, the strongest risk factor for breast cancer is age: the older a woman, the higher her risk. Additionally, early age at menarche has been consistently associated with an increased risk of breast cancer, with an estimated 22% decrease in risk associated with a five-year delay (Koprowski et al, 1999). Conversely, the younger a woman is when she begins childbearing, the lower the risk of breast cancer (Collaborative group on hormonal factors and breast-feeding, 2002). Indeed, childbearing in general reduces the risk of breast cancer; the higher the number of full-term pregnancies, the greater the protection (Collaborative group on hormonal factors and breast-feeding, 2002). Women who have been through the menopause have a lower risk of breast cancer than pre-menopausal women of the same age and childbearing pattern (Collaborative group on hormonal factors in breast cancer and hormonal replacement therapy).

Breastfeeding:

Women in developed countries are at increased risk of breast cancer when compared with women from less developed countries. We know that women who breastfeed reduce their

risk of breast cancer compared with women who do not. Furthermore, the longer a woman breastfeeds, the greater the protection: the risk is reduced by 4% for every 12 months of breastfeeding (Collaborative group on hormonal factors and breast-feeding, 2002). A large part of the variation between developed and developing countries is thought to be explained by the fact that women in developed countries tend to have fewer children on average and a limited duration of breastfeeding [(Collaborative group on hormonal factors and breast feeding (2002), Collaborative group on hormonal factors and breast feeding (2002)].

Hormonal factors:

Higher levels of endogenous hormones have long been hypothesized to increase breast cancer risk. Studies show that post-menopausal women with the highest levels of oestrogen and testosterone have two to three times the risk of women with the lowest levels (Key et al, 2002). However, the link between these hormones and pre-menopausal breast cancer risk is less clear (Eliassen et al, 2006). A relationship has been found between high insulin levels and breast cancer, which might explain the 20% increased risk of breast cancer for women with diabetes shown in a recent meta-analysis (Larsson et al, 2007).

The use of oral contraceptives (OCs) increases the risk of breast cancer in current and recent users, but there is no significant excess risk ten or more years after stopping use (Collaborative group on hormonal factors in breast cancer, 1996). Cancers diagnosed in women who have used OCs also tend to be less clinically advanced than those detected in women who have never used them (Collaborative group on hormonal factors in breast cancer, 1996). Indeed, in 2010 only 1% of breast cancers in women in the UK were linked to OCs (Parkin DM, 2011). Use of hormone replacement therapy (HRT) on the other hand, is associated with a 66% increased risk of breast cancer, compared to non-users (Parkin DM, 2011).

Previous breast cancer and benign breast disease:

Benign breast disease is a generic term describing all non-malignant breast conditions, some of which carry an increased risk for breast cancer while others do not. Women with proliferative breast disease without atypia have a two-fold increased risk, whilst those with atypical hyperplasia have a more than four-fold increased risk (Hartmann et al, 2005). Women are also more likely to develop breast cancer in the same breast as a benign breast lesion than in the opposite breast (Hartmann et al, 2005). Overall, women with a previous in situ tumour have double the risk of invasive breast cancer compared to the general population, and it is higher in the same breast than in the other breast (Robinson et al, 2008). Further, a previous diagnosis of breast cancer raises the risk of developing a second primary breast cancer (Rubino et al, 2010).

The role of inheritance:

There is growing evidence that the most important determinant is inheritance (Boyd et al, 2002). A woman with one affected first-degree relative (mother or sister) has approximately double the risk of breast cancer of a woman with no family history of the disease; if two (or more) relatives are affected, her risk increases further (Familial breast cancer, 2001). Small proportions of women have a particularly strong family history of breast cancer and are at very high risk. Mutations in the breast cancer susceptibility genes, *BRCA1* and *BRCA2*, are present in the majority of families with four or more affected members (Peto et al, 1999). Intermediate-penetrance gene variants that confer a two-to-three-fold increase in risk have been found in other genes, such as *CHEK2, ATM, BRIP1,* and *PALB2*. Some low-penetrance gene variants have also been identified, but are beyond the scope of this thesis (Turnbull et al, 2008).

Weight:

Overweight and obesity, as measured by a high body mass index (BMI; BMI= weight in Kg divided by height in meters squared), moderately increases the risk of post-menopausal breast cancer and is one of the few modifiable risk factors for breast cancer. Compared to lean women (BMI 22.5-24.9), overweight post-menopausal women (BMI 25-29.9) have a 10-20% increased risk of breast cancer, while obese post-menopausal women (BMI > 30) have a 30% increase in risk. Women with a BMI under 22.5 have a 15% reduction in risk compared to women with a BMI of 22.5-24.9 [Reeves et al (2007), Parkin et al (2011)]). It is also interesting to note that women with dense breasts have an almost five times higher risk of breast cancer than those with less dense breasts (McCormack et al, 2006). Menopausal status, weight, and number of children, each affect breast density, meaning that there several confounders that confuse whether or not breast density represents an independent risk factor.

Other Lifestyle factors:

A study published in December 2011 estimated that over 3% of breast cancers in the UK were linked to inadequate levels of physical activity (less than 150 minutes of moderate physical activity per week) (Parkin DM, 2011). Furthermore, estimations at the same time suggested that more than 6% of breast cancers in women in the UK were linked to alcohol consumption (Parkin DM, 2001). In spite of extensive research, findings are generally inconsistent and inconclusive on the effects of dietary factors on breast cancer risk. A meta-analysis of 45 studies (Boyd et al, 2003) reported that higher total fat intake increased breast cancer risk by 13%. Other risk factors include for breast cancer include shift work (Megdal et al, 2005), in-utero exposure to higher levels of oestrogen (Xue et al, 2007), and ionising radiation (John et al, 2007).

Breast cancer Symptoms and diagnosis

Breast cancer rarely causes symptoms in its early stages (Pintz C, 2011). The symptoms of breast cancer include (Dixon et al, 1995):

- A lump in the breast
- A change in the size or shape of the breast
- Dimpling of the skin or thickening in the breast tissue
- A nipple that turns in on itself (i.e., that becomes inverted)
- A rash (like eczema) on the nipple
- Discharge from the nipple
- A swelling or a lump in the armpit

Women aged 50–70 years receive invitations every three years to attend screening through the NHS Breast Screening Programme (NHSBSP, 2002). Women over the age of 70 years are encouraged to continue to attend every three years although they are not routinely invited. However, there is evidence that breast self-examination does not reduce either morbidity or mortality in breast cancer (Thomas et al, 2002). Optimal assessments of breast abnormalities are by a combination of clinical examination, imaging, and sampling of the lesion for cytological/histological assessment. These three investigations collectively comprise the 'triple assessment' (Morris et al, 2001) and form the cornerstone of diagnosis.

Breast cancer treatment, reconstructive surgery, and long term implications

The available treatments include surgery, chemotherapy, radiotherapy, biological and hormonal agents, or a combination of the above. These are tailored to both the disease stage at presentation as well as the patient's needs and preferences. Here we consider the available options, together with the indications and contraindications.

Surgery is the mainstay of treatment for ductal carcinoma in situ (DCIS) and invasive breast cancer, and is typically the first treatment option (NICE, 2009). However, early diagnosis may allow for conservation surgery with local excision, rather than mastectomy. Although approximately 60–80% of newly diagnosed cancers are amenable to breast conservation surgery, only around 23% of breast cancer patients diagnosed through screening ubdergo mastectomy. In most cases, this is due to tumour size (relative to breast size), tumour

multicentricity, inability to achieve negative surgical margins after multiple resections, prior radiation to the chest wall or breast, other contraindications, or patient preference (Senkus, 2013). Indeed, breast conserving surgery is contraindicated in specific cases, including: patients where the ratio of the size of the tumour to the size of the breast would not result in acceptable cosmesis; where there is multifocal disease; and, where local radiotherapy is contraindicated. Several trials have compared mastectomy and breast conservation surgery, concluding that conservative surgery plus local radiotherapy is appropriate, provided the margins of the resected specimen are tumour-free, and acceptable cosmesis is possible [Curran et al (1998),Veronesi et al (2001), Veronesi et al (2002), Fisher et al (2002), Holli et al (2001), Fisher et al (2001)]

The most significant prognostic indicator for patients with invasive breast cancer is metastatic spread to axillary lymph nodes. Guidelines from the Association of Breast Surgery (2009) recommend obtaining histological lymph node status for all operable invasive breast cancers. Others prognostic indicators include tumour size, hormone receptor status, and the patient's menopausal status [Veronesi et al (1993), Chetty et al (2000)]. The recommended practice from NICE (2009) advocates that minimal surgery, rather than lymph node clearance, be performed to stage the axilla in patients meeting the following criteria: those with early invasive breast cancer; no evidence of lymph node involvement on ultrasound; and, those with negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique (NICE, 2009). These results typically guide systemic adjuvant therapy.

Adjuvant therapy continues to play an important role in the management of breast cancer [EBCTCG (2000), Malmstrom et al (2003) and include chemotherapy, hormonal therapy, trastuzumab (Herceptin®), radiation therapy, or, a combination thereof. Clinical trials have demonstrated that adjuvant chemotherapy reduces the risk of recurrence (EBCTCG, 2005). However, not all women with breast cancer need adjuvant therapy; patients at higher risk of cancer recurrence are more likely to benefit. In addition to a woman's age and menopausal status, several prognostic factors help to determine the risk of recurrence [Goldhirsch et al (2005), Lonning PE (2007)]. These include the cancer stage, grade and its proliferative capacity, as well as hormone receptors and HER2 status.

Several studies support preoperative chemotherapy for women with operable breast cancer (Wolmark et al, 2001). Results from non-randomized studies have shown that chemotherapy administered before surgery resulted in high rates of clinical response (50-80%) but low rates of pathologic complete response (<5%) [Van der Hage et al (2001), Fisher et al (1998), Mauri et al (2005)]. These studies concluded that reducing tumour size with chemotherapy allowed for breast-conserving surgery. Unfortunately, not all patients are suitable for

chemotherapy or surgery, and the management of metastatic breast cancer is often guided by a patient's symptoms. Usually an oncologist, with input from the palliative care team, delivers therapy. In some cases, surgery may be limited to the control of local disease (Association of Breast Surgery, 2009).Oncoplastic breast reconstruction techniques are increasingly becoming the standard of care in breast cancer management. This may result in a significant improvement in the overall health related quality of life (HRQOL). The recently completed National Mastectomy and Breast Reconstruction Audit (NMBRA) involving more than 18,000 women examined a wide range of clinical and patient-reported outcomes (Jeevan, 2011). This national audit was commissioned to answer several questions related to the provision of breast reconstruction services across England and Wales. First, to assess if women undergoing mastectomy had sufficient information to make an informed decision about breast reconstruction, and if they were happy with that decision. Secondly, to evaluate the outcomes following mastectomy with or without reconstruction. This audit found that compared to 2006, more women with breast cancer in England underwent immediate reconstruction at the time of their mastectomy; one in five for 2011, compared to one in nine for 2006 (Jeevan, 2011). This audit also concluded that there was variation in the provision of care and that there were potential unmet needs as a result of the available reconstructive options. The decision making process was scrutinized during the audit. Specifically, concerns were raised about how the offer of immediate reconstruction was communicated to patients, as the proportion of women accepting an offer varied regionally from 17 to 62 per cent. The audit also noted that the demand for breast cancer surgery had increased over the last decade, which corresponded with the increase in the disease's incidence (Jeevan, 2011). This increase in patient numbers will contribute to increase pressures on already stretched clinical services, and potentially increase the amount of unmet need. The current BAPRAS guidance (British Association of Plastic Reconstructive and Aesthetic Surgeons, 2012) advocates that in the absence of significant contraindications, immediate or delayed breast reconstruction should be offered to all suitable patients requiring mastectomy. The positive physical and psychological effects of breast reconstruction have been highlighted in the NMBRA. The audit also outlined specific information needs necessary for a successful outcome. A PCI tool that could identify unmet need has the potential to improve outcomes following surgery.

The diagnosis and treatment of breast cancer is a life-changing event that necessitates a systematic approach. The aims of long-term follow up include the detection of early local recurrence, or contralateral breast cancer, the identification of therapy-related complications, and the provision of support and information to facilitate a return to normal life [2013 European society for medical oncology guidelines (ESMO); (Senkus, 2013)]. These may be

ambitious goals in a busy outpatient with pressures on resources and time, or that lack training and expertise within the clinical team. With increasing clinical demands, an instrument that can identify patient needs has clear advantages.

The ESMO guidance emphasises the psychological needs of patients with a history of breast cancer. Such women often have increased levels of anxiety and depression following their initial treatment (Senkus, 2013). Fatigue and depression are often present in the months following adjuvant treatment such as radiotherapy and chemotherapy (Allemani, 2013). Indeed, many other common needs may be overlooked, remained undetected, or be unaddressed in long term survivors, and include social, family and intimacy issues (Senkus, 2013). If we aim to ensure a return to the pre-morbid quality of life that these women enjoyed, then as clinicians we must develop and implement mechanisms that support a holistic approach to breast cancer management.

Breast Cancer and Health Related Quality of Life

Health-related quality of life (HRQOL) and patient-reported outcome measurement (PROMS)

High quality cancer care aims to improve a range of patient outcomes, including survival and health related quality of life (HRQOL), representing the patient's physical, psychological, and social response to the disease and therapy (WHOQOL, 1998). It includes measures of physical symptoms (pain, fatigue, vomiting), physical functioning (e.g. mobility, self-care), emotional functioning (anxiety, depression, stress) and social and family functioning. It is a patient-subjective measure capturing important information that cannot be achieved by traditional objective measures, such as tumour response or survival. More recently, the Food and Drug Administration (USA) introduced the umbrella terms patient-reported outcomes (PROs) or patient-reported outcome measurements (PROMs) as to encompass any measures obtained directly from the patient, which include areas of HRQOL, as well as broader concepts such as patient satisfaction with care.

Over the last three decades, HRQOL has become a significant outcome measure for cancer patients in clinical trials. In this setting, patient-reported HRQOL data is commonly required alongside biomedical outcomes such as progression-free survival, and overall survival to assess the value of a given therapeutic intervention. Patient-reported HRQOL has also been found to predict treatment response and survival in a number of advanced solid cancers (Efficace et al, 2006). More recently, PROMs are increasingly being used by

the National Health Service (NHS) as quality indicators when assessing service delivery and treatment outcomes (incl. health economic outcomes) (DoH, 2007).

HROL and PROMS in clinical practice

The routine care of individual patients in oncology clinics requires a regular measurement of symptoms, functioning, and HRQOL, both before and during treatment. This plays an important role in informing clinicians of patient concerns, and in supporting treatment decisions. However, there is a growing need to study the potential role of HRQOL measurement in routine clinical practice with the aim of improving patient care through better detection of problems, better control and monitoring of symptoms, and enhanced communication and shared decision-making. There are a number of assessment tools currently being used by various health and social care professionals (Kanatas et al, 2009) but these tools do not yet cover all the domains required for a holistic assessment. Furthermore, a lack of co-ordination between health and social care often prevents the effective sharing of patient information. This results in patients having repeated assessments on their care pathway, repeatedly providing the same information to different professionals.

Health Related Quality of life and Breast Oncology

The health-related QOL (HRQOL) assessment is now regarded as a key component of clinical oncology trials (Versmessen et al, 2012). Radiotherapy for breast cancer tends to be stressful and may increase fatigue, skin irritation, and breast pain during the first year (Prescott et al, 2007). Attendance at daily radiotherapy treatments for up to six weeks may also have an impact on the patient's QOL, although it is hoped that use of the hypofractionated schedule can reduce this burden by shortening the overall treatment time. There are a number of studies looking at the use of HRQOL in oncology practice. They showed benefit for patients including better symptom control and wellbeing [Velikova et al (2004), Valderas et al (2008)].

Sprangers (Sprangers MAG, 2002) considered that HRQOL can be measured reliably and validly, to help clinicians gain insights into a patient's perspective of their disease and treatment. However, patients may change their perspectives during the course of their disease, referred to as a 'response shift,' which in standardized questionnaires may result in patients reporting a stable QOL over time, while concurrently exhibiting deteriorating clinical health [Schwartz et al (1999), Sprangers et al (1999)].

Seen from the patient's perspective, a diagnosis of breast cancer may have multiple implications: it may be viewed as a sudden, unexpected threat to life; it may cause acute hospitalisation; it usually involves surgery with the removal of either a breast or part of a breast; it creates a need for medical decisions; it may necessitate additional treatments; and,

it may give rise to associated symptoms and other practical problems. These and many other factors can cause an acute and severe disruption to the patient's daily life (Hewitt et al, 2004). HRQOL data is used in two ways in the interpretation of randomised clinical trials (Groenvold et al, 2010). First, the researchers simply use this information in the interpretation of their results. If, for example, the available research data show no difference in survival between two treatments but the HRQOL data shows a clear advantage, then researchers may conclude that this is a potential argument in favour of treatment. Second, the availability of HRQOL data can provide patients with improved information when making treatment decisions, via access to more patient-orientated insights into the results. The use of HRQOL data may convey information about the consequences of treatment that would otherwise be unavailable, and therefore provide a better basis for decision-making by the patient.

HRQOL is now considered an important endpoint in clinical cancer trials. It has been shown that assessing QOL in cancer patients could contribute to improved treatment, and that it could even be used as a prognostic factor, in much the same way that medical factors are used [Montazeri et al (1996), Montazeri et al (2003). Above all, studies of QOL can further indicate the directions needed for more efficient treatment of cancer patients. Among the QOL studies in cancer patients, breast cancer has received most attention for several reasons. First, the number of women with breast cancer is increasing: each year over 1.1 million women worldwide are diagnosed with breast cancer, and 410,000 die from the disease (Montazeri A, 2008). Second, the early detection and treatment of breast cancer have improved, with cancer survivors now living longer. Third, breast cancer affects a woman's identity. In addition, it is believed that females play important roles as partners, wives, and mothers within any family; when a woman develops breast cancer, all members of the family are affected, making breast cancer a disease of the whole family. The overall consequence of this myriad of factors, is that QOL is becoming an increasingly important research topic; particularly due to increased longevity and the psychosocial impact of the loss of a breast. Although other reasons could be added, it is crucial to recognize that with continuing advances in medical practice, studying the impact on QOL is highly relevant for any cancer, regardless of anatomical site or gender.

A descriptive analysis of the 230 papers published between 1990 and 2000, (Mandelblatt et al, 2004) on non-biomedical outcomes in breast cancer patients (QOL, preference, satisfaction and economics), found that the most frequently reported outcomes were: HRQOL (54%), followed by economic analyses (38%), and patient satisfaction (14%); with only 9% measuring patient preference (Mandelblatt et al, 2004). Over the past ten years, much clinical effort has been expended looking at improving the treatment of breast cancer

and survival from it; the question is now: to what extent have studies of quality of life in breast cancer patients added to the extensive knowledge base, or contributed to improved outcomes in breast cancer care? Whilst this is very difficult to answer, it is possible to try to investigate the contribution of QOL studies to breast cancer care as a whole. There are several useful review papers on QOL in breast cancer patients but most published papers have either provided an overview or have been systematic literature searches with much focused objectives (Montazeri A, 2008).

Evidence is accumulating that the multifaceted sequelae of breast cancer do not cease with the conclusion of treatment. Two recent reports make clear that the period after completion of active treatment brings its own set of unique, and in some cases, still poorly understood challenges (Hewitt et al (2005). Many breast cancer survivors experience persistent physical symptoms related to cancer and its treatment, including: fatigue [Barton-Burke M (2006),Lawrence et al (2004), Bower et al (2006), pain or abnormal sensations in the arm or breast (Erickson et al 2001), hormone-related symptoms [Ganz et al (1998), Ganz et al (2002), Carpenter et al (1999) and sexual dysfunction [Ganz et al (2002), Kornblith et al (2003)]. The prevalence of these long-term physical symptoms is not trivial: for as many as a third of breast cancer survivors, fatigue may continue to be problematic five to seven years into survivorship (Bower et al, 2006); equally, a third of long-term survivors suffer post-surgical pain and troublesome physical sensations (e.g., numbness, paresthesia) in the arm, breast or chest wall (Kornblith et al, 2003). Hormone-related symptoms including vasomotor symptoms (hot flashes, sweats, palpitations), urinary incontinence, vaginal dryness, and cognitive and mood changes are common in breast cancer survivors too (Carpenter et al, 1999), and occur at higher rates than in age-matched healthy peers (Ganz et al, 1998). Furthermore, approximately 20–30% of breast cancer survivors experience sexual problems including general sexual disruption, decreased frequency of intercourse, and difficulties reaching orgasm that can persist 20 years post-treatment (Kornblith et al, 2003). These physical symptoms can inhibit psychosocial adaptation, disrupt the ability to perform normal life roles, and decrease the HRQOL for years after the conclusion of primary treatment [Carpenter et al (1999), Ronson et al (2002), McWayne et al (2005)]. Persistent physical symptoms also serve as a continuous reminder of cancer, and result in significant psychological morbidity including anxiety, depression, problematic levels of fear of recurrence [Deimling et al (2002), Holzner et al (2001)], and symptoms of post-traumatic stress disorder for up to 20 years after treatment (Kornblith et al, 2003).

Specific support for the protective role of physical activity comes from a growing number of intervention studies investigating the effect of physical activity during and after cancer treatment on symptom and physical domains of the HRQOL. Indeed, several recent reviews

on the impact of physical activity in cancer survivors, both on- and off-treatment, show that physical activity can have positive effects on: physical symptoms such as fatigue, pain, cognition, sleep, fitness, body composition; biological changes such as immune functioning; and, on psychosocial measures including depression, anxiety, self-esteem, and multiple aspects of QOL, including the HRQOL [Irwin et al (2004), Schwartz AL (2004), Oldervoll et al (2004), McTiernan A (2004), Pinto et al (2005), Schmitz et al (2005), McNeely et al (2006)].

Mortality and Survival related to breast cancer

Breast cancer was the most common cause of death from cancer in women until 1998; since then there have been more deaths from lung cancer in women (Lavelle et al, 2007). By 2010, breast cancer was therefore the second most common cause of cancer death among women, accounting for around 15% of all female deaths from cancer (ONS, 2010). Between 2005 and 2009, 85% of women in England survived longer than five years after a diagnosis of invasive breast cancer (Stapelkamp et al, 2011). The National Institute for Health and Clinical Excellence (NICE) guidelines on the use of trastuzumab estimate that approximately 40-50% of women presenting with early or localised breast cancer, will eventually develop metastatic breast cancer (NICE, 2006). Data from the West Midlands Cancer Intelligence Unit indicates that about 5% of women and men diagnosed with breast cancer between 1992 and 1994 had metastases at the time of their primary diagnosis. In addition a further 35% of all those with a primary diagnosis went on to develop metastases in the 10 years following diagnosis (SBCTF, 2007).

Overall, patients with breast cancer therefore survive much longer today, compared with twenty years ago. Indeed, the number of cancer survivors in the UK population has been increasing each year (Maddams et al, 2009), largely because of advances in diagnosis and treatment. Maddams et al (Maddams et al, 2012) used data from the National Cancer Registry to estimate cancer prevalence in the UK for 2009. In that study, projections were made to 2040; they revealed that by 2040, nearly three-quarters of all breast cancer survivors will be 65 and over, representing an increase from 59% today to 73% in 2040 (Maddams et al, 2012). This research also projected the increases in breast cancer among over 65-year-old patients to be almost double those in younger patients (Maddams et al, 2012). It can therefore be concluded that the population needs will be increased accordingly, with a significant change in the demands placed on the National Health Service (NHS). As part of a holistic approach to care there is an emerging need to be able to identify potential issues and

to manage them efficiently. The identification of issues, and patient needs related to breast cancer diagnosis and treatment may be as challenging as their management. The current research projections for population change must be taken into account in the allocation of future resources. Plans need to be made now, to ensure that the varied and increasing needs of cancer survivors can be met in the future. By proactively managing need, we may be able to reduce how this increasing burden affects the NHS.

Therefore, as survival rates are increasing and therapeutic options are becoming more diverse, there is a growing need for a tool that can identify the needs of this evolving situation. Only then, we will be able to improve the quality of life of patients with breast cancer, and be able to allocate our resources according to both disease and social determinants.

CHAPTER 2. An Assessment of Need in Breast Cancer Patients and the Role of a Breast Cancer Specific Patient Concerns Inventory (PCI)

This part of the thesis provides a short overview of the needs of breast cancer patients. In particular, it addresses the physical and psychological needs relevant to its diagnosis and treatment. A review is made of the current UK guidance for breast cancer care, together with the various tools used to assess need. Ultimately, the chapter concludes on the requirements of effective needs assessments.

What guidance exists in the UK?

In an attempt to meet the ever increasing needs of the breast cancer population, the National Institute of Clinical Excellence (NICE) published updated guidance on 'Improving outcomes in breast cancer' in 2002 (NICE, 2002). Following this, a process was put in place in England to monitor the progress made toward implementing the recommended changes in service organisation and delivery. Since breast services were the first to utilize multidisciplinary teams (MDTs) breast cancer MDTs were the first to be reviewed in 2001, and again in the 2004-2007 review round (BCCOM, 2007).

The 2002 NICE guidance required that each MDT had two core members in all the key disciplines (BCCOM, 2007). These included a designated consultant breast surgeon, a designated breast care nurse, a designated imaging consultant, a designated histopathologist, a consultant oncologist and an MDT co-ordinator. Of the 174 breast cancer MDTs that were included 88% achieved full core team membership by the 2004-2007 peer review round, although only half of the teams met the NICE 2002 requirement. The overall compliance against all measures outlined in the 2002 guidance was around 77%, with 5% of teams having compliance levels under 50% (BCCOM, 2007). A review period limited to a maximum of three years was presented in the NICE 2002 guidance (NICE, 2002) but 40% of cancer networks did not consent to this requirement (BCCOM, 2007). However, in spite of only 69% of teams allocating a key worker, there was high compliance with patient experience measures, such as patient surveys, in most breast cancer teams (SBCT, 2007). MDTs bring together staff with the necessary knowledge, skills, and experience to ensure high quality diagnosis, treatment, and post-treatment support. Effective MDTs ensure good communication between primary, secondary and tertiary care and are thus in a position to

address most patient needs that arise. Compliance with these guidelines moves us closer to a situation where the holistic needs of breast cancer patients are achievable.

The role of primary care

Often the Primary care setting may be the first point of contact for patients with physical, social, and psychological problems associated with breast cancer treatment. It is estimated that an average practice of 10,000 patients will have around 23 registered patients who consult their GP with breast cancer each year (Birmingham research unit, Annual prevalence report, 2007). Unfortunately, the level and quality of treatment vary across the country, according to the patient's age and socioeconomic status [Coleman et al (2001), Coleman et al (2001), Macleod et al (2000)]. Physical access to services also remains inequitable, with 7% of the population of England and Wales living over 50 km from their local radiotherapy centre. This variation in treatment access can result in differences in clinical need between breast cancer patients and creates the search for a better way that will ensure patient satisfaction through the recognition and the effective management of disease specific issues. It is a challenge to promote a follow-up regimen that maintains patient confidence and takes into account the issues of patients who may be living with a potentially life threatening condition. However, focusing on the active identification of issues in both primary care and the community, using a validated tool to improve teamwork and a holistic approach, could go a long way to managing these needs [de Bock et al (2004), Grunfeld et al (1996).

What is need?

The National Health Service (NHS) was created from the ideal that good quality healthcare should be available to all. Three principles (NHS, 2012) have guided the development of the NHS: that it meet the needs of everyone; that it be free at the point of delivery; and, that it be based on clinical need, not the ability to pay. The first point in particular is difficult to define however, due to the inherent complexity of the concept of 'need' (Asadi-Lari et al, 2003). 'Need' as a natural right in the pursuit of happiness, was introduced in the ancient Greek civilisation by Aristotle in the Nicomachean Ethics (Melden AI, 1957). Today, the Medical Research Council considers need to exist when a patient's functioning falls below a minimum specified level, and where there is a remediable cause (Stevens et al, 1998). Buchan et al have defined health service needs in economic terms, as 'those for whom an

intervention produces a benefit at reasonable risk and acceptable cost' (Buchan et al, 1990). However, a more holistic approach has been proposed by Maslow (Maslow AH, 1968), where needs are hierarchically organized into five levels (Figure 1). Here, basic needs are at the bottom of the hierarchy, and the need for self-actualisation is at the top. This theory argues that individuals will be motivated to meet higher need levels only when lower order needs are satisfied.

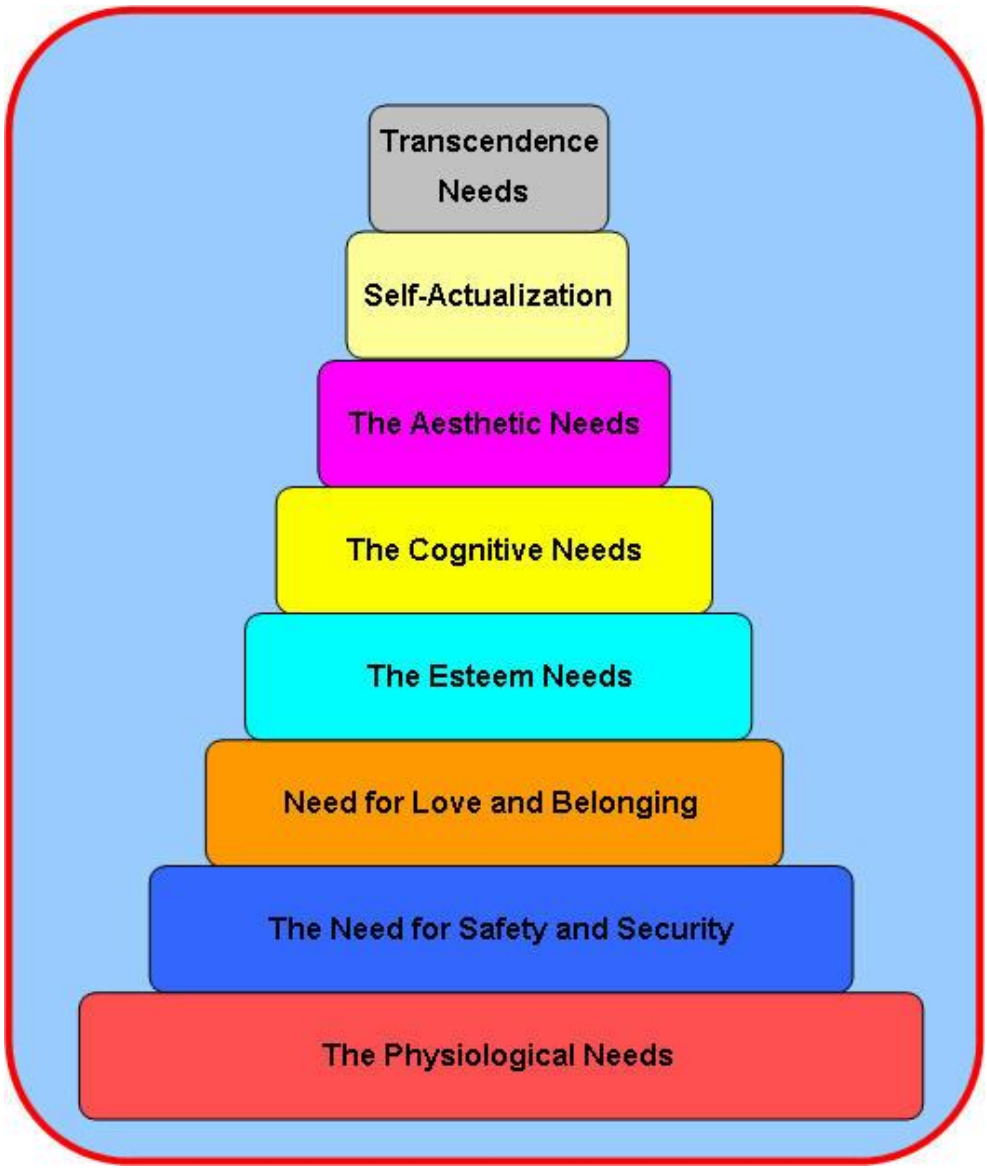


Figure 1 Maslow's Hierarchy of Needs

Assessing multidimensional need in Breast cancer

Need assessment in oncology necessitates the inclusion of a direct and comprehensive assessment of the multidimensional impact of cancer on the lives of patients and should address important domains of physical, functional, emotional, social, spiritual, and practical needs [Ferrell et al (1997), Bonevski et al (2000), Soothill et al (2001)]. A better understanding of patient needs can help clinicians and nurses to focus their care on those that are most relevant [Holmes et al (1997), Wen et al (2004)]. In 2008 Schmid-Büchi et al., divided the needs of women with breast cancer into four key categories: physical and treatment-related needs; psychological needs; social needs; and, informational and support needs (Schmid-Büchi et al, 2008).

Physical factors

Breast cancer patients typically have a range of needs that have to be met in order to establish a positive patient-doctor relationship (Davis et al, 2004). Prevalent among these are physical and treatment related needs, where several studies have described fatigue and lack of energy during treatment among both long term survivors and cancer patients [Haberkorn et al (2013), Schultz et al (2005), as well as symptoms such as impaired arm/shoulder movements and lymphoedema (Raupach et al, 2002). It has also been found that menopausal women with a history of breast cancer treatment tend to report a higher frequency of menopausal symptoms [Schultz et al (2005), Ayers et al (2013). Given that the incidence of breast cancer increases with a woman's age - a 60-year-old woman has a higher risk of being diagnosed with breast cancer in the next 10 years than a 40-year-old woman - a significant number of patients with breast cancer will potentially be at an age close to / or at menopause. This adds an extra dimension to their care needs. Indeed, such women also report additional physical complaints, including: impaired sexual functioning, sleep disturbance, reduced libido, hot flashes, reduced concentration, and a reduced interest in sex (Hodgkinson et al, 2007). These complaints frequently give rise to problems related to body image and a perceived loss of femininity (Davis et al, 2004). Many women with a history of treatment for breast cancer can have physical symptoms that can be somewhat overwhelming with a negative influence in their quality of life.

Psychological factors

From a psychosocial perspective, patients report body image problems, together with the loss of a sense of attractiveness, femininity and sexuality (Schultz et al, 2005). Research suggests that these challenges to the self-image and general well-being of the patient are such that significant psychiatric morbidity can result (Wen et al, 2004), with women tending to suffer

from anxiety, stress and depression, than is often related to the fear of either spread or recurrence of the cancer (Hodgkinson et al, 2007). Empirical studies focusing on the social and psychological needs of breast cancer patients, such as that by Hodgkinson et al (Hodgkinson ,2007), have concluded that breast cancer patients experience depression due to the fear of their cancer returning. Additionally, more than half of long-term survivors indicate that they were unhappy with the way things had turned out for them (Schultz et al, 2005), with anxious and depressed women perceiving significantly more unmet needs (Hodgkinson et al, 2007).

In order to combat the emotional demands of breast cancer, one of the most commonly expressed needs is the need to retain a sense of control over their life. Maslow et al (Maslow AH, 1968) suggest that this sense of control can be achieved for most patients, by improving the patient doctor relationship: offering a higher level of involvement in treatment-related decisions, and by facilitating the discussion of expectations about the course of their treatment. According to Hodgkinson et al (Hodgkinson et al, 2007), there is a significant correlation between the number of unmet needs among breast cancer patients and their level of anxiety and depression. The effect of breast cancer on the patient's psychological well-being has been clearly documented. Other effects that include their social functioning need to be taken into account at the review outpatient clinic.

Social factors

Hanson Frost et al (Hanson-Frost et al, 2000) identified that women newly diagnosed with breast cancer felt that their function in society was more severely impaired. The majority of these patients expressed a need for empathic listening and for emotional support, which was usually provided by their partner and family. However, the extent to which their family provides these emotional needs varies considerably; Schultz et al (Schultz et al, 2004) for example revealed that, although 50 per cent of women experienced an improvement in their family relationships, 30 per cent experienced a deterioration in their relationships. The study by Hanson Frost et al (Hanson-Frost et al, 2000) however, suggests that there is no significant difference in either the psychosocial measures, or the marital or sexual relationships, between women with stable breast cancer and the newly diagnosed. The effect of disease on social functioning may be profound. In order for a patient to be able to reach the pre-disease levels of function in society, simple interventions such as identifying and addressing the informational needs may be all that is required.

Informational Needs

Finally, breast cancer patients have a wide range of informational needs. Lobb et al (2001) report that as many as 80 per cent of breast cancer patients interviewed in their study wanted access to as much information as possible, with just 16 per cent of respondents stating that they wanted limited information. Specifically, the information requested included: details about treatment; possible side effects; life expectancy; the risk that other family members might develop breast cancer; things which they could do to help themselves; and, remission (Opatt et al, 2007). This was expanded upon by Hunter et al (2004) through semi-structured interviews, who found that the majority of breast cancer patients wanted information to help them cope effectively with treatment side effects and to manage their illness. In addition, patients wanted to know what "was considered normal" in both psychological and physical terms.

It is important to note, however, that many of the patients expressed a clear preference for how they wanted this information communicated to them. Opatt et al (2007) report that a large proportion of women want their cancer specialist to first ask them whether or not they wanted specific information. Decision making is also important to patients; Hanson Frost et al (2000) report that 53 per cent of women in their survey wanted to collaborate in the decision making process about their treatment, while 23 per cent wanted to be the sole decision maker, and 23 per cent wanted the decision to be made by the doctor.

There are other factors needing consideration too. Katz et al (Katz et al, 2005) suggest that the desire for information also extended to a desire to learn about complementary therapies and support groups. In addition, women that have had to overcome barriers when obtaining health information tend to have significantly lower psychosocial well-being, and a lower perception of their health competence (Arora et al, 2002). It is therefore arguable that there is an unmet need for easily accessible additional information, particularly in relation to support groups and complementary therapies [Hodgkinson et al (2007), Lobb et al (2004)]. Difficulties in obtaining the required information often has clear negative effects (Lobb et al, 2001), making the accessible provision of information a key factor for the patient.

Maslow and need assessment in oncology

Attainment of basic needs, as detailed above, are simply steps along the path to self-actualisation according to the Maslow model of clinical need (Maslow AH, 1968) (Figure 1). If a need is identified, action is recognised as desirable by clinicians: inaction will result in

dissatisfaction and a persistence of the need. A need assessment should directly measure the divergence between a patient's experiences and expectations (Bonevski et al, 2000).

Cancer survivorship is an ongoing challenge, for both patients and their relatives; they do not return to a pre-cancer-diagnosis state of functioning, and retain specific and unique needs (Hodkinson et al 2007). According to Maslow for example (Maslow AH, 1968), breast cancer patients have high needs for safety and security: the needs to find safe circumstances, stability, protection and to regain a more predictable life. However, there is considerable individual variability in the reaction of breast cancer patients to their illness and treatment; we do not understand why some women present with supportive care needs, why others have no specific needs at all, and why some have unsatisfied needs. Identifying patients with unsatisfied needs at an early stage of their treatment provides the opportunity to address these needs and enhance the quality of care [Bonevski et al (2000), Boberg EW (2003)]. Unsatisfied need and symptom burden have a significant impact on a patients' well-being during both treatment and their long-term adjustment (Holmes et al, 1997).

Unmet needs and Health related Quality of Life

Two conceptually different morbidity outcomes, unmet needs and health-related quality of life (HRQOL), are used to identify cancer patients in need of clinical attention. Hansen et al (Hansen et al, 2012) have confirmed that patient-perceived unmet needs during cancer rehabilitation are associated with decreased quality of life (QOL), advocating the use of questions to identify unmet clinical needs in patients. This is confirmed elsewhere in the literature, which has found that cancer patients experience significantly more psychological, interpersonal, health policy and system difficulties and other problems of living [Hansen et al (2012), Welch-McCaffrey et al (1989)]. It is possible to measure psychological adaptation to breast cancer by assessing quality of life, satisfaction with care, and needs; however, the needs assessment differs from the other constructs in that it directly identifies patients with higher levels of need, and suggests specific interventions for them [Bonevski et al (2000), Foot et al (1995), Park et al (2012)]. Evaluating a patient's psychological needs is important if we are to offer timely, effective interventions. Furthermore, Caucasian cancer patients report more unmet psychological needs [Lam et al (2011), Harrison et al (2009)], and require more psychological support.

Interventions based on specific unmet needs, could also result in less depression, and enhanced QOL among breast cancer survivors (Park et al, 2012). The same study concluded that needs diminish with advancing duration of survival; most needs are seen in survivors of

less than one year, followed by survivors of one to three years, with the least needs in long-term survivors (over five years since surgery) (Park et al, 2012). It is difficult to know if this is because over the five years patients are seen in an outpatient clinic and their needs are gradually identified or it is because the patients come to terms with the issues and put up with functional or emotional disability. Consequently, earlier psychosocial interventions that aim to meet unmet needs, may improve the overall QOL of breast cancer patients.

The doctor-patient relationship and areas of conflict

Recognition of the importance of specific aspects of the doctor-patient relationship in breast cancer is evidenced in NICE guidance. The statement *"Members of the breast care team - particularly those providing direct clinical care - should have special training in communication and counselling skills,"* emphasises a new role for the clinician. Clinical care is important but this should be provided as part of a holistic approach that is delivered appropriately at different stages of the cancer journey.

Failing to address core patient needs often results in conflict in the doctor patient relationship. However, empirical research suggests that the extent to which the needs of breast cancer patients are met by their doctors varies considerably. A review of the literature reveals that the most significant area of conflict surrounds the decisions that are made about treatment. In a study conducted by Fagerlin et al (Fagerlin et al, 2006), 50 per cent of surgeons who were surveyed reported conflict with patients over decisions about different options for surgical treatment. However, the findings suggest that clinical experience affects individual perceptions of the nature of the conflict, with high volume surgeons being more likely to experience conflict. This higher incidence of conflict may be because such surgeons are more likely to favour breast-conserving surgery (BCS), whereas patients tend to prefer complete mastectomy due to concerns about cancer recurrence.

Lobb et al (2001) who conducted a series of interviews with doctors and breast cancer patients expand upon these ideas. They conclude that much of the conflict concerning treatment options can be traced to the failure of doctors to provide patients with relevant information about their treatment options. This results in many patients obtaining information about breast surgery options from the popular media, and from family and friends, which may not provide a balanced view of the benefits and risks of different treatment options in their specific cases. Wen and Gustafson (2004) support this, finding that just 50 % of women undergoing treatment were aware that both BCS and mastectomy

resulted in equal survival rates. After a breast cancer diagnosis the patient is faced with a plethora of life changing decisions. Often the decision favouring a mastectomy is based on society perceptions since often it is seen as a way to "take it all out as quickly as possible." These perceptions can lead women to prefer mastectomy even when their surgeons don't, resulting in conflict that could be easily avoided by better discussion of the options available.

Breast cancer patients may also have cause to complain about the failure of doctors to empathise with the experience of their patients. In particular, almost 60 per cent of breast cancer patients surveyed by Opatt et al (Opatt et al, 2007) felt that their doctors did not attempt to ask them about their emotional needs, or to address their anxieties about treatment. One patient who was interviewed in this study stated that she often felt that her doctor was impatient when dealing with her queries about treatment, and made her feel that her questions were not warranted. This is supported by Siminoff et al (Siminoff et al, 2000) who argues that the presence of specific characteristics in the patient-doctor relationship are more likely to reduce conflict. In particular, those breast cancer patients with a higher level of participation, and who spoke more when interacting with their doctor, were typically more knowledgeable about their cancer and consequently experienced higher levels of satisfaction. In contrast, those patients who asked more questions of their doctor were less likely to experience satisfaction – this has been attributed to the fact that many of these women had conducted independent research prior to the visit and therefore had higher expectations of their doctor that were not met. Interestingly, the results of the research suggest that those doctors who used more affective utterances (specifically, phrases which focused on the emotions of their patients) were more likely to have satisfied patients.

The patient-doctor interaction may have a direct bearing, not only on patient satisfaction, but also on the patient's sense of regret. In their study, Siminoff et al (Siminoff et al, 2000) indicated that patients who spoke more were significantly less likely to feel conflicted or regretful about their decisions. It is clear, therefore, that the avoidance of patient-doctor conflict is dependent on the extent to which doctors are capable of meeting both the information and psychosocial needs of their patients.

Resolving conflict and meeting needs in the doctor patient relationship

Most studies in this area suggest that conflict in the doctor-patient relationship can be resolved if doctors display greater empathy, thereby establishing shared understanding with their patients. Halpern (2007) defines this as exhibiting 'engaged curiosity' about the emotional state of their patient, arguing that this can be achieved if physicians become more

self-aware and more adept at recognising their own emotions, and the sources of any negative feelings. Lobb et al (2001) expand on this, and argue that doctors need to listen deliberately for the emotional concerns that patients may have, and which may be obscured by their concrete clinical demands. Indeed, many clinicians tend to focus their attention on the clinical facts presented by patients, rather than on the emotional meanings that often underpin their words.

Aside from the importance of engaging in empathetic communication with patients, Wen and Gustafson (2004) also argue that physicians need to be careful to ensure that their patients are regularly updated on their available treatment options at all stages of their relationship. It is also essential for doctors to have a detailed discussion with their patient when the diagnosis is made in order to establish what information needs the patient has, and to determine the extent to which the patient wants to collaborate in the decision making process. Although research suggests that the majority of patients want to take an active role in decision-making, this is not true of all patients. Recognising the individual characteristics and specific requirements of patients is an important step towards reducing conflict in the patient-doctor relationship (Siminoff et al, 2000).

Hanson Frost et al (2000) expand upon this theme, suggesting that all clinicians should be provided with tools to make them capable of improving informed decision making, even within practice settings where it is possible for patients to gain access to several clinicians. An example of one such tool is a decision board, where it is possible for patients to understand the range of treatment choices available for the local therapy of breast cancer. The results of a randomised trial conducted by Hanson Frost et al (2000) revealed that the use of the decision board was associated with significantly lower levels of decisional conflict between the patient and the doctor, with a higher level of patient knowledge and satisfaction. The use of the board also meant that patients were significantly more likely to opt for BCS when compared to those patients who did not use the board. Although there are fundamental differences, a breast cancer specific patient concerns inventory (PCI) may result in similarly reduced levels of conflict by providing a patient 'platform' that quantifies the specific issues occurring along the cancer journey.

Clinician communication skills and patient experience

The quality of the patient-doctor interaction, rather than the frequency and length of consultation appears to have the greatest effect on patient reported outcomes (PROs) (Tan et al, 2011). Although one might expect a positive outcome, such as a reduction in treatment

related symptoms, this is not necessarily the case. Tan et al (2011) report that as patients discussed and sought information from their physicians at baseline, about their cancer treatment, quality of life, and other cancer-related issues, there was a tendency for patients to report a greater number of cancer-related issues the following year. Elsewhere, the collection of health-related quality of life data from patients has led to a better subsequent quality of life and emotional functioning (Velikova et al, 2004). In a study by Detmar et al (2002), the use of patient-reported quality of life assessments during consultations, led to a greater percentage of patients identifying moderate to severe problems in various health domains. Conversely, Stark et al (2004) observed that anxiety could be exacerbated through medical discussions. Unidentified concerns during review appointments can build up and develop into significant problems later on, long after the cancer treatment has ended. Patient satisfaction with the consultation depends on their perception of a given doctor's interpersonal and clinical skills. The persistent failure of the clinician to recognise issues may affect the patients' confidence levels towards the treating team, and to the treatment options offered.

We know from both the literature, and clinical experience that good communication skills are crucial in the clinical care of women with breast cancer [Fallowfield et al (1999), Maguire et al (1999)]. However, it appears that the relationship of a patient's experience to a clinician's communication skills is much more complex. Patients with cancer want a relationship with their doctors [Jefford et al (2002), McWilliam et al (2000), Butow et al (2002); this relationship is a dynamic process that can be affected by the clinician's communication skills. Communication skills can be enhanced by training but in doing so, may not always improve patient experience (Fallowfield et al, 1999). It appears that patients primarily want information to maintain hope and trust throughout the cancer journey [Hulsman et al (2002), Leyden et al (2000)]. A central feature of effective therapeutic relationships is mutual communication: a non-judgmental, inclusive orientation towards the other person [Hack et al (2005), Feldman-Steward et al (2005), Kreps G (1998), Roter DL (2000). Good quality oncologist-patient communication should serve as an information exchange platform that takes into account the relational needs of patients (Hack et al, 2005). Early research into cancer communication and the patient-doctor relationship, described patterns of information exchange with a clear dominance of talk by clinicians [Kaplan et al (1989), Siminoff et al (2006), Butow et al (1997), Nussbaum et al (2003). Effective patient-centred communication is dependent on both the clinician's expressed recognition of the patient's needs, as well as the communication of complex medical information (Step et al, 2009). In the context of communication between the head and neck cancer patient and

clinician, a head and neck cancer Patient Concerns Inventory has been developed (Rogers et al, 2009).

The Patient Concerns Inventory (PCI)

Patient symptom checklists are tools that may aid the early identification of symptoms that if they remained unidentified they may place patients at risk and may affect their health related quality of life (Mitchell AJ, 2007). The PCI concept, initially developed by Professor Rogers (Rogers et al, 2009) at the Merseyside Head and Neck cancer centre in partnership with the evidence based practice unit of Edge Hill University, started as a checklist for use with head and neck cancer patients. The PCI was developed due to the inherent limitations of existing HRQOL questionnaires: the number of domains and items, their wording, and the scoring systems used, as well as their limited ability to inform clinical consultations.

The use of the PCI in Head and neck cancer

In head and neck cancer the use of a PCI (Rogers et al, 2009) helps to focus consultations onto patient need, and to promote multidisciplinary care. The purpose of the head and neck PCI is to identify concerns that patients would like to discuss during their consultation, covering a range of issues including: hearing, intimacy, fatigue, finance/benefits, percutaneous endoscopic gastrostomy (PEG) tubes, relationships, regret, support for family, and wound healing. A 28-week pilot study that ran from August 2007 with 123 patients using a touch-screen computer looked at this in more detail (Rogers et al, 2009). In this short questionnaire, in which the median time to complete was eight minutes, patients most frequently selected the following concerns: fear of recurrence (37 %), dental health/teeth (27 %), chewing (24 %), pain in the head/neck (20 %), fatigue/tiredness (19 %), saliva (18 %), and swallowing (18 %). The two multidisciplinary team members patients most commonly wished to see were also identified as the dentist (19 %) and the speech and language therapist (10 %). The vast majority felt the PCI made a difference (quite a bit/very much) to their consultation, as it made it ‘a bit more personal,’ ‘reminds them of the points they want discussed,’ and ‘allows the consultation to get straight to the point’. Although the PCI raised many disparate issues, it did not noticeably prolong the consultation.

The rationale for a breast cancer specific PCI

Since the merit of a PCI has been demonstrated in Head and Neck Cancer, it is important to explore the incorporation of this reliable and valid PRO tool [(Kanatas et al (2012), Flexen et al (2012), Rogers et al (2012), Ghazali et al (2013), Kanatas et al (2013)] in the management of other cancers. In patients with breast cancer for example, PRO tools exist, but even the best instruments do not address all of the important surgery-specific and

psychometric issues relevant to oncologic breast surgery patients (Jacobsen et al, 2005)). Issues like fatigue, anxiety, body image, sexuality, and upper-body limitations are some of the lingering factors that have a strong impact on the health related quality of life (HRQOL) following breast cancer diagnosis and treatment. While many women with early-stage breast cancer return to good levels of health, others struggle to regain their pre-cancer quality of life (QOL).

In breast cancer, there are several surgical and drug therapies available, each with similar survival rates, but different side effects that affect the HRQOL. Hence, an effective PCI instrument should support a patient tailored approach to identifying needs. A PCI is different to the current HRQOL questionnaires; it is designed with a practical intent, to be used in clinical practice to screen patients for concerns, before that information is used directly to inform communication and patient care. It does not generate a score that allows measurement and monitoring of issues over time. HRQOL questionnaires are designed as outcome measures that compare different groups of patients. Although there have been many studies using them in clinical practice, they are not specifically designed for clinical practice.

The National Comprehensive Cancer Network recommends a simple screening tool referred to as the distress thermometer (DT) (Mitchell AJ, 2007) which allows screening of large numbers of patients without the need for complex scoring. Such tools are available for holistic assessment but are neither specific to breast cancer, nor to the potential range of items reflected in the head and neck PCI. Although PCIs have been shown to be of clinical value in head and neck cancer patients, the value of such tools in breast cancer patients is not currently known. Hence, this current study seeks to develop a PCI for breast cancer patients and to undertake a preliminary evaluation of that PCI in a routine outpatient clinic.

PCI and the patient-doctor relationship

The implementation of successful symptom management relies on the appropriate exchange of information between a physician and patient. Patient self-efficacy during this interaction is a key component in the perceived ability of a patient to obtain medical information and attention regarding their chief medical concerns from their physicians (Maly et al, 2004). It has been suggested that vulnerable patient populations might receive suboptimal care due to a decreased sense of control over the health care process, and that this results in less confidence in their ability to get physicians to attend to their health concerns [Woodward et al (1987), Greene et al (1986). The PCI may play a role in empowering patients from this group, and may help to uncover disease or treatment-related symptoms that were previously unreported; thereby potentially enhancing a patient's QOL. The use of a PCI in breast cancer clinics could therefore increase patient self-efficacy within the patient–doctor encounter,

resulting in faster resolution of their symptoms. Regardless of who initiates the information exchange, it remains the doctor's awareness of common symptoms that provides the opportunity to discuss treatment options and ultimately treat them.

Recently, studies have emerged in breast cancer patients investigating whether differences in patient-doctor communication could impact on the prevalence and/or resolution of breast cancer related symptoms (Maly et al, 2010). Depression was highlighted to be the most common symptom reported by patients (66%), yet physicians were the least aware of it (26.3%); this is probably because doctors tend to focus on the details of cancer treatment during patient visits, and may overlook psychiatric symptoms (Maly et al, 2010). In addition, physicians may feel less well-equipped to deal with psychiatric issues than with medical problems [Valente et al (1994), Maguire P (1985). A breast specific PCI may be in a position to identify patients with depression and in need of more extensive evaluation and specific management.

Another area that is worthy of specific note in the patient-doctor interaction, is pain; a common symptom among breast cancer patients. It is documented in the literature that younger age and the presence of co-morbidity tends to be inversely associated with pain [Badger et al (2001), Boyar et al (2006). Further, a lack of information on pain management has been identified as a significant barrier against pain control among minority groups (Cleeland et al, 1997). Reluctance to report pain might lead to reduced physician awareness of the symptom, and therefore inadequate pain assessment and management. There are well documented differences in the communication between doctors and patients from ethnic minorities [Johnson et al (2004), Cooper et al (2003). These differences of care may contribute to disparities in health. A breast cancer specific PCI could play an important role in identifying patients with pain in low income and ethnic minority groups by an improvement in the quality of the patient-clinician interaction.

Pressures of time in routine outpatient clinics encourage a more tightly controlled doctor-centred consultation with less attention paid to the social and psychological aspects of a patient's illness (Howie et al, 1992). Potentially, the use of a breast cancer specific PCI will encourage a participative style in a clearly defined format that could reduce the time spent on consultations by identifying areas for attention more rapidly. Overall, this tool specifically targets the patient-clinician consultation, helping the clinician to identify themes that they may otherwise miss but in addition can help women feel listened to.

The PCI at key stages in a breast cancer patient's journey

Limited evidence suggests that patients are often unhappy with the care received at key transition periods in their care, particularly between the end of treatment and long-term

survivorship [Ganz et al (2004), Cox et al (2003), Gotay et al (1998)]. Patients in this group may, for example, feel let down after eagerly anticipating the end of their primary treatment, and may have specific concerns such as fear of recurrence (FOR) as well as sexual function and fertility [Gotay et al (1998), Northhouse et al (1981), Hodgkinson et al (2003), Hewitt et al (2007), Kim et al (2006), Connell et al (2006)]. The use of breast specific, or general HRQOL tools is a common method for recording the post-treatment sequelae, with several studies reporting that the most common concerns are psychological and social [Ganz et al (2002), Gotay et al (1998)]. However, HRQOL tools were developed to assess newly diagnosed patients and those receiving treatment; hence they may lack the ability to identify issues specific to long-term survivorship. In addition, when using HRQOL tools, it can be unclear to clinicians whether a specific item is a problem for which patients need help, as they are only required to select a score or to rate the presence and severity of an item (Armes et al, 2009); there is no need to qualify what have been recorded. Another aspect of breast cancer care that HRQOL tools have not been specifically designed for is the assessment of long-term hormonal treatment and its side effects. It has been reported that the use of hormonal therapy in patients is a significant predictor of unmet needs (Armes et al, 2009). The published literature also suggests that there is an association between FOR and psychological distress, with reduced QOL scores [Sneeuw et al (1992), Humphris et al (2008)]; for example, Armes et al (Armes et al, 2009) have reported that FOR is a significant predictor of unmet need, and that 30% to 50% of breast cancer survivors have unmet needs . Furthermore, cognitive behavioural therapy has been employed effectively to help patients with the negative effect posed by the threat of recurrence (Humphris et al, 2008). A breast cancer specific PCI may therefore be an important first step in the systematic assessment of patient need at key stages along the cancer journey. Furthermore, the breast cancer specific PCI may be better suited to capturing the concerns of these patient groups than HRQOL tools, allowing greater scope for clinicians to offer education and support.

What a needs assessment tool should be

In summary, we have seen that need is a difficult concept to define, and that breast cancer patients are a unique group with very specific needs. Moreover, it has been demonstrated that the tools currently used to assess need in breast cancer are insufficient in several key areas. Therefore, a new approach is needed, and learning from our positive experiences in head and neck cancer, a breast cancer specific PCI may be a more suitable and effective tool with which we can move forward.

A need assessment tool should be able to assess the gap between normative and perceived need (Carr et al, 1976). Here, normative need refers to what expert opinion based on research, defines as need; and, perceived need is defined as what people think their needs are, or feel their needs to be. Breast cancer specific supportive care needs assessment tools do exist, and have been used in patients [Skrutkowski et al (2011), Halkett et al (2007), Rapport et al (2006), Can et al (2004), McTavish et al (1995). However, methodological weaknesses during their development limit their general applicability, including small sample sizes, specific patient groups, and specific aspects such as positive adjustment following breast cancer (Boot et al, 2010). Also most of these have tended to focus on the identification of informational needs, and do not include aspects that seek to identify depression or FOR. In contrast, a PCI tool that is based on the experiences in head and neck cancer, allows for the ability to raise a variety of concerns and to direct the patient for appropriate care.

The breast cancer specific PCI should be a tool that can be used effectively in a busy clinical practice in order to identify patient concerns efficiently. In addition, it should act as a communication tool between clinicians and patients that can at least mitigate aspects such as a clinician's poor communication skills, or a patient's reluctance to voice their concerns. Finally, the tool must be easy to use so that it could be completed in primary care or online at home. These factors would ensure that the patient has a greater role in the management of their disease, as well as ensuring the maximum benefit for community based services. These aspects should be taken into consideration during the development of a breast specific PCI.

The next stage was the development of the PCI for breast cancer patients. The first consideration was the development of a suitable methodology, and this is presented in the next chapter.

CHAPTER 3. Methods Overview: Hypothesis and Study Design—a Four Phase "Proof of Concept" Study

This chapter aims to provide a summary of the methodology used throughout the thesis. First, the thesis objective and experimental hypothesis are stated with an overview of the thesis. Following this, the four-phase study design undertaken to generate the PCI is outlined. In this chapter, the various phases of the thesis, with the methodology used throughout, are outlined in detail. At the end of the chapter, the statistical analyses, together with the relevant ethical considerations used throughout the thesis, are presented.

Hypothesis and Specific objective

Hypothesis: Using a specifically developed PCI in clinical practice will help to identify patient concerns, improve consultations between professionals and patients, and help inform pathways for patients to follow so that their concerns are addressed.

Specific objective: To develop a PCI specific to breast cancer

Basic Study Format: A Four Phase Prospective Study

In order to help the reader, the four phases of this work are summarised below:

Phase 1: Identification of primary patient concerns

Step 1. Literature review and item generation (chapters 4 and 5)

Step 2. Input from clinicians (chapter 6)

Step 3. Input from patient focus groups (chapter 6)

Step 4. Input from national bodies (chapter 6)

Phase 2: A cross-sectional survey of breast cancer patients (chapter 7)

Phase 3: A before and after study introducing the breast PCI into a clinic. (chapter 8)

Phase 4: Interviews with Clinicians and specialist nurses (chapter 9)

Inclusion Criteria

Adult patients (over 18-years) with a history of either diagnosis or treatment for breast cancer were included (For non-English speakers, interpreters were provided in the clinic in line with current NHS practice)

Study Design

An observational study using quantitative and qualitative methods was undertaken. Phases 1 and 2 involved the development of a PCI tool that was suitable for use with breast cancer patients, and the measures supporting the face and content validity of the items. Phase 3 assessed the feasibility of the PCI through a before and after study. Phase 4 sought to gain the opinions of the professionals who used the PCI tool, and included interviews with the consultant that used the PCI, and two specialist nurses. Here follows a detailed summary of these phases; detailed information can be found by referring to the methods sections of the relevant chapters (Chapters 4—9).

Phase 1. *The generation of breast-specific PCI items in four steps:*

Step 1.

A structured literature review of HRQOL questionnaires specific to breast cancer was undertaken and a tabulated summary of the items raised in the measures constructed.

Step 2.

A sample of clinical specialists (n=10) were consented (Appendix 2A) and interviewed at breast oncology clinics in Leeds. They were asked a series of questions designed to identify common problems faced by breast cancer patients. This questionnaire (Appendix 2B) was based on the experiences of the principal investigator.

Step 3.

Patient recruitment for the focus groups occurred as follows: identification of eligible patients; approaching patients in clinic and providing preliminary information; provision of an information pack (Appendices 2C, 2D, and 2E); and, receiving informed consent.

Step 4.

Several national bodies were contacted, the background of the PCI was explained and they were asked to comment on the draft PCI arising from step 3. These included: The Heaven Foundation, Breast Cancer Campaign, and Yorkshire Cancer Research.

Phase 1 outcome measures

The outcome of this phase was the PCI tool, highlighting the most relevant concerns patients might wish to raise in outpatient clinics.

Phase 1 Analysis

The literature review generated a list of items that directly effected HRQOL, which facilitated item selection for the formation of a core PCI. Relevant phrases and expressions were obtained from the items discussed by the focus groups, followed by an initial qualitative reduction of the identified sentences, in which inappropriate, ambiguous, or redundant expressions, were excluded. To make them suitable for use in a questionnaire, some statements needed to be reworded.

Phase 2. *A cross-sectional survey of breast cancer patients receiving treatment in two National Health Service Hospitals.*

This aimed to provide an indication of the relative frequency of individual PCI items and to compare clinical characteristics with the identified PCI items and established breast cancer HRQOL measures (EORTC C30 and BR23) (Appendix 2-F). Patients were identified and consented (Appendix 2-H) for participation by clinic staff, from the available clinic lists. Patients with a history of breast cancer were included, while those with cancer at other sites were excluded. The principal investigator then explained the rationale for the study and provided an information pack (Appendices 2-F, 2-G, 2-H, 2-I, and 2-O), and a letter was sent to their general practitioner (Appendix 2-J). If they agreed to take part the primary investigator collected socio-demographic and treatment data from their clinical files (Appendices 2-K, 2-L).

Phase 2 outcome measures

The PCI tool was assessed through a specific cross-sectional self-completed questionnaire. This allowed analysis of patient and clinical characteristics and their relationship to the PCI.

Phase 2 Analysis

A correlation analysis resulted from patients indicating which concerns they wanted to discuss during consultations (if they were to have one at that moment in time). There was also an opportunity for patients to comment on the PCI content itself and to suggest changes.

Phase 3. *A before and after study that introduced the breast PCI into a clinic.*

The aim was to evaluate the items raised in the consultation with a specific clinician, before and after the implementation of the PCI generated through phases 1 and 2. Patients were identified and consented for participation by clinic staff from the available clinic lists. The principal investigator then explained the rationale for the study and provided an information

pack. The outcome measures were compared between two different cohorts:

1. Cohort 1 - Patients attending clinic prior to the introduction of the PCI (the 'no PCI cohort'; n=25)
2. Cohort 2 - Patients attending clinic after the introduction of the PCI (the 'PCI cohort'; n=25)

Study Measures

1. A consultation questionnaire (Stewart el al, 1999 and 2001) was used to ask patients to consider their consultation. This involved nine questions, each with four options.
2. The PCI was used.

Phase 3 outcome measures

The outcomes that were recorded included: duration of consultations; items discussed in the consultation; any onward referrals made; and, patient satisfaction questionnaire scores.

Phase 3 analysis

A framework approach (Ritchie J, 1994) was used to analyse the transcribed recordings, and to chart the problems experienced by patients in answering each question. Based on the identified needs and suggestions from the interviews, modifications were applied to the questionnaire pack. Themes were identified and coded into discrete categories relating to the concern items, the healthcare professionals, and the type of clinical action or decision made during the consultation. Outcomes were classified as medical (e.g., treatment related) or non-medical (e.g., lifestyle advice). A second independent and skilled qualitative researcher assessed the transcripts and compared the conclusions. Statistical analysis was performed as detailed in the relevant section below.

Phase 4. *Semi-structured interviews with the clinician and the specialist nurses that used the PCI in the before and after study.*

Interviews took place in a breast cancer clinic with one oncologist, and two breast cancer specialist nurses. These members of the MDT were chosen pragmatically, given availability, as well as the need to record, transcribe, and analyse the interviews. The interviews were audio-recorded, and the perceived advantages and disadvantages of the PCI from the perspective of those MDT members were analysed.

Phase 4 outcome measures

The advantages or disadvantages of a PCI breast cancer specific tool as perceived by the clinical team using that tool.

Statistical Analysis

Data management:

Completed PCI results were entered into SPSS (Version 19.0). Data from the paper questionnaires was entered manually. Data analysis was carried out by the principal investigator with DL, who was a supervisor for the thesis and the statistician of the research team.

Audio transcripts:

Qualitative data was audio-recorded with a Tascam DR-40 (TEAC UK Ltd., Watford, UK) recorder. Consultations were recorded in their entirety and were saved in MP3 format; they were transcribed verbatim. All identifiable information was removed and anonymous identity codes were used to assure that the identity of participants was not revealed, thereby maintaining confidentiality.

Reliability and Validity:

Both the interview and focus group transcripts were independently assessed and discussed by the principal investigator with an experienced member of the supervising team (BR). The themes and sub-themes were identified in this discussion through consensus. This provided a degree of reliability. Validity was assured by ensuring lines of inquiry verified the accuracy and consistency of the responses.

Power:

Sample size justification for the qualitative elements of the study was between 8-10 patients per each focus group (Morse et al, 1994), in keeping with recommended practice.

The aim was that the total number of patients was 200 responders for the phase 2 cross-sectional survey. These figures were based on a literature review and retrospective audit of the experience obtained during the development of the head and neck PCI.

Phase 3 statistical analysis:

The Mann-Whitney test was used to compare Cohort 1 (no PCI) and Cohort 2 (with PCI) for distribution of responses to ordinal questions from the consultation questionnaire, and in the distribution of tumour staging and year of most recent diagnosis. Age was compared between cohorts using the two-sample t-test, whilst Fisher's exact test compared other characteristics. The chi-squared test compared responses to question 5 of the consultation questionnaire, which was non-ordinal.

Ethical considerations

This study was approved by the Leeds Central Research Ethics Committee and the Research and Development department of the Leeds Teaching Hospitals (REC: 11/YH/0245 and REC: 12/YH/0215).

All demographic and medical data collected in this study was anonymised and stored confidentially. Patients were given study ID numbers and no reference to personally identifiable information was made. Electronic data was stored on password protected, firewalled University computers. Hard copies of the data were stored in locked filing cabinets in research offices at St James's University Hospital. Only members of the research team had access to the anonymised data file.

Indemnity arrangements

Indemnity arrangements were place in the Department of Breast Oncology conforming to the requirements of the University of Liverpool and the Leeds Teaching Hospitals NHS Trust.

CHAPTER 4. Patient Reported Outcomes in Breast Oncology - A Review of Validated Outcome Instruments (Step 1 of Phase 1)

This chapter reviews the validated Patient Reported Outcome (PRO) tools that are currently in use, as the first step of the item identification process. This is essential for both practical purposes, and the need to include the methodology. The tools' contents are analysed in chapter 5, and items are subsequently identified and assessed for potential inclusion in the breast cancer specific PCI.

Abstract

Background

Patient-reported outcome measures (PROMs) offer the potential to improve the quality clinical care delivery. They may be used to assess levels of need in specific population groups and over time they can provide evidence of the outcomes for research and quality assurance. Reliable and valid PRO measures exist for use in breast cancer patients, but even the best instruments do not address important issues such as fatigue, anxiety, body image, sexuality, and upper-body limitations.

Aims and Objectives

This review aimed to identify PRO instruments relevant to the treatment of breast cancer, and to summarise instruments with evidence of validation in the breast cancer population.

Data sources

The following databases were examined: Medline, Ebase (Excerpta Medica), HAPI (Health and Psychosocial Instruments), Science Citation Index/Social Sciences Citation Index, Ovid Evidence Based Medicine databases, and PsychINFO

Study eligibility criteria

The selection process considered the following: studies where a principal tool was evaluated; studies that were evaluating several tools concurrently; clinical tool application with sufficient reporting of methodological issues; patient-reported instruments; any published evidence of measurement reliability, validity, or responsiveness; tools specifically developed using breast cancer patients; and, English language publications.

Results

In total, 323 papers were identified that described quality of life measures. Following the identification process, 15 instruments satisfied our inclusion criteria. These included the EORTC QOL –C30 (European Organization for Research and Treatment of Cancer Quality

of Life Questionnaire) with the QLQ-BR23 module (Breast Cancer Module), FACT-B (Functional Assessment of Cancer Therapy—Breast Cancer), and SLDS-BC (The Satisfaction with Life Domains Scale for Breast Cancer), as well as the BIBCQ (Body Image after Breast Cancer Questionnaire), the HIBS (Hopwood Body Image Scale), and PBIS (Polivy Body Image Scale). The MBROS (Michigan Breast Reconstruction Outcomes Study) Satisfaction and Body Image Questionnaires respectively, the BREAST-Q and the BCTOS (Breast Cancer Treatment Outcome Scale) were also included. The chemotherapy questionnaires the BCQ and the Breast Cancer Prevention Trial Symptom Checklist that related to the use of Tamoxifen. Other questionnaires were the FACT –ES and the MAS.

Limitations

Limitations were evident in most instruments. Current HRQOL tools lack the ability to capture all expected side effects of breast cancer treatment. Internal consistency estimates of reliability were adequate for research purposes in some tools, but the internal consistency were incompletely reported.

Recommendations

(1) To use validated instruments tailored for a particular clinical practice.

(2) To develop comprehensive surgical outcome measurements, requiring both objective and subjective measures.

(3) A scale incorporating both cancer-related QOL generalizability and breast cancer issue specificity as a compromise between the first two competing recommendations.

Introduction

The evolving nature of therapeutic interventions and their integration into the care of cancer patients have transformed the cancer journey. The disease now has many of the features of a chronic disease, as improved survival has led to a long-term focus on palliation [Rowland et al (2001), Velikova et al (2004)]. This change has brought about a new and growing demand upon cancer clinicians to identify and monitor the complex adverse effects of cancer treatment, and to include these in decision-making.

The term health related quality of life (HRQOL) in patients with a history of breast cancer represents their physical, psychological, and social response to the disease and its treatment. HRQOL assessments include measures of physical symptoms (pain, fatigue,

vomiting), physical functioning (e.g. mobility, self-care), emotional functioning (anxiety, depression, stress) and social and family functioning (Absolom et al, 2011).

More recently, the term Patient-reported outcomes (PROs) or Patient-reported Outcome Measurement (PROMs) was introduced by regulatory authorities (Department of Health; DoH, 2007), as a term designed to encompass any measure obtained directly from the patient including, not only aspects of the HRQOL, but also broader concepts such as patient satisfaction with care. Patient-reported HRQOL has also been found to predict response to treatment and survival in a number of advanced solid cancers [(Rogers SN (2010), Efficace et al (2006)]. More recently, PROMs have started to be used as quality indicators when assessing service delivery and the outcomes of different interventions in the National Health Service in the United Kingdom (DoH, 2007). Several tools have been used for the measurement of patient reported outcomes in patients with previous history of breast cancer (Chen et al, 2010). These tools may be used in clinical practice before treatment, during treatment or at different times following the completion of treatment. In addition, any member of the treating oncology team can deliver them in order to monitor closely the patients' care.

Reliable and valid PRO measures exist for use in breast cancer patients, but even the best instruments do not address all the important issues salient to breast cancer treatment (Jacobsen et al, 2005). Lingering factors strongly affect HRQOL following breast cancer diagnosis and treatment, including issues such as fatigue, anxiety, body image, sexuality, and upper-body limitations. Chen et al (2010) performed a systematic literature review to identify existing breast surgery specific PRO measures, and to assess their development and validation criteria; significant shortcomings were reported in terms of formal development and psychometric evaluation. A recent systematic review conducted by Pusic et al (Pusic et al, 2009) found that only seven out of 223 PRO measures used in studies of breast surgery had psychometric evidence to support their use in the breast cancer population. The reviews from Chen et al (2010) and Pusic et al (2009) are limited to breast cancer surgery-specific instruments.

The aim of this review was to address the following aspects:

1. Identify PRO instruments that are relevant to the treatment of breast cancer (surgery, chemotherapy, and radiotherapy)

2. Review the instruments with evidence of validation in the breast cancer population

Materials and Methods

The topic ‘‘quality of life measurement following treatment for breast cancer’’ was explored. A search strategy was devised using the following key terms: ‘breast oncology’, ‘breast surgery’, ‘lumpectomy’, ‘breast conservation’, ‘breast conserving surgery’, ‘breast chemotherapy’, ‘breast radiotherapy’, ‘mastectomy’, ‘breast reconstruction’, ‘patient reported outcomes’, ‘questionnaires’, ‘quality of life’, ‘validated instruments’ and ‘patient satisfaction’. The following databases were examined independently by the primary investigator and verified by another member of the research team: Medline, Ebase (Excerpta Medica), HAPI (Health and Psychosocial Instruments), Science Citation Index/Social Sciences Citation Index, Ovid Evidence Based Medicine databases, and PsychINFO. Taking into account the time and resource limitations during a research degree, only manuscripts written in English were included. There was no time limit for the search. All instruments included in the review were identified as PRO measures measuring breast-related quality of life and/or satisfaction that had undergone development and validation with breast oncology patients. This was ensured because subsequent phases of this work the items included from the validated instruments would be closely examined to identify issues that could potentially affect inclusion in the breast cancer specific PCI. The minimum standard of appraisal of the psychometric and operational performance of the instruments involved looking for evidence of validity, reliability, and responsiveness criteria (Table 1, appendix 1). Validity is defined as an assessment of the extent to which it measures what it purports to measure; reliability is defined as the extent to which the instrument is free from random error; and, responsiveness is defined as he ability of the instrument to detect changes over time. Rather than setting a standard value for inclusion, the processes of development of the instruments were examined for evidence that their validity had been assessed. Similarly, evidence that the reliability of an instrument had been assessed was sought, rather than setting a cut-off value for the reliability coefficient (not always reported). The primary investigator obtained all data from the papers (tables 2 and 3), which were independently assessed by an experience member of the research team using the modified proforma described by Smith et al. (2005). The final short-listing of promising PROMs to formulate recommendations was based on these assessments and on discussion between reviewers. The evidence regarding validity, reliability, and responsiveness are presented in table 2.

In summary:

Selection by study design

- Studies where a principal tool is being evaluated;
- Any studies that were evaluating several tools concurrently;
- Clinical application of tools with sufficient reporting of methodological issues.

Specific inclusion criteria for disease-specific instruments

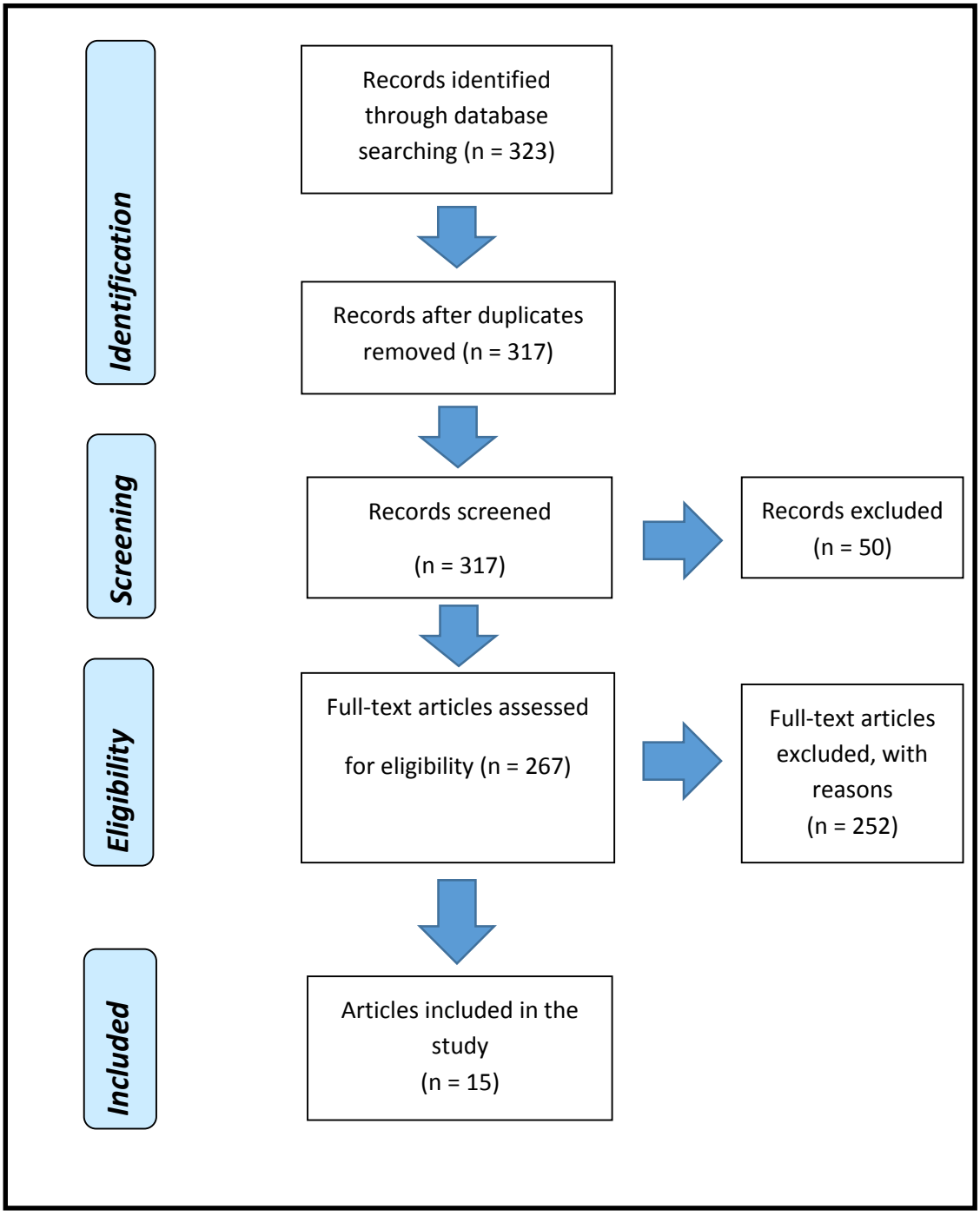
- The instrument was patient-reported;
- Any published evidence of measurement reliability, validity or responsiveness
- Tools specifically developed with breast cancer patients
- English language publications

Results

In total, 323 papers were identified that described quality of life measures. All articles were retrieved in full. Once the non-English manuscripts and editorials were excluded, 267 relevant papers indicated in their abstract and methods that they used quality of life instruments. Following a close examination, 196 studies included quality of life tools to describe and compare patient groups, but did not describe aspects that would specifically support the validity, reliability, and responsiveness of the tools. A further 56 papers were subsequently identified and excluded. Although these stated that the PRO that they employed was validated and reliable, it was not possible to obtain specific details (such as the patient groups and their characteristics) that would satisfy the inclusion criteria. Some of the PRO tools in these 56 papers were later found to be validated through specific evidence of reliability and validity in the remaining 15 papers comprising this review.

The identification process highlighted 15 instruments (Tables 2 and 3, Appendix 1) that satisfied the inclusion criteria. These were described from the following authors: Pusic et al (2009), Levine et al (1988), Fallowfield et al (1999), Feather et al (1988), Sprangers et al (1996), Aaronson et al (1993), Brady et al (1997), Baxter et al (2006), Polivy J (1977), Hopwood et al (2001), Stanton et al (2001), Alderman et al (2000), Wilkins et al (2000), Spagnola et al (2003), and Ganz et al (1995). The summary of the paper identification process is presented in Figure 2.

Figure 2 Search results included in the review



Three general quality of life questionnaires were included: EORTC QOL –C30 (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire) (Aaronson et al, 1993) with the QLQ-BR23 module (Breast Cancer Module) (Sprangers et al, 1996); FACT-B (Functional Assessment of Cancer Therapy—Breast Cancer) (Brady et al, 1997); and, SLDS-BC (The Satisfaction with Life Domains Scale for Breast Cancer) (Spagnola et al, 2003).

EORTC QLQ-BR23 and QOL-C30

This module was developed by the EORTC consisting of 23 items and covering symptoms as well as side effects related to different treatment modalities, body image, sexuality, and future perspective (Sprangers et al, 1996). The assessment comprises of five domains: body image, sexuality, arm symptoms, breast symptoms, and side effects of systemic therapy (Perry et al, 2007). The subscale measuring body image includes only four items and does not measure a multidimensional construct of body image (Baxter et al, 2006). According to Sprangers et al (Sprangers et al, 1996), the QLQ-BR23 can therefore not be recommended as a freestanding instrument for assessing the QOL of breast cancer patients, but rather should be administered in conjunction with the core instrument – the QLQ-C30. The QLQ-C30 was developed as a cancer-specific quality of life questionnaire. It has 30 items that form five functional scales, a global quality of life scale, three symptom scales, five single-item symptom measures, and one financial impact question (Baxter et al, 2006). The assessment comprises nine domains: physical, role, cognitive, emotional, social, fatigue, pain, nausea, and vomiting (Perry et al, 2007). Extensive psychometric analysis was conducted and showed adequate reliability, clinical and cross-cultural validity, and sensitivity to change over time (Chen et al, 2010).

The Functional Assessment of Cancer Therapy – Breast Cancer (FACT B)

The FACT- B is a 44-item questionnaire designed to measure multidimensional quality of life in patients with breast cancer (Chen et al, 2010).The assessment comprises six domains: physical well-being, social/family well-being, relationship with doctor, emotional well-being, functional well-being, and additional concerns (Perry et al, 2007). In its third version, the FACT-B incorporates the FACT-General (FACT-G) with five subscales: physical, functional, social/family and emotional well-being and satisfaction with doctors (Burckhardt et al, 2005). It includes the Breast Cancer Subscale (BCS), which complements the general scale with items specific to QOL in breast cancer (Brady et al, 1997). Brady et al (1997) conclude that FACT-B is reliable, relates to similar measures in an expected pattern, and performs as predicted in relation to change in clinical status over time. The FACT-B was created with an emphasis on patients' values and brevity. It is written at the sixth-grade reading level, takes approximately 10 minutes to complete. Its psychometric properties, brevity, and relevance to patients' values make its suitable for use in both research and clinical settings. The instrument was validated and underwent extensive psychometric analysis. Significant sensitivity to change in performance status and quality of life was demonstrated in two validation samples totalling 342 patients. Internal consistency reliability was high (Cronbach’s alpha 0.90). Evidence supported test-retest reliability, as well as convergent, divergent, and known group validity.

The Satisfaction with Life Domains Scale for Breast Cancer (SLDS-BC)

The Satisfaction with Life Domains Scale for Breast Cancer (SLDS-BC) is a reliable and valid scale that aims to assess QOL throughout the various phases of patient care (Spagnola et al, 2003). In comparison to the FACT-B, it offers a more user-friendly format that can assess QOL across the continuum of breast cancer care in the clinical setting.

Body image related questionnaires included the BIBCQ (Body Image after Breast Cancer Questionnaire) (Baxter et al, 2006), the HIBS (Hopwood Body Image Scale) (Hopwood et al, 2001), and PBIS (Polivy Body Image Scale) (Polivy J, 1977).

The Body Image after Breast Cancer Questionnaire (BIBCQ)

The Body Image after Breast Cancer Questionnaire (BIBCQ) was designed specifically to measure the long-term impact of breast cancer on body image in a multidimensional fashion. It is a 53-item questionnaire with six optional items specific to women with two breasts, and two optional items specific to women missing one or both breasts. The BIBCQ is easy to complete, requiring less than 10 minutes, and is acceptable to the relevant patient population (Baxter et al, 2006). Results from studies developed in Toronto, Canada by Baxter et al (2006) indicate that the BIBCQ is quantifiable and has been shown to be reliable, having minimal measurement error due to item sampling (internal consistency) and adequate reproducibility in stable populations (test-retest reliability. However, validation of the BIBCQ will be an ongoing process and further testing is required. The authors suggest that the use of the BIBCQ should be considered in the evaluation of various forms of treatment of breast cancer, when a substantial impact on body image is expected.

Hopwood Body Image Scale (HBIS)

HBIS is a 10-item questionnaire developed in conjunction with the EORTC to assess body image changes in patients with cancer (Hopwood et al, 2001). It was designed for use as a module, with the methodology not relying on a particular theoretical model, and there being no consensus on the definition of body image disturbance. Instead, the authors took a patient-focused approach to form the basis of the development of cancer-specific QOL scales (Hopewood et al, 2001). From pilot testing to final revision, the instrument underwent psychometric testing using data sets from seven treatment trials and clinical studies. It showed adequate reliability, clinical validity, discriminant reliability, and consistency of scores between different breast cancer treatment centres. Although considered psychometrically robust, the setting of a threshold is problematic as there are no agreed

diagnostic criteria for body image disturbance or standardized interview assessments (Hopwood et al, 2001).

Polivy Body Image Scale (PBIS)

PBIS is a self-concept scale developed in 1977, and is designed to measure perceptions of the self in relation to other people (Reaby et al, 1994). It is a 13-item questionnaire, which measures the psychological effects of mastectomy on breast cancer patients. It covers three domains: body image, self-concept, and feelings of satisfaction with intimate relationships. Several studies have demonstrated internal consistency (Reaby et al, 1994).

Breast Reconstruction-specific Questionnaires including the breast conserving treatment and radiotherapy questionnaires: we have identified the MBROS (Michigan Breast Reconstruction Outcomes Study) Satisfaction and Body Image Questionnaires respectively [Alderman et al (2000), Wilkins et al (2000), the BREAST-Q (Pusic et al (2009) and the BCTOS (Breast Cancer Treatment Outcome Scale) (Pusic et al, 2009).

Michigan Breast Reconstruction Outcomes Study (MBROS) Satisfaction Questionnaire

This is a 7-item instrument, which assesses patient satisfaction after breast reconstruction. Alderman et al (Alderman et al, 2000) used this instrument a postoperative questionnaire measuring General Satisfaction and Aesthetic Satisfaction with reconstruction among women undergoing first-time mastectomy reconstructions with expander/implant, pedicle transverse rectus abdominis muscle (TRAM) flap, and free TRAM flap techniques. Using a five-point Likert scale, item responses were scored ranging from very satisfied to very dissatisfied. Items were generated by an expert panel without patient interviews, and formal item reduction was not performed.

MBROS Body Image Questionnaire

This is a 9-item questionnaire developed to evaluate patient perceptions of physical appearance after breast reconstruction. An expert panel generated items without patient interviews, and formal item reduction was not performed. However, Cronbach's alpha was measured to be at 0.89, indicating adequate internal consistency for the single construct of body image. The psychometric battery of instruments used in the Michigan Breast Reconstruction Outcome Study (Body Image) included two previously published, health-related quality of life surveys: the Medical Outcome Study Short Form-36 (SF-36) and FACT-B (Wilkins et al, 2000).

BREAST-Q

The Breast-Q is a new PRO questionnaire designed to measure satisfaction and surgery-related quality of life in patients undergoing mastectomy with or without reconstruction. The development of the Breast-Q follows PRO measurement guidelines and criteria: Phase 1 – Conceptual Framework Formation; Phase 1-B – Item Generation, Preliminary Scale Formation, and Pretesting; Phase 2 – Field Testing, Final Scale Generation, and Psychometric Evaluation, using the Rasch Measurement Psychometric Analysis to guide scale construction (Pusic et al, 2009). Cronbach's alphas for the scales ranged from 0.81 to 0.98. Its test-retest reliability as measured by the intraclass correlation coefficient, ranged from 0.85 to 0.98 (Chen et al, 2010), suggesting the stability of scale (Pusic et al, 2009).

Breast Cancer Treatment Outcome Scale (BCTOS)

The BCTOS has been developed to assess patients' perceptions of cosmetic and functional outcomes of treatments for breast cancer (Stanton et al, 2001). Aesthetic and functional outcome seems to be closely related to QOL. A significant limitation is that it does not apply to women with bilateral disease.

As far as chemotherapy questionnaires the BCQ, which is related specifically to chemotherapy only (Levine et al, 1998) has been included and the Breast Cancer Prevention Trial Symptom Checklist that related to the use of Tamoxifen. Other questionnaires that may be included are the FACT –ES, which is relevant to endocrine issues (Fallowfield et al, 1999), and the MAS, a 10-page questionnaire with significant practical problems in clinical practice (Feather et al, 1988).

Breast Cancer Chemotherapy Questionnaire (BCQ)

This is an outcome measure used in clinical trials of adjuvant chemotherapy in women with stage II breast cancer (Levine et al, 1988). The BCQ consists of 30 questions that focus on loss of attractiveness, fatigue, physical symptoms, inconvenience, emotional distress, and feelings of hope and support from others. The direct evaluation of the BCQ with its comparison with the Spitzer, Karnofsky, and Rand instruments revealed that the BCQ correlated more strongly with global ratings of both physical and emotional function in patients and physicians, than the other instruments. The BCQ is a valid and responsive method of assessing treatment-related morbidity in patients receiving adjuvant chemotherapy for stage II breast cancer (Levine et al, 1988).

Functional Assessment of Cancer Therapy – Endocrine System (FACT-ES)

The FACT-ES is an 18-item self-administered questionnaire, usually administered with the FACT-B, focusing on endocrine concerns experienced during breast cancer treatment.

Mastectomy Attitude Scale (MAS)

This 33-item scale was designed to assess the attitudes and expectations of post-mastectomy breast cancer patients regarding adjustment to mastectomy (Feather et al, 1988).

Breast Cancer Prevention Trial Symptom Checklist (BCPT)

The BCPT [Ganz et al (1995), Day et al (1999)] is a 43-item self-administered questionnaire designed to examine the physical and psychological symptoms associated with the menopause and Tamoxifen usage. This questionnaire seeks to identify eight symptoms (hot flashes, nausea, bladder control, vaginal problems, musculoskeletal pain, cognitive problems, weight problems, and arm problems).

Discussion

In order to appreciate fully the impact of breast surgery in oncology, data from well-validated disease specific PRO instruments is essential. There is a need to determine which therapies are safe to use alongside conventional treatments and whether they are effective in alleviating treatment side effects and improving wellbeing. Such information would be useful for both local commissioners and breast cancer survivors wishing to make an informed choice about the provision and use of available therapies. Understanding the effect of breast cancer treatment on a patient's QOL has been a central clinical and research question (Perry et al, 2007). There are conflicting reports in the health care literature regarding the psychological effects of mastectomy (Reaby et al, 1994). For instance, traditional surgical outcomes centred on morbidity and mortality remain imperative, but are no longer sufficient on their own (Pusic et al, 2007) due to the high degree of individual variation in women's' adjustment to the disfigurement produced by mastectomy (Reaby et al, 1994). Therefore, is perhaps unavoidable that there is a propensity to use patient *ad hoc* questionnaires that have not been formally tested to ask questions of patients (Pusic et al, 2007). Consequently, in terms of reliability, validity and reproducibility, the results obtained from breast cancer studies may be compromised if increasing numbers of informally developed PRO-questionnaires continue to be used (Chen et al, 2010). Psychometric qualities that may be examined in the evaluation of an instrument include acceptability, validity, reliability (including internal consistency and test—re-test reliability and

responsiveness [Fitzpatrick et al (2006), Stanton et al (2005)]. Questionnaire responsiveness in this study was defined as the ability of a scale to detect significant change over time, assessed by comparing scores before and after an intervention of known efficacy based on various methods including t-tests, effect sizes, standardised response means, or responsiveness statistics. The information available on questionnaire responsiveness in this study was scarce.

Like the QLQ-BR23, the FACT-B was designed for use in breast cancer patients at a range of disease stages, and undergoing different treatments (Sprangers et al, 1996). The EORTC QLQ-BR23 and the FACT-B are two well-developed instruments that have been extensively tested among breast cancer patients. However, these measures are nevertheless disease-specific rather than surgery specific, and their ability to detect changes brought about by surgical intervention is less. Furthermore, questions measuring HRQOL, body image, sexual functioning, or satisfaction with appearance are not well represented. In comparison to the QLQ-BR23, the FACT-B is shorter, covering fewer symptoms and treatment-related side effects (Sprangers et al, 1996). Although the questionnaires have been translated and validated in a number of languages, the breast cancer-specific questionnaires have not yet been validated cross-culturally. However, during their study, Sprangers et al (Sprangers et al, 1996) were able to obtain a degree of cross-cultural validity as evidenced by the similarity of the results across three samples in Spanish, Dutch, and American subjects; this further suggests the suitability of the QLQ-BR23 for use in international cancer clinical trials. In the literature, the BIBCQ and HBIS are considered as two of the best-developed measures (Chen et al, 2010). Never the less, the following limitations are notable: (1) failure to address fully, surgery-specific issues, particularly related to breast conserving surgery; and, (2) measures were largely developed without the aid of newer psychometric methods that enhance the questionnaire's ability to measure individual patient outcomes. Baxter et al (2006) are concerned about cross-cultural validation of the measure, which they recommend as necessary for use in different populations. Hence, further item generation and validation if the measure is observed as sensitive to change. The HBIS was developed along pragmatic guidelines thereby theoretical underpinnings are desirable in the construction of core QOL measures. Moreover, it leans more towards an affective-cognitive-behavioural model of body image disturbance. Thereby patients and health professionals generate items; this could result in several kinds of framework bases, for example using a cognitive-behavioural paradigm or subject-objective perception of body image disturbance.

On the other hand, the PBIS may actually address important issues, but has undergone a less rigorous development and psychometric evaluation. Reaby et al (1994) raised a similar view suggesting that the state of medical progress has a perceptional impact affecting test results

between certain periods. Surgical techniques in mastectomy have improved dramatically compared to the 1970's (Reaby et al, 1994) when the PBIS was designed and used, which was a time-when surgery could potentially cause more psychological and emotional repercussions. Therefore, some aspects of the hypothetical framework involved in the questionnaire design may no longer be relevant. For example, Reaby et al (1994) hypothesized that the control group would exhibit more positive self-perceptions, and that such a hypothesis would have been only remotely conceivable decades before.

Some of the instruments reviewed, such as the BCPT, are in need of further development. Limitations include that it lacks the ability to capture all expected side effects of breast cancer treatment, such as fatigue and breast-specific pain. Internal consistency estimates of reliability are adequate for research purposes, although the internal consistency estimates were somewhat lower for the nausea and weight problems scales, which might require further refinement (Stanton et al, 2005).

Both of the MBROS questionnaires (satisfaction and body Image) have addressed specific, important issues, but have undergone less rigorous development and psychometric evaluation. The major limitation of the MBROS questionnaires is the possibility of confounding bias inherent in the use of a prospective cohort design rather than a randomized controlled trial (Reaby et al, 1994). Furthermore, outcomes of reconstruction may be affected by an almost infinite variety of confounding variables, encompassing a wide range of patient, surgeon, and study site characteristics; no matter how well designed, a cohort study cannot control for all of these factors (Wilkins et al, 2000). Alderman et al (2006) however, contend they have controlled certain variables, which was a significant or nearly significant difference across the group. Nevertheless, they acknowledge the presence of other unsuspected independent variables that may impact upon patient satisfaction. Psychometric characteristics were available in detail for the BCQ and the Breast-Q outcome measures (Table 2, Appendix 1). The BREAST-Q was developed using a newer psychometric method called the Rasch Measurement Psychometric Analysis, which is considered pivotal in creating new instruments that are more clinically meaningful and psychometrically sound (Chen et al, 2005). However, during use of the questionnaire, Pusic et al (Pusic et al, 2009) note that the BREAST-Q has limitations. According to them, the validity and reliability of the BREAST-Q needs further validation and additional procedure-specific scales to establish their psychometric properties. Furthermore, the BREAST-Q is not considered valid for patient groups that were not represented in the development i.e., the North American population. Patient perceptions of outcomes in breast surgery are not independent of their cultural environment (Pusic et al, 2009).

Concluding remarks

This review provides a categorical distinction over which PRO measures, whether freestanding or for use in conjunction with a core instrument, are appropriate for a specific study objective. It is clear from the literature that many authors have not only stressed the importance of addressing surgery-specific issues, but have recommended the incorporation of newer psychometric methods to extend their clinical utility. Reflecting on how the original literature was presented, there were limitations to some of the discussions of the limitations with specific PRO test measures. This review has delivered additional scientific literature – enabling further discernment towards better tool selection or appropriateness, by highlighting not only the strengths and characteristics found in certain PRO measures, but also some of their weaknesses. Other than concerns encompassing psychometric validation, it is also evident that cross-cultural variations pose significant challenges that are unknown until the actual selection of the study setting has begun. Moreover, this weakness is evident in many of the PRO measures reviewed, particularly in those of body image and breast reconstruction. Therefore, suggestions for future directions can be made around three key points:

(1) To use validated instruments tailored for a particular clinical practice (Ganz et al, 1995).

(2) To develop a comprehensive measurement of surgical outcomes, requiring the combination of both objective and subjective measures (Burckhardt et al, 2005).

(3) A scale incorporating both generalizability in cancer-related QOL and specificity in breast cancer issues, as a compromise between these two competing considerations (Brady et al, 1997).

This review was undertaken to identify validated PRO measures, which in turn would help to identify the issues relevant to patients during their cancer journey. The issues derived from this chapter are presented and analysed in the next chapter. This review also aimed to identify and select a validated PRO measure that would be suitable for use with the breast cancer PCI in the cross-sectional study of phase 2, and that would help to validate the breast cancer PCI. The EORTC C30 with the BR23 module was selected for this purpose since this tool has been validated in breast cancer patients and has been successfully adapted by many clinicians and researchers worldwide. This therefore allows the data from this work to be compared with the many other studies that have used the EORTC. In addition, the practical aspects of using two tools together provided valuable experience in the use of both instruments when screening for patient issues in breast-cancer outpatient clinics. In the next chapter, the validated PRO items obtained, are presented in detail.

CHAPTER 5. Item Generation for the Breast Cancer Specific Patient Concerns Inventory (PCI) (Step 1 of Phase 1)

Several validated patient-reported outcome (PRO) tools were identified in chapter 4 through an extensive literature review. In this chapter, we progress from identification to content analysis of each of the tools, in order to identify suitable items for inclusion in the breast cancer specific patient concerns inventory (PCI). Details of the item reduction process are provided as part of the first step in Phase 1 of this work.

Introduction

There are several Health- Related-Quality of life (HRQOL) instruments available (Kanatas et al, 2012) in the breast cancer literature. This is a reflection of the notion that over 60% of survivors had their overall health affected by the diagnosis and treatment of breast cancer (Schultz et al, 2005). The physical effects of a breast cancer diagnosis and treatment have been described extensively [Girgis et al (2000), Hanson Frost et al (2000), and Raupach et al (2002)]. Hot flashes, night sweats, impaired sexual function, sleep disturbance and impaired ability to concentrate, are all features that commonly present after treatment of breast cancer [McPhail et al (2000), Hunter et al (2004)]. Anxiety, distress, depression, and fear of cancer recurrence are additional issues encountered in this group of patients [Kanatas et al (2012), Schultz et al (2005), Hanson Frost et al (2000), Hoskins et al (1997), Hodgkinson et al (2007)]. The information needs of women with breast cancer, as well as their effect on treatment decisions, are important features in the cancer journey that need to be taken into consideration if we are to ensure holistic care (Marlow et al, 2003). Indeed, at least 80% of breast cancer patients wanted as much information as possible, with only 16% wanting limited information in one study (Lobb et al, 2001). Taking these factors into account, this part of the thesis aimed to identify the concerns common to patients with a history of either diagnosis or treatment for breast cancer. In addition, we seek to categorise those concerns into subgroups, in order to assist the development of the breast cancer specific PCI.

Methodology

The process used to identify the PRO questionnaires used is detailed in the methods section of Chapter 4 (page 54—55). The details of the item identification and reduction process now follow. All PRO measures cited in the papers were assessed for evidence regarding their development and validation criteria. PRO measures without evidence of any development or validation process were excluded. The items were then arranged in subgroups as they appeared in the literature, with the identification of 164 items. The next step in the item generation was to review the concerns with the view to limiting the total number used in the final PCI; 164 concerns is a significant number for a patient to consider. As a result, they may either lose interest, or feel that the PCI is not worth their time, if presented with such a number of questions. Also, some of the items within the different questionnaires were worded similarly, and could be removed without loss of content. Although it was important to reduce the total number of items, it was still necessary to include every concern identified within the initial list of 164. Therefore, in this second stage of item generation, items were revised and grouped together with similar items. This way, the total number of items was decreased to 51. The process of removing and revising the items in the PCI is outlined in Figure 3.

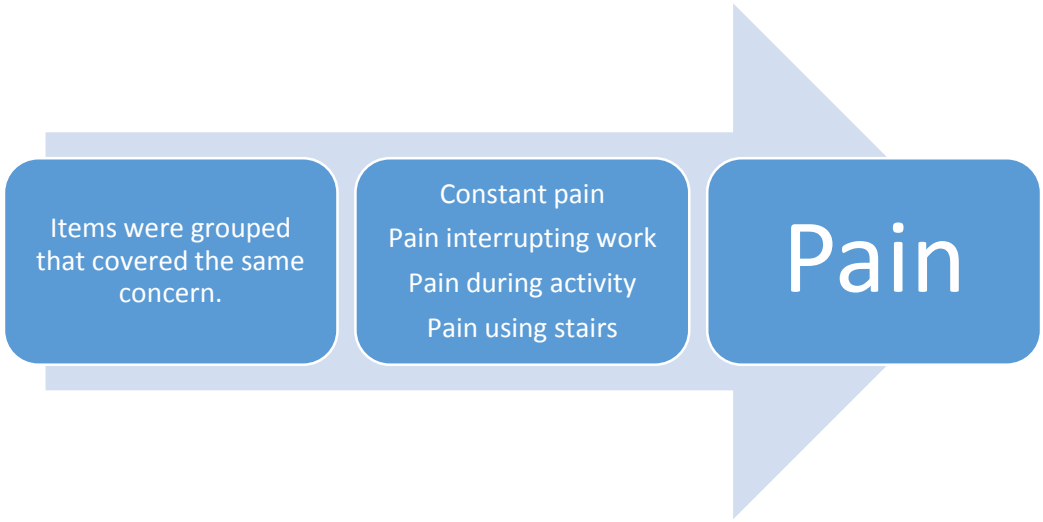


Figure 3 The process of removing and revising items in the PCI

The subgroups identified in the literature are included in Table 4 (Appendix 1). It was evident from the literature review that all of the validated tools contained specific items that are often grouped under one heading. For example: the body image specific tool (Hopewood et al, 2001) included only items relating to body image; Sprangers et al (1996) included

global quality of life domains as well as physical functioning and health-related domains; Baxter et al (2006) included sexual functioning as well as psychological state and emotional well-being related domains; and, Brady et al (1997) included social functioning and family related domains. As a result, the items derived from the various validated tools were grouped under these subheadings in the PCI. All other items, which were either non-specific information data, or which could not be accommodated in to one of the above groups, were organised under 'general information' in the first breast cancer PCI list. The number of specific items per subgroup is given in Table 5 (Appendix 1).

The final list of 51 concerns identified after the literature review and revision process, appear in Table 6 (Appendix 1). The second part of the PCI, listing the professionals that patients would like to consult with, was based on the following two factors: (1) the available Multidisciplinary Team members (MDT) for breast cancer; and, (2) the list available in the Head and Neck PCI (Table 6, Appendix 1).

Results

The items are presented below in six domains: (1) Global Quality of Life; (2) Body Image; (3) Physical Functioning and Health; (4) Psychological State and Emotional Well-Being; (5) Sexual Functioning; and, (6) Social Functioning and Family.

1. *Global Quality of life domains*

   During the past week, were you limited in doing either your work or other daily activity? (Sprangers et al, 1996)

   During the past week, were you limited in pursuing your hobbies or other leisure time activities? (Sprangers et al, 1996)

   During the past week, did pain interfere with your daily activities? (Sprangers et al, 1996)

   During the past week, have you had difficulty in concentrating on things, like reading a newspaper or watching television? (Sprangers et al, 1996)

   During the past week, have you had difficulty remembering things? (Sprangers et al, 1996)

   How would you rate your overall quality of life during the past week? (Sprangers et al, 1996)

During the past week, has your physical condition or treatment caused you financial difficulties? (Sprangers et al, 1996)

During the past week, did you feel ill or unwell? (Sprangers et al, 1996)

I am content with the quality of my life right now. (Brady et al, 1997)

Would like to know more information about breast cancer? (Faether et al, 1988)

2. *Body image –related domains*

During the past week, have you lost any hair? (Sprangers et al, 1996)

During the past week, have you felt physically less attractive as a result of your disease or treatment? (Sprangers et al, 1996)

During the past week, have you been feeling less feminine as a result of your disease or treatment? (Sprangers et al, 1996)

During the past week, did you find it difficult to look at yourself naked? (Sprangers et al, 1996)

During the past week, have you been dissatisfied with your body? (Sprangers et al, 1996)

I avoid looking at my scars from breast surgery. (Baxter et al, 2006)

I am satisfied with the shape of my body. (Baxter et al, 2006)

I feel less feminine since cancer. (Baxter et al, 2006)

I like my body. (Baxter et al, 2006)

I feel comfortable about the way I look when exercise. (Baxter et al, 2006)

I would feel comfortable changing in a public change-room. (Baxter et al, 2006)

I feel my body has been invaded. (Baxter et al, 2006)

I am satisfied with the appearance of my arm. (Baxter et al, 2006)

I am satisfied with the appearance of my hips. (Baxter et al, 2006)

I am satisfied with the shape of my buttocks. (Baxter et al, 2006)

I feel comfortable looking at my mastectomy. (Baxter et al, 2006)

I am happy with the position of my nipple. (Baxter et al, 2006)

I feel satisfied with the size of my breast. (Baxter et al, 2006)

I feel comfortable when other see my breast. (Baxter et al, 2006)

The appearance of my breasts could disturb others. (Baxter et al, 2006)

I feel that people are looking at my breasts. (Baxter et al, 2006)

How satisfied are you with the way your breast looks? (Polivy J, 1997)

Have you been feeling self-conscious about your appearance? (Hopwood et al, 2001)

Have you felt less physically attractive as a result of your disease or treatment? (Hopwood et al, 2001)

Have you been dissatisfied with your appearance when dressed? (Hopwood et al, 2001)

Did you find it difficult to look at your self naked? (Hopwood et al, 2001)

Did you avoid people because of the way you felt about your appearance? (Hopwood et al, 2001)

Have you been feeling the treatment has left your body less whole? (Hopwood et al, 2001)

Have you been dissatisfied with your body? (Hopwood et al, 2001)

Have you been dissatisfied with the appearance of your scar? (Hopwood et al, 2001)

Is there a difference between the treated and untreated areas in terms of Breast size? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast texture (hardening)? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of nipple appearance? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast shape? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast elevation? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of scar tissue? (Stanton et al, 2005)

I am self-conscious about the way I dress. (Brady et al, 1997)

I am bothered by hair loss. (Brady et al, 1997)

How satisfied or dissatisfied have you been with how you look in the mirror clothed? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the shape of your reconstructed breasts when you are wearing a bra? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how normal you feel in your clothes? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the size of your reconstructed breasts? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with being able to wear clothing that is more fitted? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your breasts are lined up in relation to each other? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how comfortably your bras fit? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the softness of your reconstructed breasts? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how equal in size your breasts are to each other? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how natural your reconstructed breast looks? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how natural your reconstructed breast sits/hangs? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your reconstructed breast feels to touch? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how much your reconstructed breast feels like a natural part of your body? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how closely matched your breasts are to each other? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your reconstructed breast look now compared to before you had any surgery? (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how you look in the mirror unclothed? (Pusic et al, 2009)

3. *Physical Functioning and health-related domains*

During the past week, were you short of breath? (Sprangers et al, 1996)

During the past week, did you need to rest? (Sprangers et al, 1996)

During the past week, did you have trouble sleeping? (Sprangers et al, 1996)

During the past week, did you feel week? (Sprangers et al, 1996)

During the past week, have you had pain? (Sprangers et al, 1996)

During the past week, have you lacked appetite? (Sprangers et al, 1996)

During the past week, have you felt nauseated? (Sprangers et al, 1996)

During the past week, have you vomited? (Sprangers et al, 1996)

During the past week, have you felt constipated? (Sprangers et al, 1996)

During the past week, have you had diarrhoea? (Sprangers et al, 1996)

During the past week, were you tired? (Sprangers et al, 1996)

Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase? (Sprangers et al, 1996)

Do you have any trouble taking a long walk? (Sprangers et al, 1996)

Do you have any trouble taking a short walk outside of the house? (Sprangers et al, 1996)

Do you have to stay in bed or a chair for most of the day? (Sprangers et al, 1996)

Do you need help with eating, dressing, washing yourself or using the toilet? (Sprangers et al, 1996)

During the past week, did you have a dry mouth? (Sprangers et al, 1996)

During the past week, did food and drink taste different than usual? (Sprangers et al, 1996)

During the past week, were your eyes painful, irritated, or watery? (Sprangers et al, 1996)

During the past week, did you have hot flushes? (Sprangers et al, 1996)

During the past week, did you have any pain in your arm or shoulder? (Sprangers et al, 1996)

During the past week, did you have a swollen arm or hand? (Sprangers et al, 1996)

During the past week, was it difficult to raise your arm or to move it sideways? (Sprangers et al, 1996)

During the past week, have you had any pain in the area of your affected breast? (Sprangers et al, 1996)

During the past week, was the area of your affected breast swollen? (Sprangers et al, 1996)

During the past week, was the area of your affected breast oversensitive? (Sprangers et al, 1996)

During the past week, have you had skin problems on or in the area of your affected breast? (Sprangers et al, 1996)

I have a lack of energy. (Brady et al, 1997)

I have nausea. (Brady et al, 1997)

Because of my physical condition, I have trouble meeting the needs of my family. (Brady et al, 1997)

I have pain. (Brady eta al, 1997)

I am bothered by side effects of treatment. (Brady et al, 1997)

I feel ill. (Brady et al, 1997)

I am forced to spend time in bed. (Brady et al, 1997)

Skin dryness is a problem from me. (Baxter et al, 1988)

I can use my arm normally. (Baxter et al, 1988)

I try to hide my body. (Baxter et al, 1988)

I am sleepy during the day. (Baxter et al, 1988)

I am happy with my level of energy. (Baxter et al, 1988)

Is there a difference between the treated and untreated areas in terms of shoulder movement? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast pain? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of ability to lift objects? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast tenderness? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of shoulder stiffness? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast sensitivity? (Stanton et al, 2005)

Would like to know more information about personal hygiene/clothing/exercise? (Feather et al, 1988)

Would like to know more information about nutrition / weight control? (Feather et al, 1988)

Would like to know more information about prosthesis /clothing? (Feather et al, 1988)

One or both of my arms are swollen or tender. (Brady et al, 1997)

4. *Psychological state and emotional well-being-related domains*

During the past week, did you feel tense? (Sprangers et al, 1996)

During the past week, did you worry? (Sprangers et al, 1996)

During the past week, did you feel irritable? (Sprangers et al, 1996)

During the past week, did you feel depressed? (Sprangers et al, 1996)

During the past week if you lost any hair, were you upset by the loss of your hair? (Sprangers et al, 1996)

I feel sad (Brady et al, 1997)

I am proud of how I am coping with my illness. (Brady et al, 1997)

I am losing hope in the fight against my illness. (Brady et al, 1997)

I feel nervous. (Brady et al, 1997)

I worry about dying. (Brady et al, 1997)

I worry that my condition will get worse. (Brady et al, 1997)

I feel there is a time bomb inside me. (Baxter et al, 2006)

I feel prone to cancer. (Baxter et al, 2006)

I feel my body has let me down. (Baxter et al, 2006)

I feel part of me must remain hidden. (Baxter et al, 2006)

I am afraid of touching the scars from breast surgery. (Baxter et al, 2006)

I feel that something is taking over my body. (Baxter et al, 2006)

I worry that the cancer is spreading. (Baxter et al, 2006)

I worry about my body. (Baxter et al, 2006)

I worry about minor aches and pains. (Baxter et al, 2006)

I feel people can tell me my breasts are not normal. (Baxter et al, 2006)

I worry about my prosthesis or padding slipping. (Baxter et al, 2006)

I worry about the risk of cancer in other family members. (Brady et al, 1997)

I worry about the effect of stress on my illness. (Brady et al, 1997)

I am bothered by a change in weight. (Brady et al, 1997)

5. *Sexual Functioning*

During the past four weeks to what extent were you interested in sex? (Sprangers et al, 1996)

During the past four weeks to what extent were you sexually active? (Sprangers et al, 1996)

Have you been sexually active during the past year? (Brady et al, 1996)

I feel sexually attractive when I am nude. (Baxter et al, 2006)

I would keep my chest covered during sexual intimacy. (Baxter et al, 2006)

My breast is painful to touch. (Baxter et al, 2006)

Would like to know more information about sexual issues? (Feather et al, 1988)

I am satisfied with my sex life. (Wilkins et al, 2000)

6. *Social Functioning/ Family-related domains*

During the past week, has your condition or medical treatment interfered with your family? (Sprangers et al, 1996)

During the past week, has your physical condition or medical treatment interfered with your social activities? (Sprangers et al, 1996)

I am able to work. (Brady et al, 1997)

My work is fulfilling. (Brady et al, 1997)

I am able to enjoy life. (Brady et al, 1997)

I have accepted my illness. (Brady et al, 1997)

I am sleeping well. (Brady et al, 1997)

I am enjoying the things I usually do for fun. (Brady et al, 1997)

I feel distant from my friends. (Brady et al, 1997)

I get emotional support from my family. (Brady et al, 1997)

I get support from my friends and neighbours. (Brady et al, 1997)

My family has accepted my illness. (Brady et al, 1997)

Family communication about my illness is poor. (Brady et al, 1997)

I feel close to my partner. (Brady et al, 1997)

My body stops me from doing things I want to do. (Baxter et al, 2006)

Is there a difference between the treated and untreated areas in terms of fit of clothing? (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of fit of bra? (Stanton et al, 2005)

Would you like to know more information about social support? (Feather et al, 1988)

Conclusions and further development

In this chapter the issues faced by breast cancer patients, that form the basis of the breast cancer specific PCI, have been presented. The next stage in the PCI development involved presenting the list of concerns (Table 6, Appendix 1) to breast cancer surgeons, oncologists, consultants, specialist nurses and other health care professionals at Leeds Teaching Hospitals, UK (Step 2 of Phase 1). A presentation was given explaining the concept of the PCI, along with the list of PCI items. That list was scrutinised by attendees, and additions or deletions were discussed, along with the appropriateness of the item terminology. The subsequent list was presented to focus groups (Step 3 of Phase 1) and then to several national bodies (Step 4 of Phase 1), who were each asked to comment and further refine the PCI. Steps 2, 3, and 4 of phase 1 are discussed in the next chapter.

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CHAPTER 6. Further Development of the Breast Cancer Specific Patient Concerns Inventory (PCI)—Study Phase 1, Steps 2, 3, and 4: Input from Clinicians, Patient Focus Groups, and National Bodies

This chapter covers Steps 2, 3, and 4 of phase 1, and has been divided into three parts: input from clinicians (step 2), patient focus groups (step 3), and national bodies (step 4). The first part includes a summary of the input from clinicians. The second part provides an explanation of the use of focus groups in the development of the instrument. The third part provides specific information of the input from National bodies related to breast cancer and the utilisation of their experience in the identification of specific patient issues.

Phase 1—Step 2: Input from clinicians in the development of the PCI

Once a list of issues was constructed, it was taken to the breast cancer clinic and given to the clinicians involved in the treatment of patients with breast cancer. At that initial stage of development it was essential, to ensure that there was a need / desire for such instrument to be developed. Another aim was to ensure, that there were not any obvious practical issues that may be a hindrance to the long term use of this tool. Ultimately the use of such a tool is dependent on the perceived long term clinical and practical benefits by the clinicians. The advantage of this approach was that clinicians could provide some input on the relative frequency of the issues presented as well as being able to provide content information. Based on the experience form the development of the head and neck PCI a pragmatic sample of 10 clinicians were included. The clinicians were chosen based on their clinical interest and clinical experience. Four consultants were chosen from the Leeds Teaching Hospitals that were involved in the management of breast cancer patients and three surgical registrars (2 final year and one on his fourth year of training). Three specialist nurses with a minimum of ten years experience in the management of patients with breast cancer were included in this step. All clinicians that were asked agreed to participate initially. All clinicians were recruited from the Multidisciplinary Team.

Consent was obtained (Appendix 2-A)

For this part of the work, the initial aim was to use a series of questions (Appendix 2-B) that were developed based on the experience from the head and neck PCI, and a Likert like scale in order to assess every issue presented. The aim was for every interview to be recorded.

Results

This approach proved unrealistic in a busy NHS clinic and the input was more general than specific. One consultant agreed to be recorded in his clinic. All interviews were less than twenty minutes in duration. Reason for the clinician poor response was mainly the limited clinical time and the extensive workload. However the clinicians verified the relevance of these items in addition to the verification that list of issues was comprehensive and included items that they frequently encounter in an outpatient clinic. No items were added or removed.

Discussion

This part of the work provided clinician input for the development of the tool based largely on clinical experience. There are limitations in the methodology of this step. Clinicians can be reluctant to have their consultation recorded and this has been the experience from the literature using audio recordings of consultations (Tattersall et al, 2002). Also other practical issues were that the primary investigator is not a breast surgeon. Those proposed recordings were at the start of this work and there was minimal familiarisation of the primary investigator and the clinical team. The overall outcome from this step although helpful was not optimal. A common issue such as 'hot flushes' was somewhat missed and was not included until much further in the development of this tool. One of the reasons may have been that in a busy clinic the focus may be on the presence or absence of cancer recurrence rather than in issues that may not be immediately life threatening.

Phase 1—Step 3: The role of Focus groups in the development of the PCI

Focus groups are a frequently used group interview format that capitalises on the natural communication between research participants, in order to generate data (Kitzinger et al, 1994). Initially, focus groups were used as a marketing strategy and were designed to assess the desirability of a product, and to test responses to the way it was positioned prior to entering the market (Buchanan DR, 1992).These groups have also been used within the communication industry, to explore the effects of films and television programmes (Merton et al, 1956). However, focus groups can also be used to explore the patient experience in health services and identify consensus, in addition to providing a basic research tool that can contribute to the development of knowledge or theories [Patton MQ (1990), Beaudin et al (1996)].

The focus group approach has several distinct advantages in the healthcare setting. One of its most significant advantages is that it has the capacity to encourage an open conversation about embarrassing subjects. Other advantages include: it does not discriminate against people who cannot read or write; it can encourage participation from those who are reluctant to be interviewed on their own; and, passive participants may engage in the conversation generated by other group members [Kitzinger J (1995), Murray et al (1994), Denning et al (1993), O'Brien K (1993), Fardy et al (1994)]. However, for this strategy to produce these advantages, the group members must be carefully chosen. Groups that work well tend to be those that are drawn together specifically for the project, such as those including people with the same disease (Kitzinger J, 1994). It is widely accepted that involving patients in research design, results in more relevant research questions, higher levels of participation, improved study design, and better interpretation of the findings [Chalmers I (1995), DoH (2005). The literature varies on the optimal size of a focus group. Whilst larger groups may generate more ideas, participants can become competitive or even aggressive. Conversely, in smaller groups participants can be tactful, constrained, passive, and tense, although they may not necessarily generate fewer ideas (Tang et al, 1995).

A patient concerns inventory (PCI) has been developed in the head and neck cancer setting that aims to identify unmet patient needs, and promote multidisciplinary care (Rogers et al, 2009). The PCI contains a list of 45 head and neck cancer specific concerns that patients may wish to discuss during their consultation. The items are designed to cover emotional, social, and physical factors, and include: anxiety, cancer treatment, chewing, and fear of the cancer coming back, mood, pain, and relationships. It also contains a list of eight professionals to which the patient may wish to be referred. The head and neck PCI was piloted in 2007, using 123 participants (Rogers et al, 2009). Patients that were involved stated that they believed it made the consultation ‘a bit more personal’, ‘reminded them of the points they wanted discussed’, and ‘allowed the consultation to get straight to the point’ (Rogers et al, 2009).

The aim of this work has been to develop a practical tool, referred to as the breast cancer specific patient concerns inventory (PCI) that can be used in the health care setting, and that is modelled on the head and neck PCI. The early development phase of the breast cancer specific tool involved an exploratory observational study, using quantitative and qualitative methods to support the face and content validity of the items. A central aspect of this work was to be able to identify the issues faced by patients, with a history of either diagnosed or treated breast cancer, during the transition period from a patient with breast cancer to a survivor. The use of focus groups in this work allowed for the identification of key issues, and obtained patient and carer perspectives on the usefulness of the PCI, as well as giving an 'empirical' indication of the frequency and importance of each item produced.

Materials and Methods

Four focus groups were arranged for breast cancer patients, and carers, at one of Leeds Teaching Hospitals. For practical purposes, two of the focus groups were arranged with patients from Leeds General Infirmary and two with patients from Pinderfields Hospital in Wakefield. The research ethics committee imposed several restrictions on the principal investigator. All patients had to be approached by the treating clinical team. Because of recruitment and attendance difficulties and practicalities, no attempt was made to match the groups for clinical or other characteristics. Ideally, all patients should be matched with respect to disease stage, age, type of treatment, and ethnicity. All patients were adults with a history of diagnosis or treatment of breast cancer. Forty patients consented to participate in the focus groups and twenty-four participated in the meetings. Study information packs were provided (Appendices 2-C, 2-D, and 2-E). The details of the method are presented in Chapter 3.

The discussions were audio-recorded, and stored in keeping with General Medical Council guidance (GMC, 2011). The recorded interviews were anonymised and a professional medical transcription company transcribed the recorded interviews. The transcribed interviews and recordings were kept in a secure storage facility within the hospital.

Patients were asked to add to, or remove items from, a draft PCI list generated by a literature review (step 1 phase 1) (Table 6, Appendix 1) and by asking clinicians managing patients with breast cancer (step 2 phase 1). The focus group was also asked to comment on the appropriateness of the terminology used within the PCI. The first focus group used the draft PCI as their starting point, the second focus group started with the revised draft, and so on until the suggested alterations were minimal. Each focus group was also asked about which health professionals a patient might want to see at various steps of their cancer journey. The principal investigator moderated the focus groups with the assistance of a specialist nurse who had additionally been tasked to ensure patient welfare.

Four focus groups were held between July and October 2011. Each focus group was instructed that the purpose of the discussion was to build consensus. The interviews took between 52 and 90 minutes, and after each session, the researchers (principal investigator and specialist nurse) recorded their immediate impressions.

Data Analysis

This study followed previously described quality standards for qualitative research (Miles et al, 1994). The two investigators read and discussed focus group audiotape transcriptions following every meeting. This allowed for formal review of the transcripts and the

identification of themes. Content analysis was used to identify key themes and sub-themes raised by the focus groups (Miles et al, 1994). A degree of reliability was afforded to the analysis through independent reading of the focus group transcripts by two members of the supervisory team. These independent readings were followed by further discussion and agreement of the themes and sub-themes until agreement was reached. Validity was assured during the focus groups by ensuring lines of inquiry verified the accuracy and consistency of the responses. After transcribing the interviews, phrases and expressions were obtained for each of the assessed items. An initial qualitative reduction of the identified sentences followed, in which expressions considered inappropriate, ambiguous, or redundant were excluded. Some of the expressions included were slightly reworded to make them suitable for use as statements in an initial questionnaire.

In order to ensure comprehensibility of the research, supervisory meetings took place on a regular basis; these supervisory meetings also ensured the continuous evaluation of the research process by the research supervisors.

Results

Twenty-four women took part in the focus group meetings; 16 from Wakefield and 8 from the Leeds area. The women were aged between 41 and 78 years. All had received surgical treatment for their breast cancer, with or without radiotherapy and chemotherapy, within the last three years. Seventeen were taking endocrine therapy at the time of the focus groups. The PCI tool following input from the focus group can be seen in Table 7 (Appendix 1).

The subgroups that were identified from the literature review (step 1 of Phase 1) and were presented in chapter 4 were used as the basis of structuring the items during the focus groups:

1. General information
2. Body Image
3. Physical Functioning and health
4. Psychological state and emotional well-being
5. Sexual Functioning
6. Social Functioning/ Family
7. Global Quality of Life

1. *General information*

A woman who has breast cancer may have no problems until she finds a lump in her breast. The diagnosis of breast cancer is a life-changing event, and the need for information about all aspect of the disease may suddenly become overwhelming. That was the case in the focus groups, with quotes such as:

'Well, things like ... you do get short of breath, which is very tiring. Also chemotherapy makes you tired. The very confusing issue, I found, was the number of choices that you have if you want to have breast reconstruction. There are so many different brand types and replacements, you know, the plastic ones, the patent ones. And you have to have a spare one. Every single thing that previously you knew nothing about, it's a whole new world I didn't think I would ever need to go into....' (Focus group 3)

'When you are first diagnosed with cancer you want to know as much as possible, I did anyway. But initially during the first week or so, I don't know, my brain couldn't take any more. There is so much information out there and you don't know what applies to you and your family, what is best for you. So many treatments you read about on the internet. And there are a lot of good stories there but they can also be confusing I think.' (Focus group 3)

2. *Body Image related domains*

Body image is how someone views them self physically; it is one's view of one's appearance. The treatment of breast cancer, especially through surgery and chemotherapy, can cause body image alterations. Bodily changes may result in a profound psychological stress that can require long-term adjustment. Quotes from the patients included the following:

'I can't say I was pleased with my scar. I didn't look at it for months, in fact it still feels very obvious today, you know, so many years later.' (Focus group 3)

'After the third treatment I noticed that in the morning there were hairs on my pillow and that was so strange... ' (Focus group 4)

3. *Physical Functioning and health related domains*

The physical effects of breast cancer diagnosis and treatment have been extensively reported in the literature. Several aspects are almost universal in the management of breast cancer, such as effects on appetite and energy levels, as well as hot flushes, pain and nausea. The patients in these focus groups raised additional concerns:

'I think mainly the fluid in my arm or the operation site' (focus group 1)

'I guess I also lost my appetite. I had this odd taste in my mouth, like metal, for weeks and weeks and weeks, and although they told me I'd put on weight, to me it was going the other way, I was losing weight. I saw a dietician and I was told that I may have to be admitted to hospital to help with my feeding, but luckily I didn't have to.' (Focus group 1)

'I had problems with the chemotherapy, hair loss of course. I had – my mouth felt different, my skin felt different - I had very dry skin. I always felt very tired, in fact I still feel tired a year or so later. But, on the other hand... I'm happy to say I'm cancer free.' (Focus group 1)

'I thought my memory wasn't very good during the treatment. It felt like I was always preoccupied, I was quite forgetful.' (Focus group 3)

'Well, I don't think, I had any pain after the operation, in fact when they drain the fluid from my arm now I don't feel anything at all. It's like that side is all numb. I had a stiff shoulder, but I think I've got better over time.' (Focus group 3)

Of the more commonly addressed concerns, sickness and pain received particular attention:

'The sickness was terrible. And I felt sick and I was drained physically and emotionally.' (Focus group 3)

'I had a lot of problems with sickness. In fact, after the first lot of chemotherapy I thought I'd die. I was sick continuously 24 hours, couldn't hold anything down, couldn't hold any water down. And it wasn't just the sickness...I felt physically ill all the time, some days not wanting to get out of bed! And the worst thing was that when I was going through that I felt like it was never gonna get better... and that was very scary.' (Focus group 3)

'I still get some pain in my arm, but I've come to terms with it now and I don't think of it too much during the day.' (Focus group 1)

4. *<u>Psychological state and emotional well-being related domains</u>*

The psychological changes in patients with breast cancer may start from the time of diagnosis and remain through remission. Women with breast cancer often feel diverse physical concerns, as well as emotional problems such as distress, anxiety, and depression. Some of these concerns were raised in the groups interviewed:

'When I was told, I was shocked initially, you know, people with cancer die, it's not something that … your brain goes numb for a bit, or that's what happened to me anyway.' (Focus group 3)

'Then, a few days later he told me that it was cancer. I was absolutely devastated. In fact both of us were. We kept it between us, we have two children, but we didn't say anything to them.' (Focus group 3)

'We put our life on hold and didn't know what it was, what treatment I am going to have. And you don't – you feel like you are going to die and, you know, all the fear is there. And well perhaps I had that for a long time.'

'Well, it was difficult to come to terms with all this, I was blaming myself for a while, I thought it was down to my smoking and drinking alcohol. That made me feel upset for a while. Also, people look at you differently when you tell them you have cancer, you know, my family was upset and my friends didn't come to see me as often as they used to. Some of them did, to be fair, but it wasn't the same, you know, they were quiet, upset?, they didn't know what to say. They felt sorry for me and that was the hardest part.' (Focus group 3)

'The first year or so I was quite upset, I was much less tolerable, I think. I hope I'm much better now.' (Focus group 3)

5. *Sexual Functioning*

During this work it appeared that the women participating in the groups agreed with the items included on 'intimacy', 'Relationships' and 'sex' but did not discuss these extensively. It may be that such issues were embarrassing, or viewed as personal. For the items relating to sexual functioning there were no comments from the patients. The facilitator asked about these items if they should be included in the list and the patients will only agree, without any other input.

6. *Social Functioning/ Family-related domains*

The effect of breast cancer diagnosis and treatment on both family and social functioning is well documented. Women in the groups gave their own perspective:

'But certainly in the first year or so you worry, this cancer, when you are told you have cancer, you worry, you want to know how extensive that is. It can be very stressful sometimes because you expect to be out of work but you don't know how long for, or if you will ever be able to go back at all...and if money is tight then other problems can crop up as well. That was a big source of stress for me.' (Focus group 2)

For the second part of the breast-specific PCI, patients were asked to indicate the people that they would specifically like to talk to, either at clinic or after referral. It was identified that further explanation was essential as to the roles of the specialists that could be involved in the management of patients with breast cancer:

'I think if there was an explanation or perhaps give us an idea of what these people do, it might be easier to know who can help with what problems. For instance, what is radiation – what's the difference between medical and radiation oncologist? And what is the difference between the surgeon who operated on me and a plastic surgeon, aren't they the same?' (Focus group 3)

Discussion

This study supports other findings on this topic, suggesting that breast cancer survivors are at risk for developing medical and psychosocial issues from their cancer and its treatment [McCabe et al (2008), Hurria et al (2003), Partridge et al (2003)]. The face-to-face involvement of patients and the facilitator ensured that the conversation remained on track, and encouraged participants to engage, without any one individual dominating the meeting. Additionally, every participant was observed by the facilitator, and was aware that the process was audio taped. Although this helped people to participate, the focus groups were thought to be an artificial environment, and this may have influenced the research outcomes. For example, people were grouped into a meeting room where they might behave differently to an attendance in an outpatient clinic, thereby affecting the quality of research results.

It was also clear from the relatively poor response to the items relating to sexual function, that focus groups are not very effective at dealing with such sensitive issues. A minimum of 10-12 participants from similar backgrounds were sought for each focus group [Miles et al (1994), Krueger et al (2000)], and it was found that smaller groups were more manageable. Patients from similar backgrounds were selected to improve the quality of the data obtained, because different cultures may find different topics more appropriate than others may, and may not discuss them as thoroughly; as a result it was notable that ethnic minorities were under-represented in our study. Similar findings have been presented elsewhere (Miles et al, 1994). This may be due to the lack of interpreters, or because breast cancer and related concerns may be taboo subjects in certain cultures; it could also be due to the catchment area of the hospitals from which the patients were recruited. This is a common problem in research of this type (Jack et al, 2009). Lack of participation was not limited to minority

groups, and it was observed that some participants did not contribute much to the discussions. Lack of participation can imply agreement, but in the absence of a clear response, it may also mean that they disagree and do not want to say so. Every effort was made by the facilitators to ensure that all participants were involved in the conversations.

There are several specific limitations to this study; the small number of participants is one. In a study of this type and size, there is also the possibility of self-selection to participate. A purposive sampling approach has been proposed to eliminate this problem [Mays et al (1995), Ashbury JE (1995)]; however, taking into account the purpose of this work, this approach was considered neither possible nor practical. Another limitation is that the patients who participated may not be representative of all breast cancer survivors, particularly those who were active survivor volunteers or were engaged in other support groups or research with a similar methodology. We tried to minimise volunteer bias by recruiting directly from the breast-cancer outpatient clinic but the sample was not designed to be statistically representative, and hence it cannot be concluded that the findings reflect the general breast cancer population. Other selection bias may include workers or those with family commitments that could not participate or who dropped out .This bias was minimised by ensuring that the recruited patients were not taking part in other studies, and that they had not previously been involved in focus group research. Another limitation is that the women willing to participate in the research were more educated about health research than average. The ethnic minorities were under-represented in the focus groups. This may be seen as a lost opportunity since a PCI type tool may be especially useful to such groups that traditionally have consultation difficulties (Epstein, 2005). This needs to be addressed with further longitudinal work in a comprehensive before-after study. Finally, only seven of the women were less than sixty-five, meaning that we may not have a balanced view of all women with breast cancer across the age spectrum.

In effect, there were no new items added to the list of issues from the step 1 of phase 1. The focus groups input was to make the items more understandable with the inclusion of explanations next to items in the PCI. Also, the role of the clinicians in the second part of the PCI has been explained and included in subsequent versions.

Phase 1—Step 4: The role of National bodies in the development of the breast cancer specific Patient Concerns Inventory (PCI)

Introduction

Increasingly, there is a drive for cancer care to move from hospitals to community facilities (Kessler et al, 2002). In this context, breast cancer may be managed as a chronic illness with

an emphasis placed on meeting the needs of people living with cancer through social support networks (Davison et al, 2000). The interaction between cancer patients is key to this, and can be considered an indication of good quality care (Lipscomb et al, 2002). Although support groups have traditionally been face-to-face, web-based support has recently been gaining popularity [Gray et al (1997), Winzelberg et al (2003), Mayer et al (1996), Wienberg et al (1996), Sharf et al (1997), Klemm et al (1999), Gustafson et al (2001), Lieberman et al (2003)]. Patients in support groups can spend time with people who understand their experience, and play an important role regardless of whether face-to-face or online.

Reported benefits of support group involvement include emotional, informational, and practical support benefits (Bjorneklett et al, 2013). Björneklett et al (2013) for example, further reported that support intervention resulted in improved cognitive function, body image, future perspective, and fatigue in patients with breast cancer. Benefits of emotional support include connecting with other breast cancer survivors, feeling understood, providing hope, as well as sharing experiences, including healing laughter [Lieberman et al (2003), Kim et al (2012)]. There is additional evidence that over 28% of internet users have visited an online support group at least once (Eysenbach et al, 2004), and that millions of people visit online peer-to-peer discussion groups daily [Griffiths et al (2009), Pinheiro et al (2008)]. Spiegel et al (Spiegel et al, 1981) provided evidence that a support group intervention for patients with metastatic cancer resulted in significant psychological benefit. In view of the large number of patients that are now part of support groups, it can be concluded that such groups are in a position to provide valuable input in the identification of common concerns faced by patients with a history of diagnosis and treatment for breast cancer. This chapter describes how national bodies and support groups were identified, in order to receive input into a patient concerns inventory (PCI) list that had earlier been designed through literature review (step 1 phase 1), the general input from clinicians (step 2 phase 1) and focus groups (step 3 phase 1) (Table 7, Appendix 1).

Materials and methods

The web-based resource ‘Just Giving’ (http://www.justgiving.com) was used to source potential groups. In total, 40 UK National bodies were identified with some degree of involvement in the management of patients with a history of breast cancer. The principal investigator accessed their contact details, and they were initially contacted via telephone. Six groups agreed to receive relevant material with a view to providing input to the development of the tool: The Haven Foundation; Breast Cancer Campaign; Breast Cancer Care; Breakthrough Breast Cancer; The Lavender Trust at Breast Cancer Car'; and, ‘Macmillan Cancer Support’. An information pack was sent to each of these that included the PCI (Table 7, Appendix 1), a brief information leaflet (Appendix 2-M), and a self-

addressed envelope. Essentially, there were asked to comment on the suitability of the items, if there were items that were missing and any practical aspects about the use of such a tool in their interaction with patients.

Results

Of the six National bodies approached, two ultimately agreed to provide input for the development of the PCI, 'The Haven Foundation', and 'Breast Cancer Campaign'. Reasons for not participating included: excessive workload of the charity staff; that the work was not directly relevant to the specific organisation; and, that they were not qualified enough to be able to comment on aspects of research. Several groups stated that they do not offer advice and support directly to breast cancer patients, because they feel that other charities such as Breast Cancer Care and Macmillan Cancer Support do so as part of their specific remit.

The Haven Foundation suggested the inclusion of 'hot flushes' and 'complementary therapy'. The 'Breast Cancer Campaign' provided useful feedback, including agreement with the suggested items and that such a list may potentially be of significant benefit to women with breast cancer. The PCI was further developed as a result of this input (Table 8, Appendix 1).

Discussion

Although the participation rate for this part of the study was significantly lower than expected, there are possible explanations. For example, the creation of the National Cancer Research Institute has fuelled an intense need to influence both national research expenditure and health-care policy (Glass et al, 2002). The economic models of both national research bodies and breast cancer charities often demands increased media communication as a tool to leverage funding (Hayes et al, 2007). Such an approach may leave no time for the development of relatively small-scale interventions, and may partly explain the low participation rate for this part of the study. However, input from 'The Haven Foundation' appeared relevant, and contributed positively in the development of the PCI.

It possible that the approach used was not appropriate-the initial contact with telephone-and a formal letter to each National body followed by a telephone conversation may have produced better results.

The next part of the study involved a cross-sectional survey of patients with breast cancer, the aim of which was to further refine the breast cancer specific PCI before rolling it out in the breast cancer outpatient clinic.

BLA NK

CHAPTER 7. A Cross-Sectional Survey of Breast Cancer Patients Receiving Treatment from Multiple Consultants at Two Hospitals.

In this chapter, two aspects of the study are considered. The first is the implementation of the breast cancer specific Patient Concerns Inventory (PCI) through a cross-sectional study is presented. This is followed by a consideration of the members of the breast cancer multidisciplinary team (MDT) that patients wished to see during their consultations .

Information from the Breast cancer specific PCI was analysed in relation to personal, clinical, and Health-Related Quality-of-Life (HRQOL) data as part of the process of its validation and development. The results from this cross-sectional study are divided as follows: (A) Issues patients would like to discuss at review consultations in Breast Cancer clinics — a cross-sectional survey; (B) Fear of recurrence (FOR) — a cross sectional study using the breast cancer specific PCI; and (C) The breast cancer specific PCI as a means to assist the identification of body image concerns in routine follow up clinics.

Aims

The aim of this cross-sectional study was to gain an understanding of the relative frequency of the individual PCI items, to assess the need for further item inclusion, and to compare clinical characteristics with the PCI items and an established, validated HRQOL measure (EORTC C30 with the BR23 module).

Materials and methods

The development of the breast cancer specific PCI took place over several stages. The initial item generation was from a comprehensive literature review, before input was gained from clinical specialists, patients, and carers. This led to a preliminary PCI (Appendix 2-N) that was then used in a cross-sectional survey of breast cancer patients, following the completion of their initial treatment. In this study we indicate the relative frequency of individual PCI items and compare PCI item selection with clinical characteristics such as age, stage, treatment, time since treatment, and established breast cancer HRQOL measures [EORTC C30 (European Organisation for Research and Treatment of Cancer) with BR23] . A convenience sample of 249 patients with a history of diagnosis and treatment for breast cancer agreed to take part in the study between February and July 2012. Based on a

literature review, and the experience obtained during the development of the head and neck PCI, we estimated that at least 200 patients were needed for meaningful results. Patient recruitment took place in the clinic by the clinical team in charge of care. Patients that expressed an interest to be included in the study were given a study information pack. The information pack contained details about the study (Appendicies 2-F and 2-G), together with the preliminary PCI tool (Appendix 2-O), as well as a consent form (Appendix 2-H) and a reply slip (Appendix 2-I). A letter was sent to general practitioners (Appendix 2-J). Patients selected for inclusion also gave consent for the principal investigator to collect demographic, social, and treatment related data from their clinical files (Appendices 2-K and 2-L). The patients that took part in this cross-sectional survey completed the PCI type tool and the EORTC C30 with the BR23 module at their home and sent these with a SAE to the principal investigator several days later.

Ethical considerations

The Leeds Central Ethics Committee (Appendix 4) approved this study.

Data analysis

SPSS Statistics version 19 was used for the statistical analysis. Response rates between patient subgroups were compared by either Fisher's exact test or the chi-squared test. Subgroup comparison in the full distribution of PCI items was performed using with the Mann-Whitney or Kruskall-Wallis test, as appropriate. Spearman's correlation was used to assess the significance of the number of PCI items with age, and for assessing the strength and significance of the association between the number of PCI items and the summary scores from the EORTC QLQ-C30 and the breast cancer module QLQ-BR23. The internal validity of the test was assessed using Cronbach's alpha for individual PCI domains, and for the test as a whole. Alpha values between 0.70–0.95 (Staquet et al, 1988) represented internal consistency.

Reliability / Validity /Rigour

This cross-sectional study aided the validation of the PCI type tool. The information packs were given after completion of the clinic appointment for the patients to take away with them. All patients had the same explanation of the study by the principal investigator.

Results

Sample description:

Survey responses were obtained from 80% (200) of the 249 patients. Depending on the stratification of data, response varied from 65% to 100% (Table 9, Appendix 1). The

response was lower among patients aged 70 and over, those with tumours that are more advanced, those with primary local disease, and those having anti-oestrogen therapy. The response rate was higher if the patient had undergone either radiotherapy or reconstructive surgery. The median (inter-quartile range) age of responders was 59 (52-68) years. Other patient characteristics are shown in Table 9 (Appendix 1).

Most recent diagnosis was stated as 2009/2010 for 54% (108), 2011/2012 for 31% (61), unknown for 16% (31). Extent of disease was detailed as follows: 51% (101) primary local, 2% (3) local recurrent, 5% (9) metastatic and 4% (8) living with cancer. Treatment was detailed as follows: 47% (93) on chemotherapy, 63% (126) radiotherapy, 47% (93) wide local excision or lumpectomy, 44% (88) mastectomy, 13% (25) reconstructive surgery, and 41% (82) anti-oestrogen therapy. Responders were from two hospital sites, 57% (113) Leeds and 32% (64) Wakefield. It was possible to derive the IMD[1] (IMD = Index of Multiple Deprivation: A measure of multiple deprivation at the small area level made up of seven domains) deprivation statistics for most, with 17% (30/178) living in an area described as one of the 20% most deprived in the country. Examination of the scores obtained from the EORTC C30 with the BR23 module (Figure 4) revealed similar patient scoring to that reported in other studies in the literature [Hamidou et al (2011), Cohen et al (2012), Moro-Valdezate et al (2013)]

	Not at all	A little	Quite a bit	Very much	Cases
E1 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	29% (57)	39% (78)	18% (36)	14% (27)	198
E2 Do you have any trouble taking a long walk?	43% (86)	34% (67)	13% (25)	10% (20)	198
E3 Do you have any trouble taking a short walk outside of the house?	84% (165)	7% (13)	5% (10)	4% (8)	196
E4 Do you need to stay in bed or a chair during the day?	73% (144)	18% (35)	7% (13)	3% (5)	197
E5 Do you need help with eating, dressing, washing yourself or using the toilet?	91% (181)	8% (15)	2% (3)	-	199
E6 Were you limited in doing either your work or other daily activities?	55% (108)	26% (51)	14% (28)	5% (10)	197
E7 Were you limited in pursuing your hobbies or other leisure time activities?	53% (105)	29% (57)	12% (24)	6% (12)	198
E8 Were you short of breath?	66% (131)	27% (54)	5% (9)	3% (6)	200
E9 Have you had pain?	34% (68)	43% (86)	15% (30)	7% (14)	198
E10 Did you need to rest?	35% (69)	42% (84)	18% (35)	5% (10)	198
E11 Have you had trouble sleeping?	35% (70)	32% (64)	19% (38)	14% (28)	200
E12 Have you felt weak?	46% (92)	36% (71)	14% (27)	5% (10)	200
E13 Have you lacked appetite?	79% (157)	11% (22)	8% (15)	3% (6)	200
E14 Have you felt nauseated?	78% (155)	14% (27)	8% (16)	1% (2)	200
E15 Have you vomited?	95% (189)	3% (6)	2% (4)	0.5% (1)	200
E16 Have you been constipated?	67% (134)	22% (43)	9% (18)	3% (5)	200

Figure 4: Individual question responses from the EORTC C30 and the BR23 module

E17 Have you had diarrhoea?	83% (161)	10% (20)	5% (9)	2% (3)	193	
E18 Were you tired?	19% (38)	51% (99)	23% (45)	7% (14)	196	
E19 Did pain interfere with your daily activities?	60% (117)	24% (46)	11% (21)	6% (11)	195	
E20 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	56% (110)	28% (55)	13% (25)	3% (6)	196	
E21 Did you feel tense?	40% (78)	42% (82)	15% (30)	3% (6)	196	
E22 Did you worry?	25% (49)	44% (85)	24% (47)	7% (13)	194	
E23 Did you feel irritable?	44% (85)	33% (65)	19% (37)	4% (8)	195	
E24 Did you feel depressed?	49% (93)	32% (61)	15% (28)	5% (9)	191	
E25 Have you had difficulty remembering things?	43% (83)	37% (71)	12% (24)	8% (16)	194	
E26 Has your physical condition or medical treatment interfered with your family life?	53% (103)	29% (56)	13% (25)	5% (10)	194	
E27 Has your physical condition or medical treatment interfered with your social activities?	54% (105)	29% (56)	12% (24)	5% (9)	194	
E28 Has your physical condition or medical treatment caused you financial difficulties?	54% (105)	29% 956)	12% (24)	5% (9)	194	

	1 Very poor	**2**	**3**	**4**	**5**	**6**	**7 Excellent**	**Cases**
E29 How would you rate your overall health during the past week?	0.5% (1)	5% (10)	10% (19)	19% (36)	35% (69)	24% (46)	7% (14)	195
E30 How would you rate your overall quality of life during the past week?	2% (3)	4% (7)	11% (22)	16% (32)	27% (52)	29% (57)	12% (23)	196

	Not at all	**A little**	**Quite a bit**	**Very much**	**Cases**
BR1 Did you have a dry mouth?	60% (119)	24% (48)	12% (23)	4% (7)	197
BR2 Did food and drink taste different than usual?	77% (152)	14% (28)	5% (10)	4% (7)	197
BR3 Were your eyes painful, irritated or watery?	66% (130)	21% (42)	7% (13)	6% (11)	196
BR4 Have you lost any hair?	76% (148)	15% (30)	2% (3)	7% (14)	195
BR5 Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	17% (7)	32% (13)	27% (11)	24% (10)	41
BR6 Did you feel ill or unwell?	64% (119)	23% (43)	9% (17)	4% (8)	187
BR7 Did you have hot flushes?	30% (57)	31% (60)	22% (42)	18% (34)	193
BR8 Did you have headaches?	59% (113)	31% (60)	7% (14)	3% (6)	193
BR9 Have you felt physically less attractive as a result of your disease or treatment?	38% (74)	34% (67)	14% (27)	14% (27)	195
BR10 Have you been feeling less feminine as a result of your disease or treatment?	45% (87)	31% (60)	14% (27)	10% (20)	194
BR11 Did you find it difficult to look at yourself naked?	47% (92)	28% (55)	14% (27)	10% (20)	194
BR12 Have you been dissatisfied with your body?	37% (72)	37% (72)	16% (31)	9% (18)	193
BR13 Were you worried about your health in the future?	12% (24)	36% (70)	26% (51)	26% (50)	195
BR14 To what extent were you interested in sex?	51% (90)	37% (65)	11% (20)	1% (2)	177
BR15 To what extent were you sexually active?(with or without intercourse)	57% (99)	35% (60)	8% (13)	1% (2)	174
BR16 Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	9% (6)	38% (26)	40% (27)	13% (9)	68
BR17 Did you have any pain in your arm or shoulder?	41% (80)	37% (73)	16% (31)	6% (12)	196
BR18 Did you have a swollen arm or hand?	74% (145)	17% (34)	5% (9)	4% (8)	196
BR19 Was it difficult to raise your arm or to move it sideways?	64% (126)	25% (49)	7% (14)	4% (7)	196
BR20 Have you had any pain in the area of your affected breast?	35% (68)	46% (91)	14% (27)	6% (11)	197
BR21 Was the area of your affected breast swollen?	71% (137)	21% (40)	5% (10)	4% (7)	194
BR22 Was the area of your affected breast oversensitive?	45% (88)	38% (74)	14% (27)	3% (6)	195
BR23 Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	61% (121)	27% (54)	9% (17)	3% (5)	197

Figure 4 Individual question responses from the EORTC C30 and the BR23 module

PCI domain	Number of items	Cronbach's alpha	Range of Cronbach's alpha with (n-1) items - i.e. if one item deleted
Physical functioning & health related	20	0.775	0.760 - 0.775
Psychological state & emotional well-being	10	0.709	0.673 - 0.716
Body image-related	9	0.640	0.581 - 0.682
Social functioning & emotional well-being	8	0.628	0.577 - 0.626
General information	6	0.237	0.128 - 0.263
Sexual functioning	3	0.598	0.411 - 0.598
TOTAL	**56**	**0.897**	**0.893 - 0.898**

Figure 5 PCI domains and Cronbach's alpha

Cronbach's alpha values are presented in figure 5 for the individual domains, and for the test as a whole. Overall, the test demonstrated internal validity. However, only two of the 6 domains demonstrated alpha values above 0.7.

(A) Issues patients would like to discuss at review consultations in Breast Cancer clinics

The PCI items selected by patients are shown ranked by order of frequency in Figure 6. The most frequent items were: fear of cancer coming back (62%, 124), breast sensitivity/pain (46%, 92), fatigue or tiredness- low energy levels overall (46%, 92), hot flushes (44%, 87), fear of cancer spreading (39%, 78), sleeping (34%, 67), fear about the future (32%, 63) and breast appearance (30%, 59). The members of the MDT that were the most frequently selected were: the breast care nurse (46%, 92), the medical oncologist (28%, 55) and the psychologist (20%, 40). It is noteworthy that 72% (143) wanted to discuss 'fear', either of cancer coming back, spreading, or about the future in general. Psychological factors were also prominent; within the psychological state and emotional well-being section of the PCI as a whole, 84% (167) wanted to discuss one or more items (median 2; IQR 1-3). Specifically, significant numbers wanted to discuss the following: 15% (30) 'mood'; 21% (41) 'anxiety'; 17% (33) 'depression'; and, 35% (70) selecting one or more of these. A

psychologist consultation was requested by 20% (40) of patients who selected a median of 4 (IQR 3-6) items from this section.

In all, 1952 PCI items were selected, with the following breakdown: 42% (816) for physical function and health; 24% (472) for psychological state and emotional well-being; 16% (313) for body image; 7% (142) for general information; 7% (138) for social functioning and family; and, 4% (71) for sexual functioning. In addition, the 'other' box on the PCI form was ticked by 7% (14) of patients with comments including: problems with clothing, skin itching, side effects from the anti-oestrogen treatment, complementary therapies, job and employment issues, and concerns about the possibility of breast cancer inheritance to close family members. The items that were presented by the patients in the 'other' box did not lead to changes to the PCI. Items were selected from six, five, four, three, two, one and zero PCI domains, by 12 % (23), 18 % (36), 22 % (44), 20 % (40), 16 % (32), 10 % (19) and 3 % (6), respectively.

Variation by personal and clinical features was analysed with regard to the number of items ticked within PCI domains and by the total number of PCI items and the total number of health professionals selected (Table 10, Appendix 1). Younger patients selected more PCI items overall, and more specifically concerning sexual function, psychological state, well-being and social functioning or family related domains. Other significant associations ($P<0.01$) indicated body-image related items, which were more relevant for patients having had chemotherapy, mastectomy or reconstructive surgery. Those on anti-oestrogen therapy selected fewer general information items, while those with wide local excisions selected fewer body-image related items. More PCI items were selected overall for mastectomy patients, and those that had reconstructive surgery selected more health professionals. With regard to health professional staff domains, the only significant correlation ($P < 0.001$) was between reconstructive surgery and the number of treatment-related professionals selected. Here, 100 % (25/25) versus 82 % (138/168) selected at least one from the list of seven professionals, 40 % (10/25) versus 22 % (37/168) selected at least three, and 24 % (6/25) versus 4 % (7/168) selected at least five.

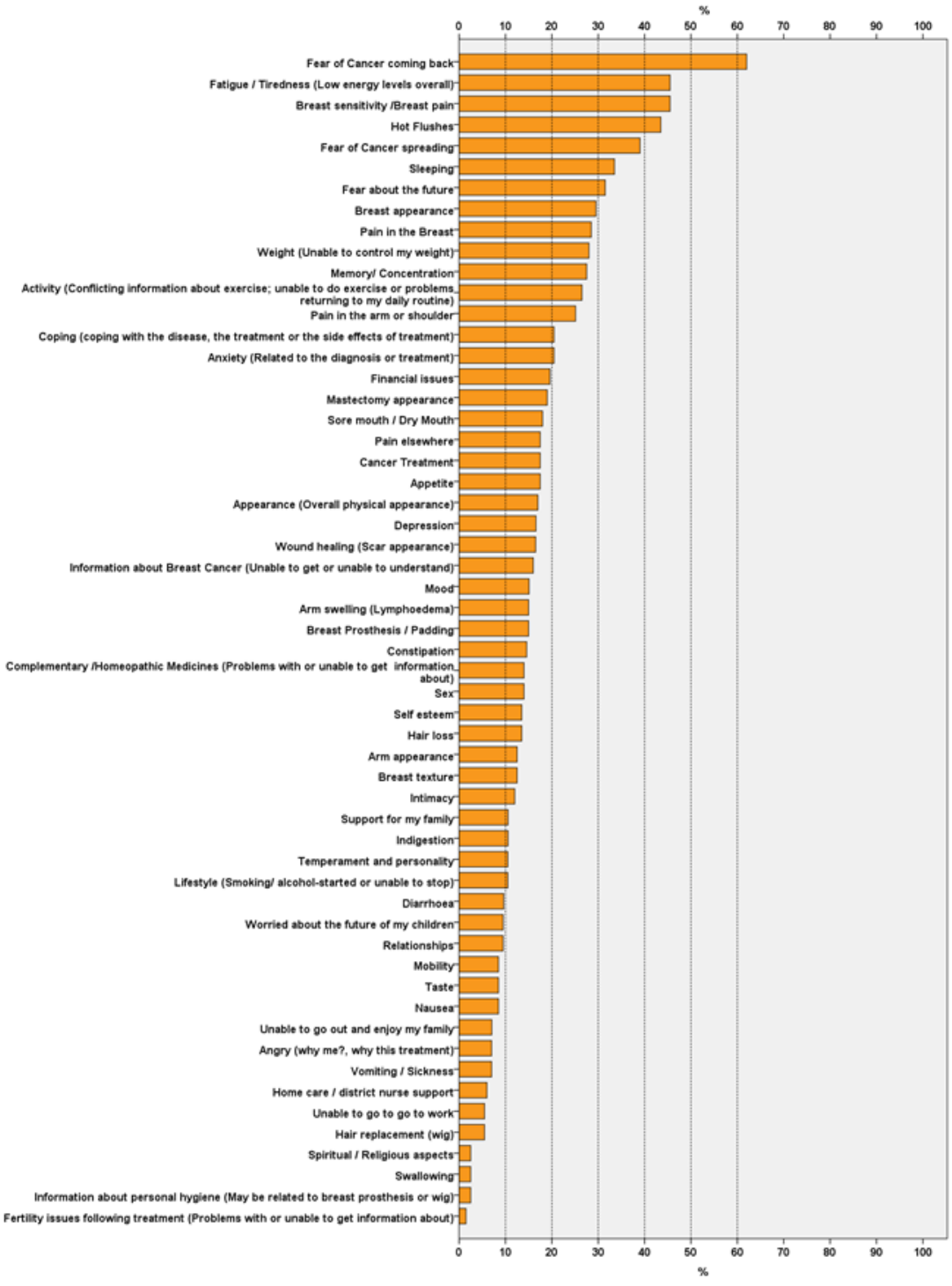

Figure 6 The PCI items selected by the 200 responders in the cross-sectional survey

A summary of the more notable correlations (P<0.001) between the number of PCI items or staff selected with the summary scores from the EORTC tools (QLQ-C30 and QLQ-BR23),

is shown in Table 11 (Appendix 1). These correlations are generally quite weak, as might be expected from summary measures, but the associations clinically plausible, and as such help support the validity of the data reported on the PCI.

(B) Fear of recurrence (FOR)

As detailed in section A of this chapter, the PCI items most frequently selected by patients were: fear of cancer coming back (62%), breast sensitivity/pain (46%), fatigue/tiredness- low energy levels overall (46%), hot flushes (44%), fear of cancer spreading (39%), sleeping (34%), fear about the future (32%) and breast appearance (30%). In addition, the members of the MDT that were the most frequently selected were the breast care nurse (46%), medical oncologist (28%) and psychologist (20%). Nearly three-quarters, wanted to discuss fears, either of cancer coming back, spreading, or about the future, and 18% wanted to discuss all three fears. For 29% only one fear was selected, with 'fear of the cancer returning' being the most frequently selected (40/57). There was a significant correlation between the number of fears selected, the number of other PCI items selected within each PCI domain, the total number of other PCI items selected, and the total number of health professionals selected (Table 12, Appendix 1). Those selecting all three fears selected a median (IQR) of 16 (9-21) and 5 (3-6), for 'other items' and health professions, respectively: more than double the median numbers selected by the other patients, and consistently more 'other items' within each PCI domain.

The relationship of number of fear items selected with specific PCI items is shown in Table 13 (Appendix 1) and Figures 7 and 8 (see below). There were associations at $P<0.01$ for 22 of the 53 non-fear items, notably for 6 of the 9 items concerning 'body image'. Associations at $P<0.001$ were found with the following: wanting to discuss hair loss, nausea, sleeping, anxiety and relationships; and, wanting to see the medical oncologist, breast care nurse, psychologist, and complimentary therapist. The associations with depression and mood were notably weaker. The group selecting only one of the 'fears' (predominantly the fear of the cancer returning) did not appear to differ much from the group selecting 'no fears at all' in regard to the number of other PCI items selected, the number of health professionals selected, or the specific items selected.

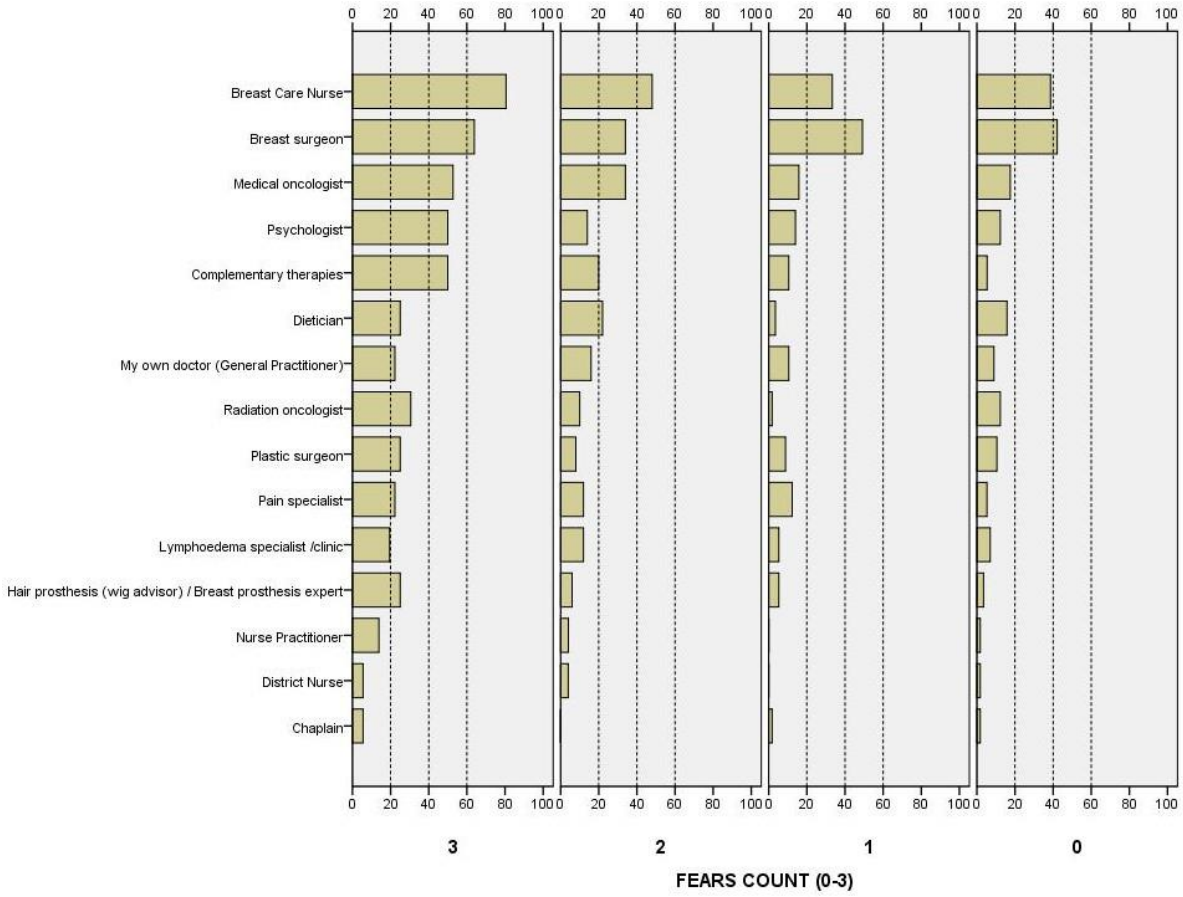

Figure 7 Percentage of patients (%) selecting professionals by number of fear items

The number of fear items was significantly associated with reconstructive surgery (Table 14, Appendix 1; P=0.003) with 88% (22/25) selecting one or more fear items and 40% (10/25) selecting all three fear items. A similar trend for selecting more fear items was seen for mastectomy patients (P=0.04). There was also a trend (P=0.05) associated with patient age, with younger patients - particularly those under 65 years - more likely to want to discuss fears. This pattern was seen for both 'fear of cancer coming back' and 'fears about the future' but not for 'fears about spread'. There was also a non-significant trend (P=0.07) for more fears to be selected for diagnoses made in 2009/2010, than for those made more recently in 2011/2012.

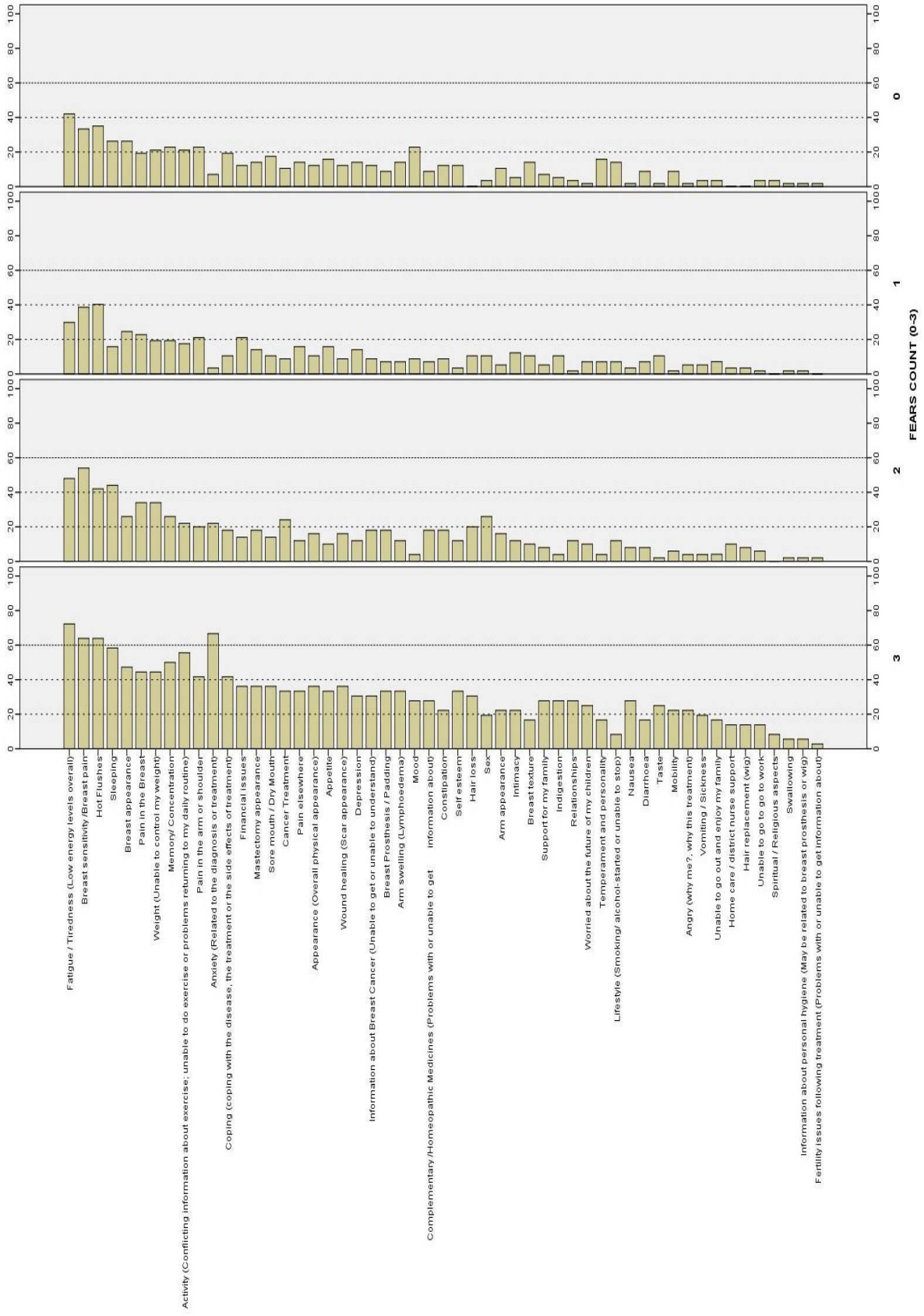

Figure 8 Percentage of patients (%) selecting items by number of fear items

A summary of the correlations between number of PCI Fear items and summary scores from the EORTC tools (QLQ-C30 and QLQ-BR23) is shown in Table 15 (Appendix 1). These correlations were generally quite weak and largely non-significant apart from the association with the 'future perspective' summary score from the EORTC BR23 scale (P<0.001). This summary score is in effect a single question 'were you worried about your health in the future?' with four potential responses: 'not at all', 'a little', 'quite a bit', and 'very much'. For patients responding 'quite a bit' or 'very much' to this question, 89% (90/101) selected the desire to discuss one or more PCI fear items, as compared to 74% (45/70) when responding 'a little' and 33% (8/24) if responding 'not at all'. In separate tests the distribution of responses to this question varied significantly (P<0.001) concerning 'fear of the cancer coming back', and 'fears about the future', but not (P=0.28) concerning 'fears about spread'. Other tests significant at P<0.01 were those comparing EORTC C30 physical functioning scores in relation to fear of the cancer coming back, EORTC C30 emotional functioning scores, and EORTC BR23 upset by hair loss scores in relation to fears about the future.

(C) Body image issues

Two-thirds (68%, 136) of patients selected one or more of the nine PCI items within the Body-image-related domain, with 28% (56) selecting 1 item, 27% (54) selecting 2-3 items and 13% (26) selecting 4-8 items (Table 17, Appendix 1) . In descending order of frequency the items selected were breast appearance 30%, weight- unable to control weight 28%, mastectomy appearance 19%, overall physical appearance 17%, wound healing – scar appearance 17%, breast prosthesis/padding 15%, hair loss 14%, arm appearance 13% and hair replacement-wig 6%. Those who selected hair replacement-wig were a subset of those who selected hair-loss. Nearly half (26/56) of those selecting just one item selected weight.

There was significant correlation between the number of body image related items selected and the number of PCI items selected in other PCI domains, the total number of other PCI items selected and the total number of health professionals selected (Table 18, Appendix 1). Those selecting four or more body image related items also selected a median (IQR) of 17 (10-23) other items and there was a clear gradient in the increase in numbers of other items across the PCI and in the number of health professionals selected as the number of body image related items increased. This is reflected also in the analysis of specific PCI items (Table 19, Appendix 1) and there were associations at P < 0.01 for 37 of the 46 non-body image related items. Associations existed at P < 0.001 for several items: wanting to discuss activity, arm swelling, breast texture, breast sensitivity/pain, indigestion,

memory/concentration, nausea, pain in arm or shoulder, sleeping, taste, vomiting, or sickness, anger, anxiety, fear of cancer spreading, mood, self-esteem, and fear about the future. Associations also existed at $P < 0.001$ for wanting to see the plastic surgeon, medical oncologist, radiation oncologist, breast care nurse, lymphoedema specialist, hair prosthesis advisor or breast prosthesis expert, and nurse practitioner.

The number of body image related items was significantly associated with treatment by chemotherapy, wide local excision/lumpectomy, mastectomy and reconstructive surgery (Table 20, Appendix 1), with an increase in items related to chemotherapy and mastectomy and reconstructive surgery and the absence of wide local excision/lumpectomy. There was also a tendency for fewer items to be selected by older patients aged 65 years and over, but no notable differences concerning the IMD deprivation measure and time of most recent diagnosis. A fuller stratification by treatment combination is shown in Table 21 (Appendix 1). Correlations between the number of PCI body-image related items and summary scores from the EORTC QLQ-C30 and the EORTC breast cancer QLQ-BR23 are summarised in Table 22, Appendix 1. These correlations were generally quite weak, the strongest of these being with the QLQ-BR23 Body image score and the QLQ BR23 systemic therapy side effects score.

Discussion

Breast cancer care was the first major cancer to be managed consistently by MDTs, and these MDTs were reviewed in the first round of the cancer peer review carried out in 2001 by the Breast Cancer Clinical Outcome Measures (BCCOM, 2007). A total of 174 breast cancer MDTs were included as part of the 2004-2007 peer review round. Of these, 88% had a full core team membership in place although only half of the teams met the National Institute of Clinical Excellence (NICE 2002) requirement to have two core members in all the key disciplines (BCCOM, 2007). Often the Primary care setting may be the first point of contact of patients with physical problems associated with the cancer and its treatment, plus social and psychological support. It has been estimated that an average practice of 10,000 patients will have around 23 registered patients who consult their GP about their breast cancer each year (Birmingham Research unit, 2007). Identifying patients with unsatisfied needs in an early stage of their treatment provides the opportunity to address these needs and enhance their quality of care (Bonevski et al, 2000). Unsatisfied needs and patient symptom burdens have a significant impact on patient well-being during treatment and on long-term adjustment (Holmes et al, 1997). Two conceptually different morbidity outcomes, unmet

needs and health-related quality of life, are used to identify cancer patients in need of clinical attention. Hansen et al (Hansen et al, 2012) confirmed that patient-perceived unmet needs of rehabilitation during the cancer trajectory are associated with decreased quality of life. In their study that included breast patients, they supported the use of 'unmet needs' questions to identify patients in need of clinical attention. According to the literature, the majority of cancer patients experience more psychological, interpersonal, health policy and system difficulties and other problems of living, than psychiatric symptoms [Cell DF (1987), Welch-McCaffrey et al (1989)]. Psychological adaptation to breast cancer could be measured in many ways including quality of life, satisfaction with care and needs assessment. Needs assessment differs from other assessment constructs in that it directly identifies patients with higher levels of need and suggests specific interventions for them [Bonevski et al (2000), Foot et al (1995), Park et al (2012)]. Therefore, evaluating patients need is important if we are to offer timely, effective interventions.

Of the 1952 items endorsed, 816 were related to physical function and care, indicating that this was a significant issue following breast cancer treatment. Indeed, the physical problems following breast cancer treatment can be overwhelming, and include postsurgical complications, skin reactions to radiation therapy, pain, numbness, functional limitations, lymphoedema, weight gain, hot flushes, and fatigue (CRUK, 2012).In this study, we specifically identified the following: fatigue and tiredness, sleeping and hot flushes, pain in the breast/arm, pain in the shoulder/elsewhere, and lymphodema. These seem to be common concerns following breast cancer treatment.

Fatigue, manifested as a global sense of loss of energy, is the most frequently reported source of distress associated with breast cancer, regardless of treatment modality (Winningham et al, 1994). Fatigue may be a symptom of directly related conditions or the result of breast cancer treatment, and includes anaemia, dehydration, chronic pain, depression, and sleep problems. It may also result from muscle mass loss and increased fat mass, particularly in those undergoing chemotherapy (Demark-Wahnefried et al, 2001). Identification in the review clinic should stimulate appropriate examination and investigation if needed, and the clinician can reassure patients and provide practical advice or treatment for its management. Furthermore, there is an opportunity to educate and reassure patients and families that fatigue is a frequent and expected side effect of breast cancer treatment. Encouraging self-care strategies may also provide benefit including exercise programs or recommending support groups such as 'The Haven Foundation'. In selected patients, the breast specific PCI may aid the monitoring of issues such as fatigue, and by proxy, aid in the evaluation of the menagement strategies.

Breast cancer survivors have 10% more sleep problems, and sleep problems that persist, than their peers without cancer. Additionally, survivors often develop hot flashes and a worse physical condition. For example, up to 90% of young breast cancer survivors experience premature menopause due to adjuvant treatment strategies such as chemotherapy, antioestrogenic agents, and ovarian ablation. Both therapy-induced hot flashes and vasomotor symptoms are common among breast cancer survivors undergoing natural menopause (Frieden et al, 2011), and their management can be difficult. Specific interventions are necessary to prevent them becoming an unmet need. However, the clinical team may lack the expertise in hypnotherapy, complementary and alternative medicine, or for pharmacological management that many women demand (Kimmick et al, 2006).

Lymphoedema was also endorsed, which is consistent with the fact that arm lymphedema affects approximately 30% of breast cancer survivors (Paskett, 2007). Some may not have troublesome lymphodema. However, it can have devastating consequences, with patients experiencing heavy, swollen, and stiff arms, with thickened, rough skin and frequent arm infections. Intervention is esential if it is flagged up as an issue, and will need addressing by the clinical team. Courses of regular, intensive physical therapy can help to reduce the lymphatic fluid volume in the affected arm.

Studies have shown that persistent pain after treatment for breast cancer is a common problem, ranging between 25% and 60% depending on the definition, measurement, and treatment (Andersen et al, 2011). There are several plausible reasons for this variation. Indeed, the most likely of these is that it can be difficult to detect pain in the clinic if not presented as an issue by the patient, or enquired over by the clinician. Additionally, some cases may relate to the need for ongoing treatment to prevent negative outcomes. It is therefore possible that the prevalence of persistent pain after breast cancer treatment has been underestimated.

The aromatase inhibitors (anastrazole, exemestane, and letrozole) used as adjuvant hormonal treatment in postmenopausal women with hormone-dependent breast cancer, can reduce bone mineral density, and increase the incidence of osteoporotic fractures. This could lead to pain, decreased physical activity, and declining functional mobility (Baum et al, 2003). A chronic pain syndrome following axillary dissection for breast carcinoma, known as post-mastectomy syndrome, often results from inadequately treated acute pain (Jacobs et al, 2006). Additionally, there are difficulties in the assessement and management of long term pain. Future studies with a tool such as the breast cancer specific PCI can provide repeat clinic assessement over time , offering a better overview of the symptoms and nature of pain following breast cancer treatment.

In this work, the significance of identifying and managing physical symptoms cannot be over-emphasized. This is particularly important because these may be the symptoms that clinicians are equipped to handle. That is in contrast with issues such as sexuality and intimacy that most surgeons are often ill-equipped to address effectively. It is evident that achieving the correct balance between rehabilitation and essential cancer surveillance is inherently difficulty in a busy National Health Service clinic. The breast cancer specific PCI may facilitate early target identification and provide an opportunity for interventions that impact both the patient-doctor relationship and the quality of the consultation.

HRQOL tools were developed to assess either newly diagnosed patients or those receiving treatment, and may therefore be inherently unable to identify the specific issues of long-term survivorship, such as FOR [Gotay et al (1998), Northhouse LL (1981), Hodgkinson et al (2003)]. In addition, with health- related- quality of life tools, patients rate the presence and severity of an item, and clinicians may be not sure if a specific item is a problem for which they need help (Armes et al, 2009). In the literature there are studies that report an association between FOR and psychological distress and a reduced quality of life score [Scharloo et al (2005), Humphris et al (2008)]. Armes et al (Armes et al, 2009) reported that FOR is a significant predictor of unmet needs. 30% to 50% of breast cancer survivors have unmet needs (Armes et al, 2009). A breast cancer specific PCI may be an important first step in the systematic assessment of patients' needs at different key moments in the cancer journey that specifically identifies issues including FOR. Pain is another common symptom among breast cancer patients. Lack of information on pain management has been identified as a significant barrier for pain control among minorities (Cleeland et al, 1997). Reluctance to report pain might lead to less physician awareness of the symptom and inadequate pain assessment. A breast cancer specific PCI may play an important role in resolving pain for low-income ethnic minority patients by improving the patient clinician interaction. Recently, studies have emerged in breast cancer patients investigating whether differences in clinician-patient communication may have an impact in the prevalence and /or resolution of breast cancer related symptoms (Maly et al, 2010). Depression was the most common symptom reported by patients (66%), yet physicians were the least aware of it (26.3%) (Maly et al, 2010). Often, physicians tend to focus on cancer treatment details during patient visits and may overlook psychiatric symptoms (Maly et al, 2010). In addition, physicians may feel less well equipped to deal with psychiatric issues than with medical problems [Valente et al (1994), Maguire P (1985)].A Breast cancer specific PCI may contribute to the resolution of depressive symptoms since it is aimed as an intervention targeting the patient-clinician consultation. The quality of the interaction between a breast cancer patient and her / his

clinician appears to have an effect on the PROs, rather than the frequency and the length of the consultation (Tan et al, 2011). One might expect a positive outcome such that of a reduction of the treatment related symptoms. However, Tan et al (Tan et al, 2011) reported that as patients discussed with and sought information at baseline from their physicians about their cancer treatment, quality of life, and other cancer-related issues, there was a tendency for patients to report experiencing more cancer-related issues the following year. Literature reports several outcomes as a direct consequence of the clinician -patient interaction. For example, an experiment revealed that the routine collection of health-related quality of life data from patients led to a better subsequent quality of life and emotional functioning (Velikova et al, 2004). In a study by Detmar et al (Detmar et al, 2002) the use of patient-reported quality of life assessments during visits led to a greater percentage of patients identifying moderate to severe problems in various health domains. Stark et al (Stark et al, 2004) observed that anxiety could be exacerbated through medical discussions. We know from the literature that good communication skills are crucial for the clinical care of women with breast cancer [Fallowfield et al (1999), Maguire P (1999)], but it appears that the relationship between patient experience and a clinician's communication skills is much more complex. Patients with cancer want a relationship with their doctors [Jefford et al (2002), McWilliam et al (2000), Butow et al (2002)], yet this relationship is a dynamic process and can be affected by the clinician's communication skills. Although these communication skills can be enhanced by training, enhanced skills do not always improve a patient's experience (Fallowfield et al, 1999). It appears that patients want information that will help them to maintain hope and trust throughout the cancer journey [Hulsman et al (2002), Leydon et al (2000)]. Therefore, mutual communication that is non-judgmental and features an inclusive orientation towards each other, is considered a central feature of therapeutic relationships [Hack et al (2005), Feldman-Stewart et al (2005), Kreps G (1988), Roter DL (2000)]. The oncologist-patient communication has been shown to serve as an information exchange platform that takes into account the relational needs of patients (Hack et al, 2005). Early cancer communication research described patterns of information exchange, revealing clear dominance of talk by clinicians [Kaplan et al (1989), Siminoff et al (2006), Butow et al (1997), Nussbaum et al (2003)]. Patient-cantered communication is dependent on both the clinician's expressed recognition of the patient's needs, as well as communication of complex medical information (Step et al, 2009). The BC specific PCI may play a vital part towards the improvement of the consultation as a process by the provision of specific points as well as by acting as an aid memoire for the patients.

Following the guidance from documents such as ' Improving supportive and palliative care for adults with cancer' (NICE, 2004) and ' Improving outcomes in breast cancer' (NICE,

2002), clinicians involved in the management of patients with breast cancer recognised the need for a holistic approach. The assessment and discussion of patients' needs for physical, psychological, social, spiritual, and financial support are key points in breast cancer care and followed locally by our institution. The breast cancer specific PCI offers a role in ensuring comprehensive care and could be incorporated into both local and national integrated care.

There are over 550,000 women living in the UK who have been treated for breast cancer (Cancer Research UK; CRUK, 2013). Survivorship after Breast Cancer together with the medical and psychological needs of these patients has become increasingly recognised [Ganz PA (2004), Ganz PA (2002), and Ganz PA (2008)]. FOR is a common challenge and unmet need among cancer survivors (Lebel et al, 2012). Recurrence may be local, regional, distant (often lungs, liver, bone marrow) including in the contralateral breast. For some patients, emotions that were put aside during cancer treatment come flooding back all at once, and they feel overwhelmed with fear. In 9% to 34% of cancer patients, the fear of cancer recurrence becomes so overwhelming that it affects quality of life (Custers et al, 2013). Patients are cancer survivors but often they are afraid that the cancer may come back and that they will have to go through the experience again. In some occasions, this emotion is so overpowering that may be one of the driving forces for prophylactic mastectomies. Recently in the literature, there is a substantial increase in the number of therapeutic mastectomies for breast cancer and an increased rate of contralateral prophylactic mastectomies [Arrington et al (2009), Jones et al (2009), McGuire et al (2009)].

Specific tools designed to identify FOR may not be practical for use in isolation in a busy breast-cancer outpatient clinic. A tool that may be able to identify FOR as an issue, as well as assessing other core issues that breast cancer patients feel overwhelmed by, may be much more practical, useful, and applicable in routine outpatient care. It is with this scope in mind that the breast cancer specific PCI has been employed in this study. Here we explore the ability of the PCI to identify a group of breast cancer patients in which FOR is a barrier that prevents them from making the transition from cancer sufferer to cancer survivors.

Using the PCI, we identified a sizeable group of patients that reported FOR as an issue following their treatment for breast cancer. Of interest was that the patients that selected more than on 'fear' had also selected multiple other items. The PCI may identify the patients that are in need of extensive support during their cancer journey. The relationship with age and FOR that has been reported previously (Lebel et al, 2013) has been confirmed once again by this study. Apart from FOR, we confirmed a series of issues that breast cancer patients need to overcome in order to escape the shadow of living with a life-threatening illness (Table 12, Appendix 1).

FOR is a common concern that may become an issue since it may not be possible to identify patients based on clinical parameters (Rogers et al, 2010). FOR has been reported elsewhere using the PCI in head and neck cancer patients (Ghazali et al, 2012), as have specific interventions, such as 'AFTER' (the adjustment to the fear, threat or expectation of recurrence). The proposed AFTER intervention targets recurrence fears, inappropriate checking behaviour, and beliefs about cancer intervention (Humphris et al, 2012). It is of interest to note that initial testing of the AFTER intervention showed acceptability, which may have applicability for patients who have been treated with cancer at other sites. A study that was conducted in women one week after breast cancer surgery indicated that FOR and anxiety regarding post-operative treatments accounted for more than 65% of the responses to the question "What concerns you most about your new diagnosis?" (Stephens et al, 2008).

FOR may be more prominent in women with a history of anxiety or depression. Costanzo et al (Costanzo et al, 2007) reported that some breast cancer survivors are at risk of sustained distress. In that study, participants reported moderate distress that appeared to be associated with FOR. Another aspect that must be taken into account in the management of patients after diagnosis and treatment of breast cancer is that both patients and their partners may be pre-occupied with FOR and that this may remain for years after treatment (Jiwa et al, 2006). Hodges et al (Hodges et al, 2005) for example, reported in a meta-analysis that carer FOR is higher than that of patients, and suggested that early intervention with the patient and their carer could prevent later development of psychological distress in both. Another aspect of interest is that there may be significant emotional distress in a small number of husbands. Walker (1997) (Walker BL, 1997) concluded that women with breast cancer are best viewed as a unit with their spouses; behavioural changes within this unit can affect either member. Also FOR may not always be obvious, but instead manifests as a variety of mental health problems.

Radiotherapy is a common modality that is often used in the management of breast cancer. FOR has such an impact on HRQOL, that patients are willing to accept the side effects of radiation therapy, perhaps in an attempt to alleviate that fear (Hayman et al, 1997). It is essential that FOR should be evaluated longitudinally. Simply waiting for FOR to recede may not be a viable clinical option for supporting the cancer survivor, as it may simply not resolve without proper intervention.

Once FOR is identified, the management of these patients can be a challenge. Several interventions have been reported in the literature. Van den Berg et al (2012) suggested the 'Breath Intervention' in order to facilitate emotional, physical, and social recovery of all breast cancer survivors. Another approach (Crane-Okada et al, 2012) includes trained senior peer counsellor volunteers, supervised by a skilled clinical team, as an adjunct in addressing

psychosocial needs of women after breast cancer surgery. Little attention has been directed to the longer-term survivorship phase for older breast cancer survivors who often continue to be affected adversely from the late and long-term effects of treatment including FOR (Crane-Okada et al, 2012). The available feedback indicated that The Mindful Movement Program experience yielded positive results and was feasible for a variety of older BCSs (29). Thewes et al (2013) explored the relationship between FOR and maladaptive metacognitions. They concluded that treatments that focus on altering unhelpful metacognitions might prove a useful approach for the treatment of FOR (Thewes et al, 2013). Literature reports suggest that mindfulness-based stress reduction (MBSR) reduce FOR and improves physical functioning, which reduce self-perceived stress and anxiety (Lengacher et al, 2012). Other suggestions for improving the management of FOR, include treatment for anxiety, the provision of social support, and better patient education (Liu et al, 2011). The use of the PCI as a tool for the identification of FOR conforms well with recent research supporting the use of such measures as well as supporting longitudinal research examining its impact (Simard et al, 2013).

It is increasingly recognised that FOR is an area that patients, carers or clinicians will not broach routinely within an outpatient follow-up appointment. The findings presented in this study confirm that FOR is a major concern for the majority of patients, and pre-appointment interventions such as the PCI may assist by giving tacit permission for these fears to be discussed. A possible reason for the low frequency of eliciting these fears by clinicians without aids such as the PCI is lack of training. Discussion of FOR in the clinic demands members of the clinical team, including senior doctors and nurses, to set aside time for this exchange to happen. Time is probably the most strained resource in the running of a comprehensive oncology service, therefore, clinician need good communications skills [(Samant et al (2010), Epstein et al (2011)] to make the most of these opportunities. These skills include: listening carefully to the fears expressed; summarising and checking for clarity of understanding; providing clear information; where possible, providing factual evidence regarding recurrence; and, discussing the potential treatment options for recurrent tumours. This discussion may occur over a number of routine appointments. The balance between realism and providing some hope [Olver (2012), Leydon (2008)] needs to be carefully balanced. However, the offer of discussing this crucial topic may be the difference between a patient developing a stable FOR, an intrusive FOR that is resistant to change, or a patient who is able to face the prospect of further disease and not be disabled by FOR.

Identifying FOR in the routine outpatient clinic may have further clinical implications. The relationship between FOR, and it role in steering the treatment preferences of patients, is complex. It may be that if a strong patient-centred approach were adopted, it would increase

the frequency of bilateral mastectomies. This example has been illustrated in a study by Corter et al (2012), where all illness perceptions were associated with FOR. In addition, beliefs on the necessity of medication were significantly correlated with FOR, although concerns were more often raised over the treatment effectiveness and there were calls for extended prescriptions.

A potential implication of PCI implementation that would require further evaluation, is that it is difficult to know when the level of FOR becomes so high that rational intervention and risk reduction strategies become near irrelevant. Indeed, if a patient believes that their risk of recurrence is near 100%, then any attempt to implement practical risk reduction could be ineffective. For example, the benefits of reducing body-weight to lower cancer recurrence risk may not be practised because of this FOR, making any attempt to persuade patients to reduce calorific intake pointless. Other important aspects to consider once FOR is identified in the outpatient clinic, will therefore be an establishment of the level at which FOR should be considered suitable for intervention. Further research will be required in order to identify the active components of an intervention (such as AFTER for example).

Many changes to our appearance may occur through life. These may be planned or unplanned, desired or not (Newell et al, 2000). There are several definitions of body image in the literature based on body size estimation, evaluation of body attractiveness, feelings associated with body size and shape (Grogan et al, 1999). The definition we use relates body image to a person's perceptions, feelings, and thoughts about his or her body [Grogan et al (1999), Muth et al (1997).

Women treated for breast cancer endure scars and disfigurement of the breast, skin changes related to radiotherapy and/or hair loss due to chemotherapy [Hopwood et al (2001), Falk Dahl et al (2010)]. These effects from the disease and its treatment are life changing and can lead to a significant alteration in body image [Falk Dahl et al (2010), Helms et al (2008)]. In turn this effect on body image can result in undesirable Health-Related-Quality-of Life (HRQOL) changes that affect the transition from patient to breast cancer survivor [DeFrank et al (2007),Holmes et al (2008), Pikler et al (2003), Hopwood P(1993), Frierson et al (2006), Collins et al (2011)]. Younger patients may be more susceptible to stress related to change in body image and report greater changes in HRQOL scores [Noguchi et al (1993), Margolis et al (1990), Kemeny et al (1988), Beckmann et al (1983)]. Brunet et al (2013) (Brunet et al, 2013) reported that women with breast cancer experienced various physical changes that negatively affected, their perceptions, thoughts, attitudes, feelings, and beliefs about their bodies. Based on these findings they highlighted the need to recognise body image concerns that could have a long lasting effect on the HRQOL.

Przezdziecki et al (2012) have recognised the link between body image disturbance, lower self-compassion, and an increase level of distress. Specific treatment options such as mastectomy may adversely affect specific aspects of body image such as problems related to sexual intimacy (Fallbjork et al, 2012). Mastectomy may alter body image so much that can obliterate sexual relationships for a period of time (Boehmke et al, 2005). Support in relation to sexuality and body image could improve relationships by modifying perceptions with a direct improvement in patient's and spouse's HRQOL (Sheppard et al, 2008). Clinicians do not always elicit such concerns from patients. One way of improving recognition of these problems is to develop tools to improve clinicians' communication with patients. Cohen et al (2012) suggested that patients want honesty, openness, and directness from their physicians during the discussion of breast-related body image issues (Cohen et al, 2012). Breast cancer patients rate the information on physical changes, sexual response, and body image as very important (Ussher et al, 2013). However, Ussher et al (2013) reported that only 41% of their patients obtained such information, hence only 34% of patients claimed to be satisfied with this aspect of their consultation.

Body image can affect a woman's treatment decisions with respect to surgical options such as mastectomy versus breast conserving surgery (Fadaei et al, 2011). A multidisciplinary approach to address the impact of body image, with specific medical and psychosocial interventions has been analysed (Bifulco et al, 2012). Younger patients take longer to make treatment decisions and require enhanced levels of support compared to older adults. The availability of breast reconstruction only partially ameliorates this effect (Metcalfe et al, 2012).

Body image changes associated with mastectomy, chemotherapy, and radiotherapy are well-recognised [Esmaili et al (2012), McGaughey A (2006), Hopwood et al (2010)]. Up to a third of women report moderate or marked breast, arm, and shoulder symptoms over 5 years of follow-up after radiotherapy, and skin changes related to radiotherapy are well document in the literature (Schnur et al, 2011). However, these appear to have little impact on body image. As expected, adjuvant treatments (chemotherapy and radiotherapy) are associated with decrease in overall HRQOL, an increase in physical problems and adverse effects on the body image [Browall et al (2008), Boehmke et al (2005)].

Tools exist to evaluate changes in body image following breast cancer, and are useful in both research and clinical settings (Hopwood et al, 2001). A number of HRQOL instruments in use in breast oncology have incorporated body image questions [Hopwood et al (2001), Sprangers et al (1996), Kanatas et al (2012), Baxter et al (2006), Polivy J (1977), Stanton et al (2005), Brady et al (1997), Pusic et al (2009)] (Table 16, Appendix 1) . HRQOL questionnaires are designed as outcome measures to compare groups of patients. Although

some studies have described their use in clinical practice, they are not specifically designed for this context. While it is tempting to use the scores derived from such tools to screen patients from problems relating to body image, thresholds to trigger specific interventions are not currently defined in breast cancer care. Furthermore, these tools are time-consuming to use and hence may not be practical in a busy clinical environment.

In other types of cancer, HRQOL tools have been used as a trigger for discussion of patients' problems of appearance (Flexen et al, 2012). HRQOL tools can help focus the consultation and are a suitable means of screening for appearance issues (Katre et al, 2008). In head and neck cancer, the PCI has been used with HRQOL tool and its role has been defined (Flexen et al, 2012). The PCI enables holistic evaluation of body image concerns in the breast-cancer outpatient clinic (Kanatas et al, 2013).

This is the first study in which the BR23 questionnaire and the PCI have been used in combination to screen for body image problems in patients with breast cancer. Although several important points have been raised, we must recognise that there are limitations to this study. The study involved a relatively small sample of patients from one area in the United Kingdom, thus the results may reflect the beliefs and practice of this group, and caution is necessary before extrapolating our findings to other settings. Future longitudinal studies need to focus on body image and could to examine whether body image state eventually returns to values similar to those before the breast cancer diagnosis. Body image should not be seen in isolation. There is a need to examine any possible associations with sexual function and quality of life. In this study there were weak correlations between the number of PCI body image items and the EORTC tool. Another limitation of this study is that a specific body image scale would have been appropriate (Hopwood et al, 2001). Items such as change in self-consciousness with appearance, less sexually attractive, less feminine, dissatisfaction with appearance when dressed, and body feeling less whole that are present in the QOL BR23 were not assessed in our study. The absence of these items may be seen as a weakness of the breast specific PCI, but these were items that there were not selected during the development of the PCI. This may be due to characteristics of the cohort of patients that were used for the development of the PCI.

The body can be viewed as a symbol of social expression (Cohen et al, 1998). Breast cancer diagnosis and treatment can result in a sustained disturbance of that view at 12 months post-diagnosis and beyond (Falk-Dahl et al, 2010). This is reflected in our study since 54% of patients were diagnosed at least two years prior to enrolment. Body image is clearly an important issue since 68% of patients selected an item from the body-image domain. In this study, the number of body image related items was significantly associated with chemotherapy and mastectomy, and reconstructive surgery. Some previous studies showed

that chemotherapy, hormonal therapy and radiotherapy do not have a negative effect on body image (Fehlauer et al, 2005). In contrast, the findings from this study are consistent with, Schover et al. (Schover et al, 1995) who concluded that chemotherapy do have a negative impact on body image, while hormonal and radiation therapy do not. Breast appearance was the item most frequently selected followed by weight and mastectomy appearance. This is not unexpected since the physical effects of breast cancer treatment on the body serve not only as a personal reminder of the disease but also as an 'announcement' to others (Rasmussen et al, 2010). Yurek et al (2000) (Yurek et al, 2000) reported that those patients who underwent a lumpectomy faced less body-change stress than women undergoing a modified radical mastectomy with or without breast reconstruction.

In this work only 14% of patients selected hair loss. This low incidence may be explained because most participants completed the PCI several months after their chemotherapy by which point hair-loss had recovered for the majority.

As it can be seen in table 18 (appendix 1), those patients selecting body image related items selected a median of 17 other items. The effect of breast cancer on body image should not be under-estimated, and this is widely reflected in the literature. Fallowfield et al. (Fallowfield et al, 1986) found that the incidence of anxiety and/or depression was as high as 38% in patients with a surgical intervention. Age was negatively correlated with the items detected.

We found that older patients tended to select fewer items and this is consistent with Al-Ghazal et al (2000) (Al-Ghazal et al, 2000) who compared the psychological outcome and satisfaction of patients undergoing wide local excision, mastectomy alone or mastectomy with breast reconstruction. This study reported that while women of all age groups face body image issues after breast cancer surgery, women between 40 and 59 years of age report more body image issues after breast cancer surgery.

The head and neck PCI has been used before as a tool to identify appearance-related concerns (Flexen et al, 2012). Appearance was highlighted as a problem on the PCI at 9% (42/454) of questionnaires, and was indicated as a serious problem on 10% (47/454) of UW-QoL questionnaires. Concerns about appearance were raised on the inventory or were shown to be a serious problem on the UW-QoL in 14% (64/454) of patients. One must be cautious comparing our findings with that work since appearance was related to the face, and the participants included male patients and patients with different socioeconomic characteristics.

The methodological weaknesses of this study include the small sample size, specific patient groups, and specific cancer-related aspects such as positive adjustment following breast cancer. In addition, patients completed the breast cancer specific PCI after their clinical consultation and there was no clear link between the PCI and subsequent consultations, as

the study took place over two institutions. These factors may have influenced the responses, and a degree of caution is required in the interpretation of the results.

The extent to which all questions contribute positively toward measuring the same concept is known as internal consistency (Staquet et al, 1988; Tavakol, 2011) and can be assessed using Cronbach's alpha. In general, the acceptable range is between 0.70–0.95, although levels above 0.85 are optimal (Staquet et al, 1988). In the context of the PCI items generated, interpreting the coefficient values (Figure 5) is not an easy task, as the list is composed of diverse items measuring diverse issues. Similarly, the PCI domains were created for the convenience of grouping loosely related items, rather than for a parsimonious set of closely related items. Indeed, we know that a low alpha value can result from too few questions, poor interrelatedness between items, or heterogeneous constructs (Staquet et al, 1988; Tavakol, 2011). Additionally, alpha is affected by test length and dimensionality, with longer tests having greater reliability, regardless of homogeneity. This may have occurred in the case of the breast cancer specific PCI, which had an overall acceptable alpha value. However, at times the analysis by domain (that is, the percentage selecting at least one item from the domain) seems appropriate.

Care was required when contemplating the removal of items at this stage of the PCI development. The balance for the PCI checklist was towards having inclusive 'content' rather than ansuring an economical set of items with psychometric methods applied to remove items that correlated poorly with other items within the domains.

The Cronbach’s alpha values are difficult to interpret, with generally low domain values, and the highest being those with the greatest number of items. The alpha for the whole PCI check list (56 items) was the highest at 0.897, which at first inspection seems at odds with the clear multi-dimensionality of the items. However, this probably reflects the large number of items as stated above. Thus, acceptable alpha values are possible even when using items with poor internal consistency, provided a scale has sufficient items. The sample size of 200 gives a reasonable denominator, while the rarity of many of the items (the numerators) inevitably detracts from assessing their usefulness as domain items.

An equally important consideration is the reliability and validity of what is being asked of patients; they are being asked to highlight concerns that they want to discuss. Reliability is therefore implied if respondents provided consistent responses (as to which issues they wished to discuss) over a specified time-period. Validity, which refers to a tool measuring what it is supposed to measure, is determined by whether someone who says they want to discuss an item of concern really does want to discuss it. Future study including more clinicians with a longitudinal design would be required to address this issue.

A key message from this phase was that the alpha value was heavily dependent on the number of items withing the scale/domain/dimension. Since PCI items should highlight slightly different aspects of the same construct, our aim was not to achive a perfect association between items, but to avoid redundancy. Internal consistency should then be assessed for each sub-construct separately. However, we do not know which items relate to which domains, or how many psychometric domains actually exist. To evaluate dimensionality further would require a factor analysis to determine whether specific items are related to particular domains, and whether all domains are sufficiently covered by the specified number of items. This would ideally require numerous items, using a Likert-type scale, and many hundreds of patients (Staquet et al, 1988). However, the sample size of 200, the less informative binary Yes/No options, and the infrequent responses to many items imply a lack of power for factor analysis in the present study.

Conclusions

The PCI may empower patients to raise issues that otherwise could be missed. This could improve self-efficacy within the patient–physician encounter. In addition, there is the opportunity for multi-professional engagement across a range of issues specific to breast cancer thus allowing for additional support, which might result in a higher rate of symptom resolution, and improved HRQOL. Finally the breast cancer specific PCI is a practical tool that may be able to assist in the holistic needs assessment of patients during the cancer journey.

Potentially the PCI may be employed in the outpatient clinic to assess the relationship between the levels of FOR and when any new information, such as the results of mammograms, is presented. For example, it has been shown that the results of imaging and their description by clinical members have an influence on the images held by patients of their tumour (Harrow et al, 2008). Some images that are memorised by patients have been shown to possess ‘active’ elements described by patients as ‘tentacles’ or ‘pincers’. Do the impressions gained by patients during clinical procedures or appointments produce conditions in which FOR is magnified? Do they lead to a quality that prevents dismissal from consciousness to the point that the fears and thoughts generated become uncomfortably intrusive? Such processes fit Leventhal’s model (Leventhal et al, 1997) of illness representations and demonstrates the fertile landscape of patient imagination, management challenges in the presentation of images, and associated stimuli (e.g., the drawing of diagrams by the clinician) associated with the cancer diagnosis and personal response to cancer threat and post-treatment coping including FOR development.

The routine use of the PCI in breast cancer patients facilitates a holistic approach to management. It identifies the need for interventions; this can have a bearing on resource allocation and should provide a direction for future research. The role of interventions such as body beauty treatments to body image (Quintard et al, 2008) and exercise need (Adamsen et al, 2009) in breast cancer patients needs to be evaluated further.

The breast cancer specific PCI may help women to engage in an honest conversation about their cancer related body image issues. It can be used as a screening tool for body image in order to identify a subgroup of patients that would benefit from focused interventions.

CHAPTER 8. Further Development of a Breast Cancer Specific Patients Concerns Inventory (PCI): A Pilot Before-and-After Study (Phase 3)

Introduction

This section of the thesis focuses on phase 3 of the development of the Patient Concerns Inventory (PCI), from the introduction and pilot use of the PCI in a before-after study of the breast cancer specific PCI in a single breast consultant-led outpatient clinic. This part of the research involves the collection and analysis of qualitative data and was designed to provide an early indication of the effectiveness of the instrument in a clinical setting.

Qualitative Research

A qualitative research is defined as an inquiry process conducted in a natural setting for understanding a social or human problem, based on building holistic pictures formed with words, and reporting the detailed views of informants (Creswell JW, 1998). Kenny et al (1980) suggested the following three conditions to help decide on the appropriateness of using a qualitative approach:

1. Consider a case study when the focus is on humanistic outcomes or cultural differences, as opposed to behavioural outcomes or individual differences.

2. The uniqueness of the situation.

3. Consider case study data when collection is not subject to truth or falsity but 'can be subject to scrutiny on the grounds of credibility.

We employed a qualitative approach since it is exploratory by definition, and it is suitable when we do not know what to expect. This approach allows both the definition of specific issues resulting from breast cancer, and for the development of mechanisms for their resolution. There is general agreement in the literature (Miles et al, 1994) that qualitative researchers need to ensure study validity; this can be achieved through peer reviews, member checking and external audits to ensure the validity of the methodology. In this study, we used the coding process in order to control any investigation bias.

Thematic coding and analysis of the qualitative data after rolling out the PCI in a consultant outpatient clinic

Thematic coding refers to any method of categorising segments of qualitative data into meaningful themes (Krippendorff K, 2004). Content analysis is a rigorous form of thematic coding with a good inter-rater reliability; codes can then be used as basis for quantitative

analysis (Krippendorff K, 2004). Content analysis involves counting instances of particular occurrences that can be anything of interest such as a specific word or phrase, a semantic category or a type of utterance for e.g. adjective, verb, laughter, silence. In 1952, Bernard Berelson published *Content analysis in Communication Research*, which was regarded as a versatile tool for social science and media researchers (Berelson, B, 1952) considered to be an unobtrusive, non-reactive method of social research (Loy, 1979). One of the uses of content analysis is to study the changing trends in theoretical content and methodological approaches. As a known unobtrusive method, content analysis is often used with sensitive topics, to corroborate the findings of other methods (Hansen A., 1998). Studies using content analysis usually involve the following six steps (Stempel GH, 1989):

1. Formulation of the research question or objectives
2. Selection of communication content and sample
3. Developing content categories
4. Finalising units of analysis
5. Preparing a coding schedule, pilot testing, and checking inter coder reliabilities
6. Analysing the collected data

Analytical frameworks including *the framework approach* (Ritchie J, 2003) and *thematic networks* (Attride-Stirling J, 2001) are gaining in popularity because they systematically and explicitly apply the principles of undertaking qualitative analysis to a series of interconnected stages that guide the process. A framework approach was employed in this work in order to describe and interpret the views of participants.

This section of the thesis attempts to answer to the hypothesis: *'Using a specifically developed Breast Cancer PCI in clinical practice, will help to identify patient concerns, improve consultations between professionals and patients, and help inform pathways for patients to follow so that their concerns are addressed.'* The Specific objective was to pilot the use of PCI in breast cancer, in a before-after study.

The outcomes that were recorded included:

1. Duration of consultation
2. Items discussed in the consultation
3. Any onward referrals made
4. Patient satisfaction Questionnaire score

Materials and methods

Inclusion Criteria

Adult patients (over 18-years) with a history of either diagnosis or treatment for breast cancer were included. For non-English speakers interpreters were provided in the clinic as per current NHS practice.

Design and research subjects

We proposed the introduction of the breast PCI (Appendix 2-N) into a clinic, with the aim of evaluating items raised in the consultation before and after its implementation with a specific clinician. The patient population was limited to 50 for several reasons. Primarily, it was a pragmatic choice, given that the interviews were to be recorded and analysed. Additionally, a literature review confirmed that this was a suitable number, and it was consistent with our experiences in the development of the Head and Neck PCI. Consecutive patients were recruited from the clinic.

The study was designed to compare the outcome measures between two different cohorts:

1) Patients attending clinic prior to the introduction of the PCI labelled cohort 1 (the 'no PCI cohort'; n=25)

2) Patients attending clinic after the introduction of the PCI labelled cohort 2 (the 'PCI cohort'; n=25)

An 9-item patient satisfaction questionnaire has been used in this study (Stewart el al, 1999 and 2001) (Appendix 2-R).This 9-item questionnaire was developed for education purposes, to provide feedback to physicians on their own perceptions on a series of patient encounters compared to their patients' perceptions of those same encounters. When examining this 9-point scale for validity and reliability the Cronbach's alpha reliability of the 9-item patient questionnaire is 0.80, n=85. Validity of the 9-item questionnaire is based on the origin of the items. This measure was chosen for practical purposes -easy to complete, brief- in addition to the fact that has been validated in breast cancer patients. This questionnaire has been used before in the breast oncology department of Leeds Teaching Hospitals.

Phase 3: The introduction of the breast PCI in to clinic

The treating consultant (KH) and the Clinical Nurse (CPN) identified suitable patients. During routine clinic appointments, patients were asked if they wanted to participate in the

study, starting at their next appointment (at least 4 weeks in advance). Those that they wished to participate were given an information pack by the clinical team. This included the study details (Appendix 2-P) and a consent form (Appendix 2-Q). On their next appointment, the patients that agreed to take part in the study attended their consultation.

The ‘no PCI cohort’ attended for their clinic appointment as normal and the principal investigator recorded their consultations. After the consultation, they were asked to fill in a brief questionnaire about their satisfaction with the consultation (Appendix 2-R) (Stewart el al, 1999 and 2001). The 'PCI cohort' was asked to complete the PCI in the waiting room prior to their appointment. The PCI used is presented in Appendix 2-O; this contained identical items to those in the PCI shown in Appendix 2-N, with the exception that the format was changed to bring it in line with the style used in the Head and Neck PCI. The consultation was recorded. After the consultation, they were asked to fill in a questionnaire about their satisfaction with the consultation (Appendix 2-R).

Data analysis of qualitative data

The audio tapes were transcribed and the transcripts were checked against each audio recording to verify their accuracy. The transcripts were then analysed using a thematic framework analysis. The framework presented (Appendix 2-T) is based on the themes derived from previous knowledge acquired during the development of the head and neck PCI [Rogers et al (2009), Ghazali et al (2013)].

Evaluation of the consultation involved: the identification of both the number and type of concerns; involvement by healthcare or supportive professionals; and, the clinical actions that resulted from the consultation. The framework approach (Ritchie J, 1994) (Appendix 2-S) was used to analyse the transcribed recordings.

The themes were then coded into discrete categories: the items of concern, healthcare professionals, and the type of clinical action or decision made during the consultation. For example, words or phrases such as “lethargy,” “exhausted,” or “run down” were categorised under the theme of “Fatigue or tiredness.” Outcomes were classified as medical or non-medical. Medical actions included: being placed on operative waiting lists, symptomatic or supportive medical treatment, investigation, and referral. Non-medical actions included: information provision, lifestyle advice, coping strategies, and reassurance. The system was developed to standardise the classification of spoken phrases or terms used by patients and clinicians for evaluation purposes.

To improve the reliability of the qualitative data analysis, a second independent and skilled qualitative researcher (BR), assessed the transcripts and compared their conclusions. Both assessors randomly evaluated one out of every four transcripts. Concordance was 78% to

100%. This enabled formation of the thematic framework, which was used to evaluate the remaining transcripts. When an item was identified by one assessor but not by the other, it was discussed until resolved, which involved building a holistic picture of either the patient, the clinician, or both. On this basis, both assessors ultimately agreed key ideas and themes. This was particularly relevant when items were missed because they were not in the framework, as they were carefully considered for potential new coding. However, for the purpose of this thesis, they were considered under "Others." The overall level of agreement for each consultation assessed was derived as a percentage using the simple formula: number of items agreed divided by the total number of items identified.

Audio-recording equipment

To ensure uniformity, audio-recordings were only conducted in consultations that involved a breast cancer surgeon, as other clinicians were not familiar with the PCI. A Tascam DR-40 (TEAC UK Ltd., Watford, UK) recorder was used to record whole consultations, which were saved in MP3 format. All identifiable information was removed to maintain confidentiality. Only recordings of complete consultations were transcribed for use (Appendix 2-U).

Study Measures and statistical analysis

1. Consultation questionnaire (Stewart el al, 1999 and 2001) asked patients to consider the consultation that day. Nine questions were asked, each with four response options.
2. The PCI.

SPSS version 19 was used for the statistical analysis. The Mann-Whitney test was used to compare Cohort 1 (no PCI) and Cohort 2 (with PCI) for distribution of responses to ordinal questions from the consultation questionnaire, and in the distribution of tumour staging and year of most recent diagnosis. Age was compared between cohorts using the two-sample t-test, whilst Fisher's exact test compared other characteristics. The chi-squared test compared responses to question 5 of the consultation questionnaire, which was non-ordinal.

Results

Cohort 1 had 24 female patients, and cohort 2 had 29. The personal, clinical and treatment characteristics of patients in both cohorts were similar (Table 23, Appendix 1).

Answers to the consultation questionnaire were generally positive irrespective of cohort (Table 24, Appendix 1). However, Cohort 1 gave better responses for seven of the nine questions (i.e. before the introduction of the PCI). The exceptions were questions 3 and 9,

asking about how much the doctor listened to what the patient said, and how much the doctor discussed personal or family issues that might affect their health, respectively. The onward referral made can be seen in Figure 9. The PCI items and health professionals selected by the 29 patients in cohort 2 are shown in ranked order of frequency in Figures 10, 11, and 12 (below) and are summarised in table 25 (appendix 1).

Patient number	**Outcome of consultation**	**Patient number**	**Outcome of consultation**
Cohort 1		**Cohort 2**	
1	**General Practitioner (GP) letter**	**25**	**GP letter**
2	**Plastic surgeon , GP letter**	**26**	GP letter
3	**GP letter**	**27**	GP letter
4	**GP letter**	**28**	
5	**GP letter**	**29**	GP letter
6	**Medical Oncologist, GP letter**	**30**	GP letter
7	**GP letter**	**31**	GP letter
8	**GP letter**	**32**	GP letter, Complementary therapies
9	**GP letter, referred for mammogram**	**33**	GP letter
10	**GP letter**	**34**	GP letter
11	**GP letter**	**35**	GP letter
12	**GP letter**	**36**	Geneticist, GP letter
13	**GP letter**	**37**	GP letter
14	**GP letter**	**38**	Breast care nurse, GP letter
15	**GP letter**	**39**	Plastic surgeon, Specialist nurse, GP letter
16	**GP letter**	**40**	Complementary therapies, GP letter
17	**GP letter**	**41**	GP letter
18	**GP letter**	**42**	GP letter
19	**GP letter**	**43**	Breast care nurse, GP letter
20	**Plastic surgeon, GP letter**	**44**	GP letter, referral for mammogram
21	**Dietician, GP letter**	**45**	GP letter
22	**GP letter**	**46**	GP letter
23	**GP letter**	**47**	Lymphoedema clinic, Breast care nurse, GP letter, Complementary therapies
24	**GP letter**	**48**	Clinical Psychologist, GP letter, referral for body scan
		49	GP letter
		50	GP letter, complementary therapies
		51	Plastic surgeon, GP letter, Breast care nurse
		52	Complementary therapies, clinical psychologist, GP letter
		53	Breast care nurse, Complementary , Dietician

Figure 9 Referrals made at the end of the consultation in the before and after study

The most frequent items were: fear about the future (48%, 14), anxiety (38%, 11), fear of cancer coming back (28%, 8), breast appearance (21%, 6), fear of cancer spreading (14%, 4), pain in the breast (14%, 4), pain elsewhere (14%, 4) and nausea/vomiting (14%, 4). The members of the MDT that were the most frequently selected were the breast surgeon (100%, 29) and the plastic surgeon (10%, 3). The number of items selected is shown in Table 26 (Appendix 1), both overall, and by domain. The items selected and discussed in the clinical consultations are shown in Table 27 (Appendix 1), and are compared in Figure 12 (see below). The duration of the consultation in minutes is shown in Table 28 (Appendix 1).

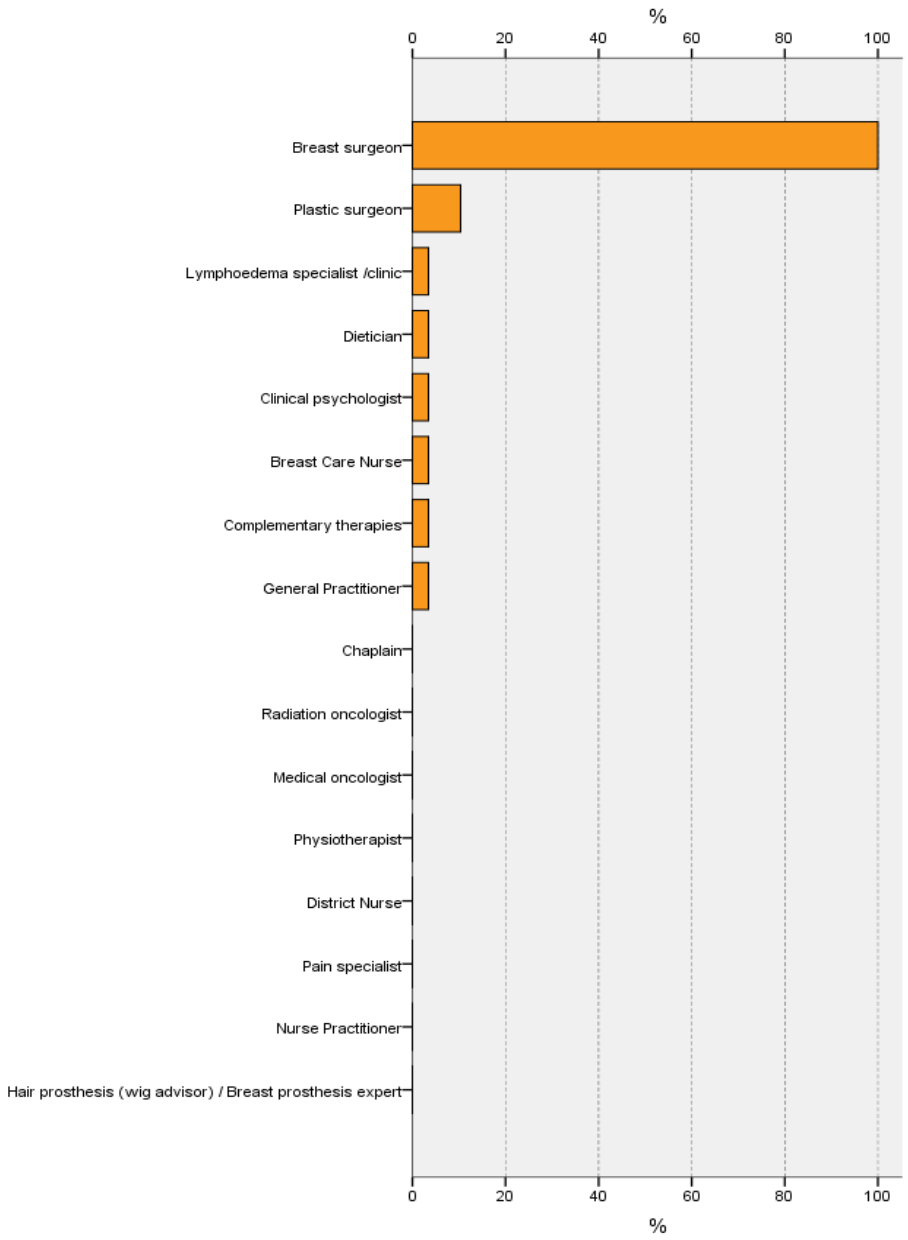

Figure 10 Health professionals selected by the 29 patients in Cohort 2 of the study.

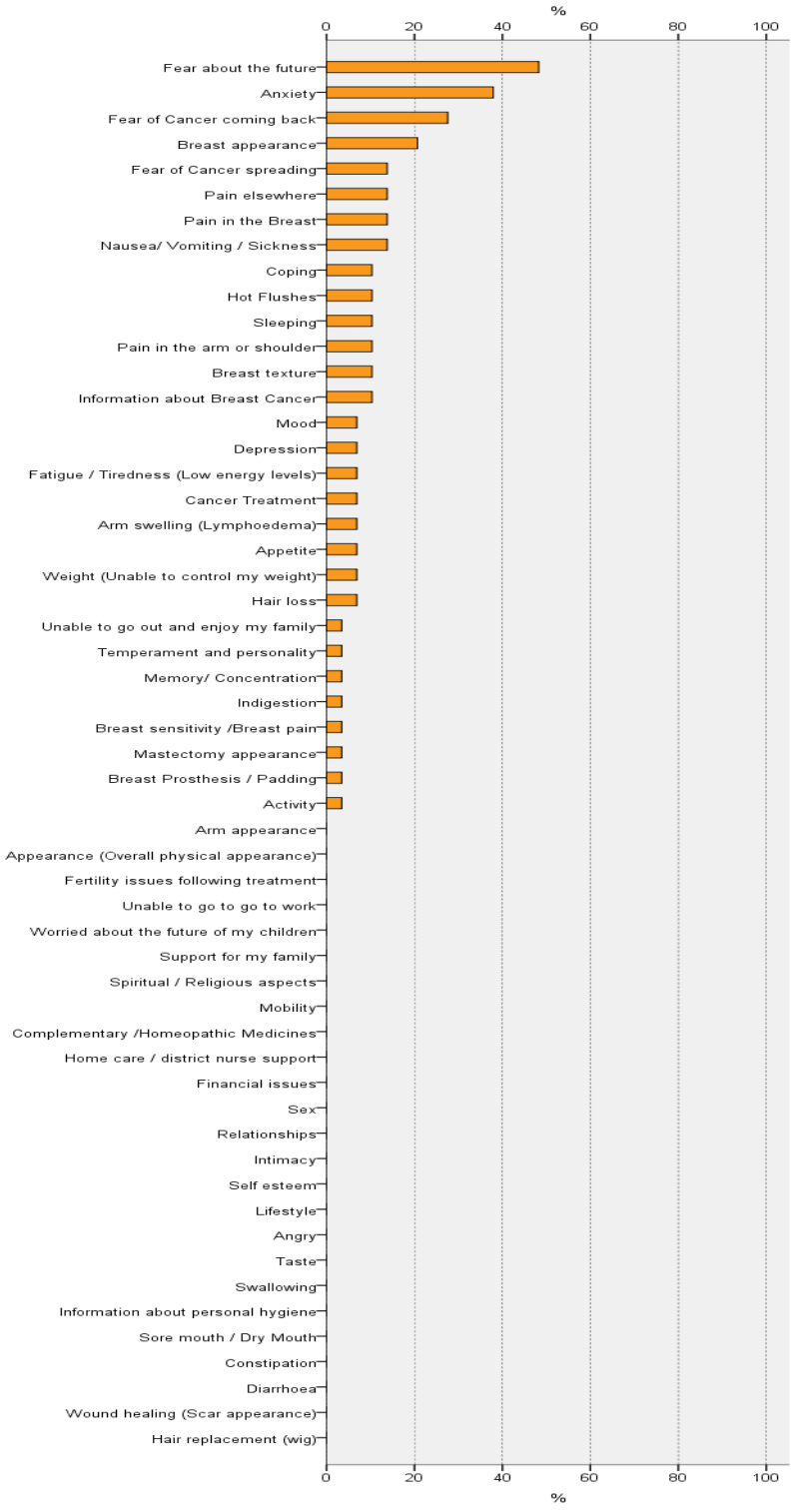

Figure 11 PCI items selected by the 29 patients in Cohort 2 of the study.

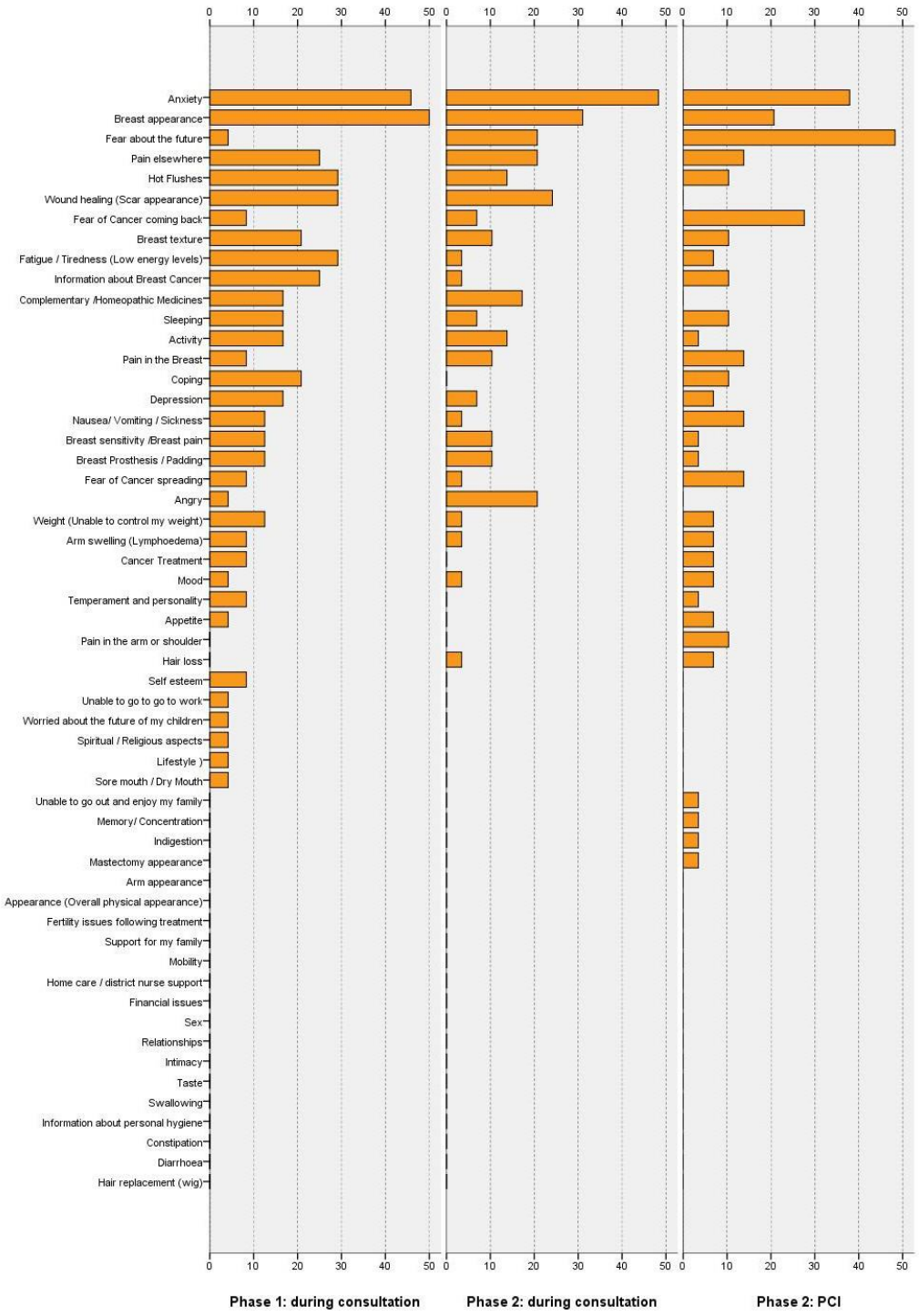

Figure 12 Items selected by all patients in the study

Discussion

Breast cancer patients have issues that may make them reluctant to volunteer in a busy outpatient review clinic especially when they do not see the same member of the treating team. If, as clinicians, we are to claim that we can respond to the issues of breast cancer patients, first we must ask the right questions. In this work the breast cancer specific PCI may provide the right questions. It can be used as an aid to the clinician-patient interaction, as a communication tool, or as a needs assessment tool in everyday clinical practice. However, using the breast cancer specific PCI as a holistic needs assessment tool makes clinical sense. During this work, the PCI was developed to identify patients' issues during the post-treatment phases. While this pilot study provides a vital initial assessment of a new tool, the results should be interpreted with caution. In the qualitative assessment, both the primary investigator and the second researcher (BR) reviewed the consultation recordings to ensure item agreement and to improve the reliability of the qualitative data analysis. However, neither were breast clinicians, which may have resulted in certain points being misunderstood and incorrectly marked. That said, this will have reduced the investigator bias somewhat, providing a trade-off of unclear weighting.

The research also involved only one consultant clinic. This may represent a disadvantage with the validation of the PCI. At this stage in the formation of the PCI tool, it arguably represents an advantages as it ensures that any changes observed in the before and after study were not attributable to differences between consultants. Neverthe less, the fact that patients were mainly recruited during the post-treatment phase in a surgical clinic, probably represents a limitations of the before and after study. This apprioach was chosen due to time constraints and practical reasons; including taking into account the availability of supportive stuff in a busy National Health Service clinic.

The study involved a limited number of patients and health professionals from one area in the United Kingdom, and the results may reflect the beliefs and practice of this group. Despite the diversity of the sample, common features were identified in consultations and they were incorporated in the development of the breast cancer specific PCI. Setting the above limitations aside there are several aspects worthy of further evaluation. Looking at the patient satisfaction from the consultation, the results obtained from this small subgroup of patients suggest that most were satisfied with their consultations (Appendix 1, Table 24). Other generic questionnaires have been considered but this 9-item scale has been employed for practical purposes and has been used before in breast cancer patients in Leeds Teaching Hospitals. The results from this scale is in agreement with other studies (Epstein et al, 2005)

and not unexpected as patients may still feel that the expression of any dis-satisfaction may adversely affect their clinical care. In addition, the clinical team may have introduced bias as this study did not include a blinded methodology. The clinician knew that he was recorded, and they may have made more of an effort to include all the possible points than under normal situations. It would be interesting to explore the outcomes of PCI use in a blinded setting as well as with more clinicians and other health care professionals. Due to the nature of the PCI, any attempts at blinding would be very difficult to ensure. Nevertheless, this should be investigated further but is beyond the scope of this thesis. When we interpret the result from this study we must keep in mind that while surveys on the satisfaction of patients are thought to favour the clinician, scales that are specific to a visit are thought to measure different aspects than those that cover the duration of the relationship between the patient and physician (Epstein et al, 2005). When the results of this section of this thesis are examined, the PCI items selected by the patients favourably supported the psychological and body image categories. In addition, pain appeared to be a common issue that needed addressing in the clinic. This may be because an issue such as fear of cancer recurrence is a frequently cited and unmet need of cancer survivors (Lebel et al, 2012). It may also be because the PCI gives a platform in order to express this particular concern to their clinical team. The answer to those questions will need addressing with a larger scale clinical study involving the PCI.

Another somewhat unexpected observation has been that 54% of patients from the first phase and 34% from the second had their more recent diagnosis in 2008/2009. In the clinical setting, that this research took place patients will be normally reviewed for three years. The identification of such patients, that as it appeared still had issues, may indicate that they represent a subgroup that may benefit from more targeted supportive care. It is unclear from this work if the PCI played a role in the identification of long term unmet needs in this patient group. A larger scale study should be in a position to clarify this point.

Looking at the results from table 25 (appendix 1) they appeared to be in agreement with the narrations seen in the appendix 2-U. When we compare these results with the literature, it may appear that there are obvious variations. For example in the second phase only 7% of patients reported depression as an issue. Yet in the literature (Heins et al, 2013) primary health care use of breast cancer patients because of depression was as high as 64%, even years after active treatment. In other studies, depression is recognised in 15% of breast cancer patients [Ganz et al (2011), Bailey et al (2005)]. This may be due to the group or indeed the population characteristics but depression is nevertheless an issue that is present in the breast cancer specific PCI that may encourage a reluctant patient group to express such an unmet need. On the other hand, it may be that in our population depression among breast

cancer patients is recognised and treated in primary care rather than remain an unmet need to be recognised and treated in an outpatient breast-cancer clinic.

Pain in the breast (14%), pain in the arm and shoulder (10%) and pain elsewhere (14%) are all items selected in the PCI cohort of this section of the study. Pain is often a concern partly due to its effect on HRQOL but partly due to its association with cancer recurrence. The treatment trajectory for these patients is unclear and beyond the scope of this study. However, it serves to highlight a current quality of survivorship for breast as well as the fundamental obligation of clinicians that must extend beyond the survival of disease and include symptom-related concerns such as the persistent pain. We must exercise caution if we aim to provide some blanket comments for breast cancer patients. We must remember that the incidence of breast cancer is higher in older adults (Deimling et al, 2007). This group of cancer survivors are particularly vulnerable to the effects of chronic pain due to high incidence of multiple co-morbidities related to aging (Deimling et al, 2007). Clinicians must prioritise pain as a chronic concern in cancer survivors, and should support clinical guidance and resources. The PCI cohort of this study may have unravelled a common issue in breast cancer. We know that surgery-related chronic pain is common in breast cancer survivors. Chronic pain has been reported to be as high as 50% of mastectomy patients (Jung et al, 2003). In breast-conserving surgery patients, pain is reported to be around 39% [Jung et al (2003), Tasmuth et al (1995), and Perkins et al (2000)]. It is also reported in the literature that chronic pain is one of the most distressing symptoms of cancer patients and an area that has been ignored clinically (Sun et al, 2008).

Pain, anxiety, and depression often occur together (Asmundson et al, 2009). Findings from the Galloway et al (2012) study suggested that anxiety and depression may be common among newly diagnosed breast cancer patients, and that these patients may be experiencing an appreciable amount of pain even before oncologic treatment starts (Galloway et al, 2012). In this before and after study, 34% of patients had their diagnosis in 2008/09 hence allowing more than three years after their treatment. One would expect that depressive symptoms were by now recognised and treated. Interestingly anxiety remain an issue even after all these years, but we must take into account that anxiety and depression can develop at different points on the treatment continuum from the point of abnormal finding to diagnosis, completion of treatment and survivorship, and throughout palliative care (Pirl WF, 2004). Clinicians may promptly treat depression during survivorship but may be more reluctant or effective in treating anxiety related to disease or its treatment. The breast cancer specific PCI provides a comprehensive list of issues that relate to anxiety, depression, and pain, and can be employed as part of a multidisciplinary approach to holistic patient care. Smith et al (2011) that breast cancer patients have persistent issues with fatigue , pain sleep, distress,

fear of recurrence (FOR), concerns about employment and uncertainty over the future (Smith et al, 2011). Most of these results are reflected in this before and after study with the exception of the concerns about employment. In cohort 2 of this study, 48% of patients expressed a fear about the future (Figure 7). The difference of the PCI when compared with other tools is that contains a continuum of domains and can identify issues as diverse as fear of the future , anxiety family and financial issues relatively quickly in a busy routine outpatient clinic. The PCI can identify issues relating to FOR, fear of cancer spreading and fear about the future. Indeed, FOR has often been identified in studies as a common response and a prevalent unmet need [Kim et al (2008), Hodgkinson et al (2007), Deshields et al (2005), Cowley et al (2000)]. In this somewhat limited pilot study, ethnic backgrounds were not adequately represented. A larger study should be able to assess the needs of patients of varying cultural backgrounds.

In cohort 2, 21% of patients selected breast appearance as an issue that they would like to discuss in the outpatient clinic. We must remember that the impact of issues related to treatment such as surgery, chemotherapy, and radiotherapy may result is significant levels of psychological symptoms. This is reflected in this before and after study and has been presented before by others. Fallowfield et al. (Fallowfield et al, 1986) found that the incidence of anxiety and/or depression was 33% in mastectomized patients and 38% in breast-conserved patients.

Coping is an important determinant of adaptation to cancer and may be defined as the adaptation to a demanding situation (Tunks et al, 1988). Other definitions have been presented in the literature (Heim E, 1991). In our study 10% of patients selected coping as an issue. The PCI can identify coping as a concern but it there is no consensus of how best to deal with that group of patients. Several proposed coping strategies have been proposed and may be employed by the patients [Endler et al (1990), Singh et al (1985)]. The clinician may not be equipped to deal with that issue and the involvement of another expert from the MDT may be required. A coping strategy that often employed by cancer patients is talking to others, family and friends (18%). As seen in various studies, women approach their partners, close relatives, and friends as their informal helpers (Pistrang et al, 1992). This was not seen in this study and may explain the larger proportion of patients selecting this issue. It is can be concluded from table 25 (Appendix 1) that the PCI can identify a range of psychological issues that may be beyond the expertise of the breast cancer surgeon.

The breast cancer specific PCI includes sexual functioning items and these are intimacy, relationships, and sex. It is of note that none of the patients in this part of the study selected any of these items as issues Table 25 (Appendix 1). The literature is clear in that sexual problems occur with significant frequency, and are present in women who do not undergo

mastectomy, as well as to those who have subsequent breast reconstruction [Ganz et al (1992), Broeckel et al (2002), Burwell et al (2006), Meyerowitz et al (1999), Rowland et al (2000), Taylor et al (2002), Yurek et al (2000)].

The lack of selected items as well as the lack of discussions in the clinic about sexual function issues may be due to several factors. From the clinician point of view despite the prevalence of sexuality and intimacy problems among large numbers of breast cancer survivors, few interventions have been developed specifically to address these issues [Newell et al (2002), Shell JA (2002)]. That may be one reason that clinician seem to be reluctant to explore that issue in clinic. Another reason may be that multidisciplinary teams may not have the expertise to deal with sexual functioning issues. This lack of selected items in that domain is reflected in the literature. Sbitti et al (2011) reported that 100% of patients in their study have never spoken with their doctor about sexual dysfunction issues following breast cancer (Sbitti et al, 2011). Clearly more research in the management of such issues may be of benefit and programs involving psycho-educational interventions should be supported (Rowland et al, 2009).

The above discussion is based on the results obtained from a small number of patients.Unfortunately some of the predicted effects did not materialise. The most important outcome from this before and after study was derived from the analysis of the patient satisfaction questionnaire (Appendix 1, table 24). It appeared that the satisfaction was reduced after the introduction of the PCI. At present, this is difficult to explain; it may be that the PCI raised patient expectations of what their clinician could deal with. Of course, this may have not been possible because of lack of time in a busy NHS outpatient clinic, lack of expertise / training of the clinical team members. This has to be evaluated further is a study of bigger size.

The evaluation of consultation duration, and any onward referrals made, revealed that 100% of patients wanted to see a breast surgeon. Currently, there is a supportive network of specialist breast-cancer nurses to deal with transient and less distressing issues in the current clinical setting. However, whenever an issue requires clinical intervention, an appointment is made with the breast surgeon. It is possible that this has introduced bias in this part of the study with the inclusion of patients that were told that they needed to see a breast surgeon. It is also well documented (Shell JA, 2002) that patients with an appointment in a consultant-led breast clinic expect to see the consultant. A larger scale study may provide results that are more comprehensive. In addition, it appears that less items were discussed in cohort 2 of this study, and that the consultation duration did not increase compared to the non-PCI group. We must exercise caution in the interpretation of these results due to a possible selection bias and the limitations on internal validity that were imposed by compromises in

the study design. Nevertheless, the PCI appeared to result in a more focus consultation, with a better utilisation of the available time.

A typical breast cancer follow-up clinic for surveillance provides an opportunity for patients and their doctors to address items of concern. In this clinic, a proportion of the appointment time involves patient–doctor discussions, where the range of issues discussed will vary according to individual patients. Usually the first part of the consultation involves the discussion of specific surveillance results from a mammogram or an ultrasound. Then specific issues may be elicited and discussed. All clinical appointments involve a patient physical examination that is taking place in different consultation room. This change in the set up involves time that sometimes in a busy clinic can at the expense of patient issues.

Two out of the twenty-nine patients in the consultation talked about family bereavement and the effect on the psychological state. It appeared that the loss of a spouse in the one patient and the loss of a mother had a marked effect on the overall patient well-being. This can be correlated with published data. In two studies of breast cancer patients, less social support, greater precancer trauma history, and more stressful life events directly predicted higher levels of posttraumatic stress disorder symptoms and general distress [Andrykowski et al (1998), Green et al (2000)]. A range of mediating factors may further exacerbate or ameliorate the stress of cancer treatment, including social support, concurrent stressful life events, and comorbid conditions, lack of economic resources, and individual characteristics. Because of that, family bereavement is an item that should be consider for inclusion in the breast cancer specific PCI. The statuses of separated, divorced, or widowed also significantly increased the likelihood of patients becoming severely distressed. Previous studies that used community samples have established that being widowed, not married, or socially isolated were related significantly to shorter survival [*Schaefer et al (1995), Goodwin et al (1987),* Kornblith et al (2001)].The identification of these group of patients can benefit from simple interventions such as social support. Social support can directly influence adjustment through reassurance – i.e., by making patients feel greater control, and by knowing that others would be able to help them (Friedman et al, 2000).

Another item that needs to be included in the breast cancer specific PCI is 'Skin changes '. 4/29 patients attended the consultation and required further support with respect to erythema or what they described as a 'rash' on the skin around the skin area. The breast cancer specific PCI accounts for 'wound healing'. However, the skin changes were a frequent issue and seem to be related with the effects of radiotherapy. In a study by Hill-Kayser et al (Hill-Kayser et al, 2012) changes in texture and colour of irradiated skin were reported in 48% of women following treatment for breast cancer. Schnur et al (Schnur JB et al, 2011) concluded that skin toxicity affects numerous dimensions of QOL, and assessment approaches and

psychosocial interventions should address this. Inclusion of this item in the PCI would allow the development of specific approaches that may include education approaches participants' own creativity and problem solving.

There are items on the PCI that were selected by the patients but were not discussed in the consultation, including 'Unable to go out and enjoy my family', memory /concentration, indigestion and mastectomy appearance. The first three are parameters often associated with chemotherapy and radiotherapy rather than surgery and hence the consultant surgeon considered appropriate to focus the consultation at aspects traditionally discussed in surgery. Mastectomy appearance may have been included under the umbrella of breast appearance and this may have been the reason of not including it in the discussion.

Homeopathic medicine is an item that was brought up in the consultation but not marked by the patients. These may be an indication that clinicians try to incorporate all available options for patient care. From the patient point of view, this may be an indication that more information needs to be available to patients about options that are available in community rather than those limited in a tertiary service.

It is of interest to note that items such as anxiety, breast appearance, fear about the future and fear of cancer coming back, scored highly in the items selected by the patients in the PCI. Some such as anxiety and breast appearance were adequately discussed in the consultation whilst items about fear of cancer coming back and coping with the disease or its treatment, were addressed significantly less.

A significant variation is seen in the PCI items selected by the patients in the cross-sectional study (Figure 6) when compared to those selected by Cohort 2 (PCI cohort) in the before and after study (Figure 11). There may be several reasons for that variation. One may be that patients selected the PCI items at home in the cross-sectional study, where they are probably in a more comfortable and non-threatening environment, without the same time pressures experienced in a busy surgical clinic. Also, these patients did not come into contact with the clinician immediately afterwards. Thus, they y were less likely to feel embarrassed by the items selected. Additionally, variation may be related to the wording of the opening statement of the PCI, which prompted patients to choose the issues present at that moment in time only. The cross-sectional study included patients from more than one hospital that had treatment from more than one consultant. The before and after study included patients from one hospital that had treatment from a specific senior consultant. Thus, these results do not compare like with like, as several potential confounders changed between assessments. This specific result must therefore be interpreted with particular caution.

Conclusions

This part of the study provided an insight in the use of the PCI in practice. It appears that introducing the PCI in a busy routine outpatient clinic is possible with no adverse practical difficulties. In addition, it provided relevant information that contributed to the further development of the PCI. New items such as bereavement, skins changes, and appearance were raised during the consultations and incorporated in the PCI. Appendix 2-V shows the final PCI. Future research needs to identify the specific question content, as well as how such content might be associated with satisfaction.

Adequate assessment of needs and HRQOL may identify subgroups of breast cancer patients requiring better supportive care targeting. Modern clinical care is beginning to recognise the importance of the perspective of the patient in health care and more investigations are needed to understand the importance of the inter-relationships among health needs and patient satisfaction.

Offering the breast cancer specific PCI online with high accessibility may result in patient motivation, and may provide skills that could promote self-management of specific issues. The breast cancer specific PCI may contribute to a generation of 'expert' patients with a favourable effect on their satisfaction and on National Health Service resources.

The identification of pain as an unmet need in the PCI can stimulate research into its assessment and management, and hence could provide valuable knowledge of this neglected issue in cancer survivorship.

With items related to pain, anxiety and depression the PCI may be the optimal strategy in order to identify and to tailor interventions targeting anxiety, depression, and pain among breast cancer patients.

Coping with the disease or its treatment is an issue that it can be identified in the psychological state and emotional wellbeing domain of the PCI and includes a range of psychological issues that may be beyond the expertise of the breast cancer surgeon.

The lack of selected items on the PCI as well as the lack of discussions in the clinic about sexual function issues may highlight inadequacies in the clinical team as well as the lack of effective interventions. Clinicians may use the PCI as a means to overcome established taboo subjects such as sexual functioning following breast cancer treatment. Specialist oncology nurses are best suited to offer support and guidance with respect to intimacy issues and can use the PCI as an icebreaker in order to overcome an embarrassing direct approach that may have a negative effect on the professional-clinician relationship.

This study evaluated the early experiences and impact of introducing the PCI into clinical practice in a cohort of one consultant's clinic, where both doctor and patients were unfamiliar with the tool and this novel approach. This should be taken into account in the interpretation of the results. Further evaluation in the clinical setting would be essential in order to ensure that this evolving tool reaches stability. At present, it appears that the PCI is best utilized as an adjunctive tool that can be incorporated into consultations. It has the very real potential to change the current clinical setting, with direct benefits to patient care.

CHAPTER 9. Further Development of a Breast Cancer Specific Patients Concerns Inventory with Input from the clinicians that used the PCI in the before and after study (phase 4)

This chapter covers phase 4 of the study. This was the final part of the thesis, and involved gaining feedback from the consultant surgeon and the two specialist breast cancer nurses that used the breast cancer specific PCI in the before and after study (phase 3), in order to evaluate the Patient Concerns Inventory's (PCI) practical usefulness in patient care.

Aims

To gain feedback from the consultant surgeon and the two specialist breast care nurses that used the PCI (phase 3) as to their experiences of using the PCI and its potential merit of use in the breast cancer setting.

Materials and methods

Qualitative semi-structured interviews took place in a breast cancer clinical setting and recorded the perceived advantages and disadvantages of the PCI and experiences of its use. One clinician and two specialist nurses who used the PCI were included in phase 4. They were a pragmatic convenience sample. Lines of questioning were based on the literature review and experience from the development of the Head and Neck PCI. The interviews were audio-recorded, and stored in keeping with General Medical Council guidance (GMC, 2011). A professional medical transcription company transcribed the interviews and the transcripts were checked for accuracy against each recording.

Ethical considerations

Permission from the Leeds Central Research Ethics Committee was given to record the clinicians (12/YH/0215).

Data analysis

Content analysis of the interviews was performed using the questions as themes and involved the identification of the perceived advantages and disadvantages of the PCI based on their experiences (Miles et al, 1994).

Reliability

To improve the reliability of the qualitative data analysis, a second skilled qualitative researcher, also assessed the transcripts. Themes and responses were then compared and discussed with agreement reached by consensus.

Results

This was a qualitative assessment, and relevant direct quotes are tabulated below that identify the advantages and perceived disadvantages of the PCI in breast cancer from the perspectives of the surgeon and clinical nurse specialists. Some concerns of using the PCI in breast cancer were identified but in the main, its use was seen as advantageous as reported below.

Role of the PCI as perceived by the clinician: Interview with the breast cancer surgeon

Question 1: What was your experience of the PCI use in the clinic?

Response from clinician:

> **"***It is a very helpful way of trying to break down areas that patients often want to discuss. It has all the different complaints commonly seen in a breast cancer clinic. One issue that will need to be addressed is that it will need somebody to be available for help to complete the PCI especially ethnic minorities or for example people with dyslexia. Several language translations will be required in order for the PCI to be adapted in the area of Leeds"*

Question 2: Do you feel that the PCI affected your clinics for example in terms of duration?

Response from clinician:

> *"It is helpful for patients to have a chance to sit down and work out ahead of time what they would want to discuss. The hardest consultations as a clinician are the ones that it seems as though the patient has no concerns and as you wrapping up the consultation they bring out something else they would want to discuss and this can mean that the clinic does not run as smoothly as it might... I think what is useful with*

this tool is that it gives the patient a chance to reflect on the journey and focus to what they would want to discuss with the clinician that immediate time.

Having a written outline of issues is helpful to patients. Inevitably, it may make patients to select things that they would not otherwise going to discuss. Also, the referral pattern is helpful. For example cosmetic aspects... a consultation with a plastic surgeon may be more appropriate."

Questions 3: How about aspects of care, or issues that we as surgeons have difficulty talking about (for example intimacy and sexuality)?

Response from clinician:

"*Of course the same applies to religious concerns. This is the area least documented in the clinical notes. The spiritual aspect of been a cancer patient is very rarely discussed. Unless somebody is active in faith themselves is very difficult to engage in the consultation. The PCI is another way that can be used to approach taboo aspects of the human nature. Some patients are hesitant to discuss sexual matters in the clinic. The primary function of the breast is for breast feeding and that has been overlooked in a way because of the sexualisation of the breast in the media. This tool helps to normalise talking about issues that perhaps as British people we are having difficulties to discuss, although how often the people would tick the box remains to be seen."*

Role of the PCI as perceived by the breast care nurses

Question: This is a tool designed for a holistic approach to patient management. Do you think that a tool like this will help your practice?

Response from specialist nurse 1:

"At present not enough funding is available for more breast cancer nurses. I think traditionally we rely very heavily on breast care nurse giving holistic support to patients as they go through the different stages of the journey. A tool like this is very helpful, it can be used in the same way as the Distress thermometer for example is a patient has concerns in multiple areas, clearly this patient needs more input not only from medical professionals of one form or another but from their designated breast cancer care. There are some patients that they are very good in expressing when

they need care, whereas there are others with issues that they do not tend to contact us and are living with a considerable level of anxiety...yet they go unnoticed. Clearly, any tool that can identify these patients will be very useful especially in the outpatient clinic where help is readily available.

I have some concerns as to how this will work in clinic. A lot of our patients are elderly and they may not be in a position to fill the forms...they may feel upset ... they may feel that they will not get the right treatment ... and disadvantage. We have to be careful of how to use this in clinic. Completing this with a nurse can be an option but it is time consuming...there are not many of us, sometimes is difficult. This will add time to fill and time to deal with the issues ...especially if they have many"

Response from specialist nurse 2:

"This checklist can be useful to help patients remember any problems that may have.

I have some concerns…one concern is that patients may become anxious if they see this list at the beginning of their treatment…they may worry… they may think that all these problems will come…may become unnecessary distressed. This list needs to be completed with support ... not alone at home.

Another problem is that this list may raise the patients expectations…they may think that if their problem is there I could do something about it ... well I may be not … that if for different reasons, resources, busy clinic, staff away, lack of expertise, all these may be a problem rather than trying to help by identifying the issues…

Other than that … sorry … I think this list will be helpful and it may result in extending the team with further experts such as a clinical psychologist, or can help us acquire further skills through further training … can result in a comprehensive package of care."

Discussion

The consultant surgeon confirmed that the issues that have been included in the PCI are commonly seen in a breast cancer clinic, which supports and validates the phases 1 and 2 of its development and adaptation from the head and neck PCI (Rogers et al, 2009). The

description of the PCI as a tool that can help patients to reflect on the cancer journey and identify concerns that they would not otherwise discuss, may be a valid one but further research is required in order to verify it. The use of different language translations will be of benefit and needs to be addressed in the further development of the breast cancer specific PCI.

The PCI may be used partly as 'written proof' in the clinical notes that items that traditionally are difficult to approach, such as religion, have been included in the consultation. Apart from that, the PCI may be an aid to communication as it may help to normalise talking about issues that patients may have difficulty to discuss. Further evaluation of this suggestion would be necessary in a larger scale clinical study.

In the current financial climate, resources might be a limitation in the use of the PCI. The practical aspects of the PCI need to be taken into account and their perceived benefits need to be evaluated further against the cost of its introduction in a busy NHS clinic.

It was expected that introducing a new intervention in a busy clinic would be difficult. This was partly due to the attitudes of clinic staff that the research may affect the timing of appointments, and hence patient care. Because of the nature of this before and after clinic and the fact that the PCI was completed whilst patients were waiting to see the clinician, there was no notable effect on the practicalities of running the clinic. In addition, clinicians appeared to be reluctant to have their consultations recorded. This has been the case in other studies using audio recordings of consultations (Tattersall et al, 2002). These issues were surpassed with organisation and gradual 'desensitisation' of the clinicians. At the start of the before and after study, only one patient was recorded, but that number was gradually increased, and the PCI was accepted into the clinic.

The consultant involved ultimately accepted the PCI as a tool that could promote, co-ordinate and provide high quality clinical care. Practitioners in a busy NHS practice would like their daily work to be easier, safer, and faster. Comments from the consultant and specialist nurses included that the PCI could make their work more efficient and accurate. Furthermore, the PCI could help them to anticipate, prevent, and solve clinical problems.

In a resource driven environment, the co-ordination of clinical teams may not be an easy task. Some concerns were raised with the use of the PCI in an NHS clinic. In particular, it is a reality that clinicians may not be trained to deal with specific issues selected by a patient. This of course can be accommodated by referring patients to other members of the MDT, primary care, or voluntary organisations who have the necessary expertise. Factors such as this may have implications on funding as well as on teaching and training. The broader feasibility would need to be tested in studies that rolled out the Breast PCI across a number

of organisations and clinics. By identifying patient concerns and managing them, could ultimately help with their condition, their experiences of services and satisfaction with care.

CHAPTER 10. Concluding remarks: the future scope and potential use of the Patient Concerns Inventory (PCI) and similar tools.

Some practical difficulties were encountered during this study. The principal investigator was not part of the breast cancer surgical team. That created recruitment difficulties that were imposed by the Research Ethics Committee (REC).

Following four meetings and presentation of the research protocols to the local REC, it was agreed that the clinical team should approach the patients initially for this study. This allowed a period of four weeks for every patient to decide whether they wished to participate in one of the four phases of this study. It is difficult to know the precise impact of this decision on this research. It may have affected the participation rate. On the other hand, it may have reduced potential investigator bias by not allowing an initial contact with the principal investigator.

The methods section is an accurate reflection of the initial protocol. An aspect that was different was step 2 of phase 1. This had to be modified because of time constraints in consultant led National Health Service clinics. The impact of this was likely to be minimal, taking into account the interaction with clinicians during the third and fourth phase of this study.

The development of the breast specific PCI was based on information generated by patients following diagnosis and treatment or during their treatment. For the PCI to be used during the pre-treatment phase it will need further development.

Evaluation in the clinical setting will be required for the validation process of the PCI. The longitudinal effect needs to be assessed. It is possible that patients will stop pointing out issues in the PCI if these are consistently ignored or not resolved. This is a classical method of generating a persisting unmet need.

During this work, several points with a direct effect on patient care were recognised. As clinical standards of care increase, expectations on the clinical team also increase. As an inevitable consequence, there is a clear need to develop a new set of skills for the proper provision of modern care. In addition, the National Health Service as an organisation, is currently undergoing significant scrutiny in terms of cost effectiveness, with services in the secondary care sector being rationalised, and where possible being relocated to primary care settings. The breast cancer specific PCI has the potential to provide the multidisciplinary team (MDT) with a tool that could form part of the clinical framework that ensures appropriate, optimal, and accessible care. For example, it may be possible to provide a

username and password to all newly diagnosed patients with breast cancer; with minimal guidance these patients could use the PCI in their home environment, thereby ensuring continuous care and a 'point of contact' with the clinical team. The results from the PCI could then be directed electronically to a designated member of the extended team with the responsibility to triage and direct the patients to an appropriate member of the clinical team. The PCI may be of benefit if used by the clinician as an aid memoire in a busy outpatient clinic. This would ensure that the clinician includes all relevant or most common patient generated (and therefore of significance to the patient) issues in their consultations.

The use of the PCI in a community setting could divert clinical services away from hospitals for transient and less significant symptoms that do not require specialist intervention. Properly trained in the use of the PCI, specialist primary care services could offer significant cost-savings compared with an approach that is based on the delivery of those same procedures being carried out in a consultant-led service. This would be of even greater significance in the putative consultant (or specialist based service). In order to ensure optimal clinical care provision, it is essential that consistency should also be assessed for quality assurance, and this may be incorporated into a PCI training programme. Equally, the PCI may be used in the primary care setting where the General Practitioner or community nurse could utilise the tool to identify issues, before communication with the relevant clinical team.

The PCI may be the start of a model of care that has the 'expert patient' as the central figure. This would ensure that all key aspects of care are examined, and that those aspects are those that matter most to the individual patient. Only in this situation will any Health Service be able to deliver a truly tailored (patient centric) service that ensures patient satisfaction over their complex and uniquely individual cancer journey. This journey may be completely different to that which textbooks, training, and peer pressure lead clinicians to believe in. A patient centric evidence base may describe multiple diverse journeys, which intersect with the clinician and pathology led journey only at specific "hard" points.

The overriding purpose of modern medical training is to create a competent clinician at specialist level who can provide core medical or surgical treatments, which meet the needs of their patient population. Sometimes there is an over-emphasis on clinical rather than communication or personal skills. A balance must be found between the anatomical, physiological, and pathological based cognitive and psychomotor skills and those based in the interpersonal and attitudinal domains. The PCI can be used as both a communication-skills tool and a tool that focuses the consultation, thereby bridging this gap.

The use of the PCI could aid the clinician in the identification and management of traditionally difficult issues, such as those related to social or sexual function. Some patients find the clinical setting intimidating and may not feel able to express their concerns to clinical staff regardless of attempts by those staff to appear open to enquiry despite attending regularly as part of their cancer surveillance program. Indeed, it may be because they are appearing in a "cancer clinic" where they are "glad to be alive" that they feel unable to engage. The PCI can help patients in this group to vocalise their concerns in multiple and varied environments with consistency, therefore ensuring that some concerns are not missed completely.

The PCI encourages the interaction and use of the expertise of multiple teams that can collaboratively accommodate and resolve difficult clinical problems. Integrated care pathways describe, for a specific clinical condition, the tasks to be carried out together with the timing and sequence of these tasks and the discipline involved in completing the task (Baker J, 1996). Further research is needed to provide evidence that the incorporation of the breast cancer specific PCI in integrated care pathways can make a real clinical difference. There is a need to assess the presence of a relationship between PCI use, and a variety of measurable outcomes including patient recovery, physical function, and emotional health.

Screening interventions are designed to identify disease in a community early, thus enabling earlier intervention. A screening tool for the identification of psycho-oncological treatment need in breast cancer patients has been developed (Meraner et al, 2009). However, this is only applicable to the psycho-oncological treatment need rather than to the range of issues that may be present in breast cancer patients. The breast cancer PCI includes a range of items that are part of validated health-related quality of life tools and has the potential to be used on its own. Further work will be essential in order to verify the ability of the PCI to be used as a screening tool on its own, or together with a health-related quality of life measure.

Drawn from the experience of the breast cancer patients participating it appears that there are several issues that breast cancer patients would like to discuss. As clinicians, it seems we have a tendency to discuss the cancer and its treatment but these may not be what our patients want to discuss in an outpatient clinic. During this work, the principal investigator published papers related to the head and neck PCI and the details of these have been given in chapter 11. A direct comparison of the issues that patients would like to discuss in the head and neck and breast cancer clinics has been made (Kanatas et al, 2013). For 447 HNC patients, 8% (37) wanted to discuss 'mood', 13% (57) 'anxiety', 9% (41) 'depression', with one or more of these 20% (91). HNC patients wanted most (39%, 174) to discuss fear of recurrence. For 200 BC patients, 15% (30) wanted to discuss 'mood', 21% (41) 'anxiety', 17% (33) 'depression', with one or more of these 35% (70). Also, 62% (124), wanted to

discuss fear of recurrence, 39% (78) fear of cancer spreading and 32% (63) fear about the future, with 72% (143) one or more of these. These are presented in detail, in Figures 13 and 14 below.

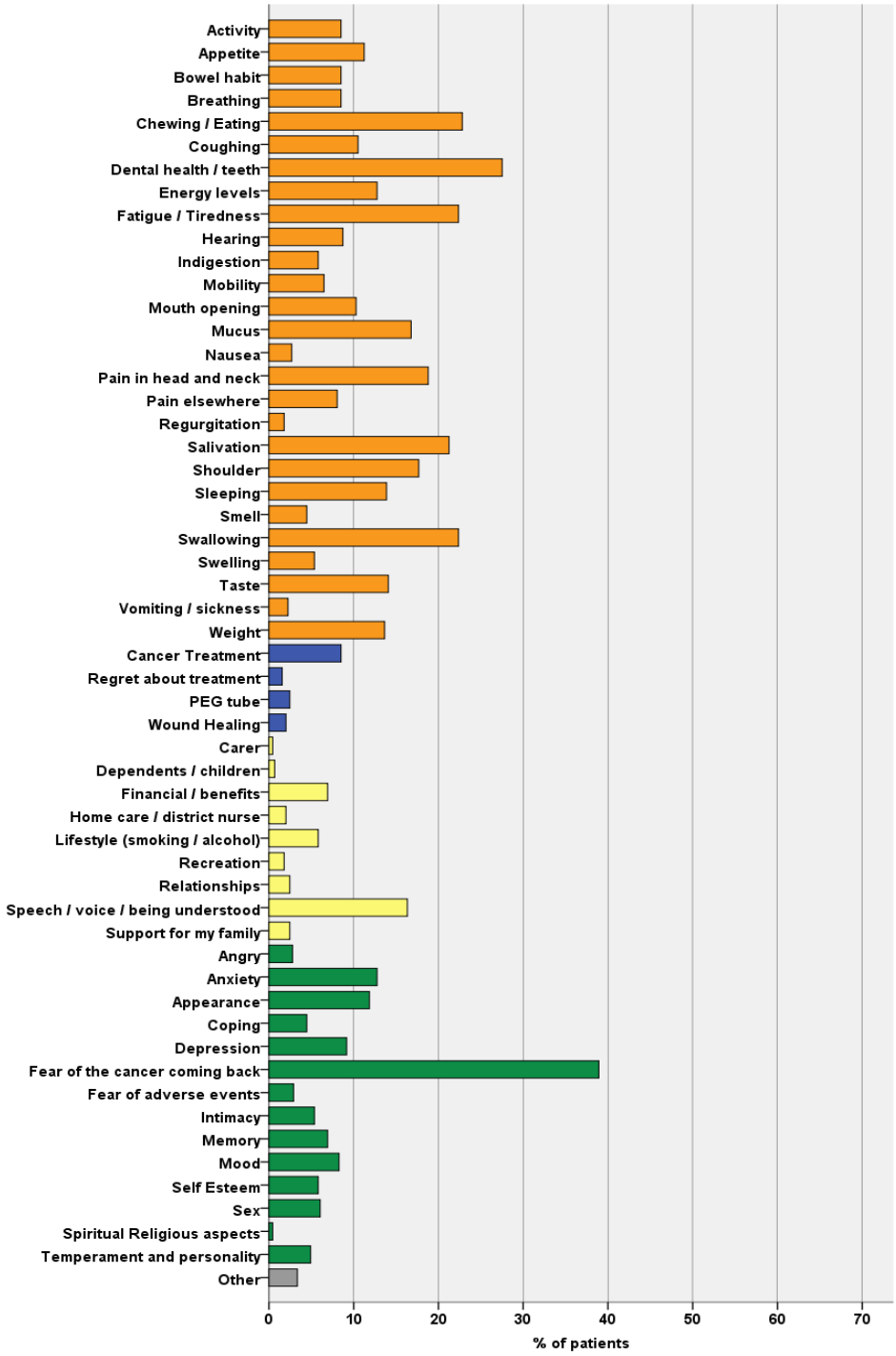

Figure 13 A typical PCI profile of issues patients wish to talk about in their consultation with their head and neck cancer consultant / doctor

(N=447 patients) H&N domains-Physical and functional well-being (GOLD), Treatment related (BLUE), Social care and well being (Yellow), Psychological, emotional, spiritual (GREEN), Others (GREY)

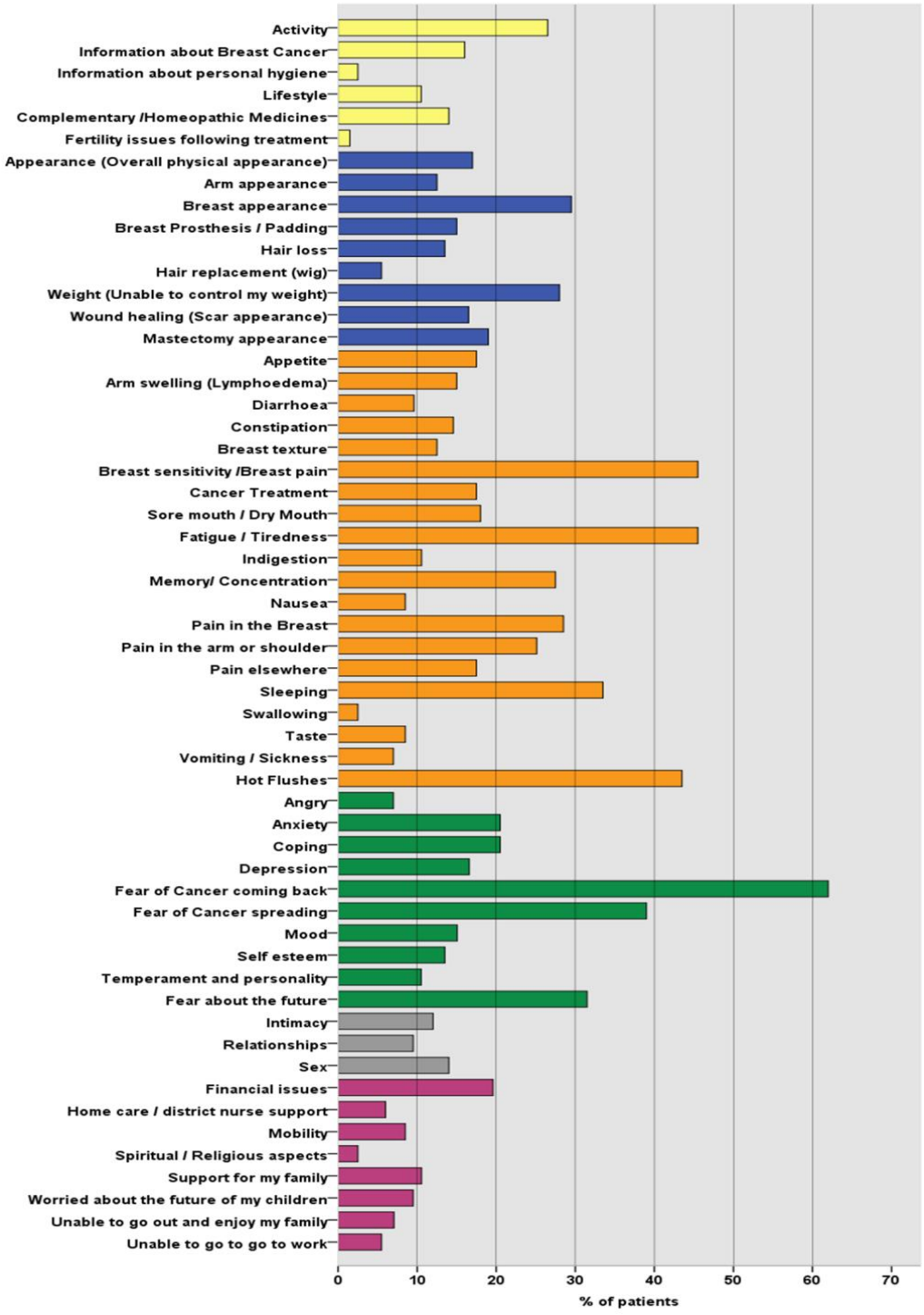

Figure 14 A typical PCI profile of issues patients wish to talk about in their consultation with their Breast cancer consultant / doctor

(N=200 patients) Breast Cancer domains-General Information (YELLOW), Body image (BLUE), Physical Functioning and health (GOLD), Psychological, emotional (GREEN), Sexual Functioning (GREY), Social functioning /Family related (PURPLE)

There is a range of items and there is variation between the two different types of cancers. Considering these variations there is scope for the development of the PCI for other cancer types as well as for chronic diseases such as diabetes and osteoarthritis.

Finally, the PCI allows patients to tell us what they want to discuss, and facilitates collaborative care. Through the PCI, patients can communicate their concerns and needs as adults in partnership with the clinical team managing their illness, allowing for improved assistance in managing their cancer and its consequences. This is very much in keeping with the move away from paternalism within modern clinical practice and embracing the issues around survivorship in cancer.

CHAPTER 11. Research Dissemination

This thesis provided the author with the opportunity to be involved in the preparation of a number of papers. Some of these papers were related to the use of the patient concerns inventory (PCI) as a tool in oncology in general, and some were directly related to the breast cancer specific PCI. Some of these papers have been published, or are in the process of publication in peer-reviewed journals. Details of these manuscripts are presented in Appendix 3.

The papers related to the head and neck PCI in particular, gave the author the opportunity to gain valuable experience in the preparation of manuscripts, as well as in understanding the various research methods required. In addition, results were disseminated by other means, with parts of this research forming the basis for both oral and poster presentations at National and International meetings. This research also gave the opportunity for the author to gain a range of skills from interacting within diverse teams, to establishing valuable research networks.

The literature review for the breast cancer specific PCI has been published and cited as follows:

> *Kanatas A, Velikova G, Roe B, Horgan K, Ghazali N, Shaw RJ, Rogers SN. Patient-reported outcomes in breast oncology: a review of validated outcome instruments. Tumori. 2012 Nov;98(6):678-88.*

The head and neck PCI related papers that have been published alongside this work include:

> *Ghazali N, Kanatas A, Langley DJ, Scott B, Lowe D, Rogers SN. Treatment referral before and after the introduction of the Liverpool Patients Concerns Inventory (PCI) into routine head and neck oncology outpatient clinics. Support Care Cancer. 2011 Nov;19(11):1879-86.*
>
> *Kanatas A, Ghazali N, Lowe D, Rogers SN. The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. Int J Oral Maxillofac Surg. 2012 Jan 18. [Epub ahead of print]*
>
> *Kanatas A, Ghazali N, Lowe D, Udberg M, Heseltine J, O'Mahony E, Rogers SN.Issues patients would like to discuss at their review consultation: variation by*

early and late stage oral, oropharyngeal and laryngeal subsites. Eur Arch Otorhinolaryngol. 2013 Mar;270(3):1067-74.

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APPENDICES

Section 1: List of Tables

Section 2: Supplemental Study Material (Letters, Forms, and Other Documents)

Section 3: Publications in Support of the Thesis

Section 4: Letters and Approvals from the Research Ethics Committee and the Leeds Teaching Hospitals Research and Development Departments

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APPENDIX SECTION 1: LIST OF TABLES

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Table 1 (Chapter 4): Appraisal of the psychometric and operational performance of the instruments: inclusion criteria [Fitzpatrick et al (1998), Fitzpatrick et al (2006)

- Validity
- Reliability (includes internal consistency and test-re-test reliability
- Responsiveness

Table 2 (Chapter 4): Psychometric Qualities of the instruments included in this study

	BCQ	EORTC QOL-BR23	EORTC QOL C30	FACT-B	FACT-ES	BIBCQ	Polivy BIS	Hopwood BIS
Validity	+	+	+ BR23 module	+	+	+		+
Reliability (includes internal consistency and test-re-test reliability	+	+	+	+	+	+	-	+
Responsiveness to change	+	No evidence in favour	+	+	+	No evidence in favour	No evidence in favour	No evidence in favour

	BCTOS	MAS	BREAST-Q	MBROS-S	MBROS-BI	SLDS-BC	BCPT
Validity	+		+		+		
Reliability (includes internal consistency and test-re-test reliability	+		+	+	+	+	+
Responsiveness to change	No evidence in favour	No evidence in favour	+	No evidence in favour	+	No evidence in favour	No evidence in favour

(The '+' sign indicates that there are evidence that the specific property has been assessed)

Table 3 (chapter 4): Breast cancer-specific quality of life instruments. All these instruments satisfied the inclusion criteria.

	Measure and authors	Purpose	Domains	Scale	No. of items	Reliability	Validity
1	Breast Cancer Chemotherapy Questionnaire (BCQ) **Levine et al (1988)**	Developed to measure outcomes of women with stage II breast cancer receiving adjuvant chemotherapy	Seven domains: Consequences of hair loss; emotional dysfunction; physical symptoms; trouble and inconvenience associated with treatment; fatigue; nausea; positive well-being	Seven point Likert scale ranging in responses	30	Internal consistency ranging from .89 to .91	Correlation coefficients between BCQ and Spitzer QL-Index was .62
2	European Organization for Research and Treatment of Cancer QOL Breast Cancer Specific Version (EORTC QLQ-BR23) **Sprangers et al (1996)**	Designed to measure QOL in the breast cancer population at various stages and with patients with differing modalities	Five domains: Therapy side effects; arm symptoms; breast symptoms; body image; sexual functioning	Four point Likert scale ranging from 1 (Not at all) to 4 (Very much)	23	Reliabilities ranged from .70 to .91	Discriminant validity of mutually exclusive groups based on their initial performance status scores produced medium to large effect sizes ranging from .43 to 1.1
3	European Organization for Research and Treatment of Cancer QOL Cancer Specific Version (EORTC QLQ-C30) **Aaronson et al (1993)**	Cancer specific questionnaire designed to measure QOL in the cancer population	Nine domains: Physical; role, cognitive; emotional; social; fatigue; pain; nausea and vomiting; global health status and quality of life	Four point Likert scale ranging from 1 (Not at all) to 4 (Very much); 1 (Very poor) to 7 (Excellent)	30	Reliabilities ranged from .69 to .90.[14] Test-retest reliabilities ranged from .63 to .87	Correlation coefficient between the QLQ-C30 and the Profile of Mood States (POMS) was .56 [16].

4	Functional Assessment of Cancer Therapy – Breast Symptom Index (FACT-B) [19] **Brady et al (1997)**	Specific to breast cancer patients	Six domains: Physical well-being; social/family well-being; emotional well-being; functional well-being; relationship with doctor; additional concerns	Five point Likert scale ranging from 0 (Not at all) to 4 (Very much)	37	Internal consistency was .90	Spearman correlations between FBSI and FACT ranged from .34 to .84
5	Functional Assessment of Cancer Therapy – Endocrine System (FACT-ES) [20] **Fallowfield et al (1999)**	Focus on endocrine concerns experienced during breast cancer treatment	One domain: Endocrine concerns	Five point Likert scale ranging from 0 (Not at all) to 4 (Very much) and comprises a total score	18	Internal consistency was .79 Test-retest reliability was .93	Discriminant validity of known groups comparing adjuvant chemotherapy and those without any endocrine therapy produced a significant *t* score with the adjuvant chemotherapy group experiencing more endocrine symptoms than the non-endocrine therapy group
6	BIBCQ (Body Image after Breast Cancer Questionnaire) **Baxter et al (2006)**	Designed to assesses the long-term impact of breast cancer on body image.	There are six domains: vulnerability, body stigma, limitations, body concerns, transparency, and arm concerns		53	Good reliability was found for the six scales (ranging from 0.77 to 0.87).	The BIBCQ distinguished between women treated with lumpectomy and mastectomy, and between women with breast cancer and a control group, supporting the validity of the BIBCQ
7	Polivy BIS (Body Image Scale) **Polivy (1977)**	Design to measure an individual's satisfaction with various body parts. Measures the psychological effects of	It covers three domains: body image, self-concept, and feelings of satisfaction with intimate relationships	6-point Likert-type scale ranging from (1) very dissatisfied to (6) very satisfied	13-item	Psychometric analysis showed adequate reliability	The scale demonstrated criterion-related, convergent, and construct validity as indicated by its correlation

		mastectomy on breast cancer patients					with the Body Image Visual Analogue Scale (r = .78, p < .001)
8	Hopwood BIS (Body Image Scale) **Hopwood et al (2001)**	Designed for assessing body image changes in patients with cancer, suitable for use in clinical trials.			10-item	The scale showed high reliability (Cronbach's alpha 0.93)	Good clinical validity based on response prevalence, discriminant validity (P<0.0001, Mann–Whitney test)
9	BCTOS (Breast Cancer Treatment Outcome Scale) **Stanton et al (2001)**	The BCTOS was designed to assess women's subjective evaluation of the aesthetic and functional outcome after breast cancer treatment.	Three domains included functional status, cosmetic status and breast-specfiic pain	The 22 items lead to the subscales. The Aesthetic Status subscale consists of 7 items. The patient rates these items according to symmetry between treated and untreated breast on a 4-point Likert scale	22 items	Developed from literature review and expert opinion alone, the BCTOS also underwent psychometric analyses that showed adequate internal consistency (Cronbach's alpha 0.81–0.91)	There was no comparison with other patient reported outcome measures
10	MAS (Mastecto my Attitude Scale) **Feather et al (1988)**	Designed to assess the attitudes and expectations of post-mastectomy breast cancer patients regarding adjustment to mastectomy		4-point Likert scale	33-item	Reliability of the knowledge assessment tool was analyzed by calculating the coefficient alpha for those who responded to all 36 questions (N = 326). The coefficient alpha was 0.61	
11	Breast-Q **Pusic et al (2009)**	Measures satisfaction and surgery-related quality of life in patients undergoing mastectomy with and	A conceptual model for the impact of breast surgery was developed with scales that examine: (1) psychosocial well-being, (2)	Summary scores ranging from 0 (very dissatisfied) to 100 (very satisfied)	7	Test-retest reliability, as measured by intraclass correlation coefficients, ranged from 0.85 to 0.98.	Validation studies examining convergent and discriminant validity of the new measure relative to

		without reconstructio n	physical wellbeing, (3) sexual well-being, (4) satisfaction with breasts, (5) satisfaction with overall outcome and (6) satisfaction with care.	for each scale			multiple existing measures have recently been completed
12	MBROS-S (Michigan Breast Reconstruc tion Outcomes study-Satisfactio n questionnai re) **Alderman et al (2000)**	Designed to assesses patient satisfaction after breast reconstructio n	Factor analysis was used to group the 7 items into 2 domains measuring General Satisfaction (5 items) and Aesthetic Satisfaction (2 items)		7	Cronbach's alpha was not calculated.	
13	MBROS-BI (Michigan Breast Reconstruc tion Outcomes study-Body Image questionnai re) **Wilkins et al (2000)**	Designed to evaluate patient perceptions of physical appearance after breast reconstructio n			9	Cronbach's alpha was found to be 0.89, indicating adequate internal consistency for the single construct of body image	
14	SLDS-BC (The Satisfactio n with Life Domains Scale for Breast Cancer) **Spagnola et al (2003)**	Developed to measure satifaction with life among breast cancer patients	Five domains: Social functioning; appearance; physical functioning; communicatio n with medical providers; spirituality	Seven point Likert-type scale ranging from 1 (A "delighted " face) to 7 (A "very unhappy" face	32	Reliabilities ranged from .90 to .93	Correlation coefficient between SLDS-BC and FACT-B was .59
15	(BCPT) Breast Cancer Prevention Trial Symptom Checklist	Questionnair e designed to examine the physical and psychologica l symptoms associated with menopause and Tamoxifen usage	8 symptoms (Hot flashes, nausea, bladder control, vaginal problems, musculoskelet al pain, cognitive problems, weight problems, and arm problems).		43	Hot flashes = 0.83, nausea = 0.65, bladder control = 0.73, vaginal problems = 0.79, musculoskeletal pain = 0.82, cognitive problems = 0.85, weight problems 0.59, arm problems = 0.72	Content & Face Validity – Formulated by adapting items from existing questionnaire s of menopausal symptoms

Table 4 (Chapter 5): **Domain groups obtained from the literature**

8. **Global Quality of Life domains**
9. **Body Image-related domains**
10. **Physical Functioning and health-related domains**
11. **Psychological state and emotional well being-related domains**
12. **Sexual Functioning**
6. **Social Functioning/ Family-related domains**

Table 5 (Chapter 5): **Number of specific items obtained from the literature review**

1. **Global Quality of Life domains-10**
2. **Body Image-related domains-54**
3. **Physical Functioning and health-related domains-49**
4. **Psychological state and emotional well being-related domains-25**
5. **Sexual Functioning-8**
6. **Social Functioning/ Family-related domains-18**

Table 6 (Chapter 5): Breast Cancer Specific Patients Concern Inventory-Version 1 Following reduction process from Literature Review - grouped alphabetically

If you were to attend a clinical consultation today which of the following concerns would you wish to discuss with your Breast specialist / Consultant doctor

- Activity
- Angry
- Anxiety
- Appearance
- Appetite
- Arm swelling
- Bowel Habit (Diarrhoea or constipation)
- Breathing
- Breast texture
- Breast appearance
- Breast sensitivity /Breast pain
- Breast Prosthesis / Padding
- Cancer Treatment
- Carer
- Coping
- Dependants /Children
- Depression
- Dry mouth
- Energy Levels
- Fatigue / Tiredness
- Fear of Cancer coming back
- Fear of Cancer spreading
- Financial issues
- Hair loss
- Hair replacement
- Home care / district nurse support
- Indigestion
- Information about Breast Cancer
- Information about personal hygiene
- Intimacy
- Lifestyle (smoking/ alcohol)
- Memory/ Concentration
- Mobility
- Mood
- Nausea
- Pain in the Breast
- Pain in the arm or shoulder
- Pain elsewhere
- Relationships
- Self esteem
- Sex
- Sleeping
- Speech
- Spiritual / Religious aspects
- Support for my family
- Swallowing
- Taste

- Temperament and personality
- Vomiting / Sickness
- Weight
- Wound healing / Mastectomy appearance
- Other

If you were to attend a clinical consultation today which of the following members of staff would you like to see or be referred on to:

- Oncoplastic Breast surgeon
- Breast Care Nurse
- Clinical Oncologist
- Chaplain
- Clinical Psychologist
- Dietician
- Family doctor
- Lymphoedema specialist
- Medical Geneticist
- Medical Oncologist
- Medical Prosthetic
- Nurse Practitioner
- Occupational Therapist
- Palliative Care Team
- Research Nurse
- Social worker

Table 7 (Chapter 6): The PCI type tool following the input from the focus groups

If you were to attend a clinical consultation today which of the following concerns would you wish to discuss with your Breast specialist:

- Activity (Information about exercise; returning to my daily routine)
- Angry (why me?, why this treatment)
- Anxiety
- Appearance (overall physical appearance; breast appearance)
- Appetite
- Arm swelling
- Bowel Habit (Diarrhoea or constipation)
- Breast texture
- Breast sensitivity /Breast pain
- Breast Prosthesis / Padding
- Cancer Treatment
- Coping (coping with the disease, the treatment or the side effects of treatment)
- Depression
- Sore mouth
- Fatigue / Tiredness (Low energy levels overall)
- Fear of Cancer coming back
- Fear of Cancer spreading
- Financial issues
- Hair loss
- Hair replacement
- Home care / district nurse support
- Indigestion
- Information about Breast Cancer
- Information about personal hygiene
- Intimacy
- Lifestyle (smoking/ alcohol)
- Memory/ Concentration
- Mobility
- Mood
- Nausea
- Pain in the Breast
- Pain in the arm or shoulder
- Pain elsewhere
- Self esteem
- Sex
- Sleeping
- Spiritual / Religious aspects
- Support for my family
- Swallowing
- Taste
- Temperament and personality
- Vomiting / Sickness
- Weight
- Wound healing / Mastectomy appearance
- Other, please state

If you were to attend a clinical consultation today which of the following members of staff would you like to see or be referred on to:

- Breast surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)
- Plastic surgeon (This doctor performs your breast reconstruction)
- Medical oncologist (This specialist administers anticancer drugs or chemotherapy)
- Radiation oncologist (He or she administers radiation therapy)
- Breast Care Nurse
- Chaplain
- Psychologist (He or she may help with anxiety /depression)
- Dietician
- Lymphoedema specialist /clinic
- Hair prosthesis / Breast prosthesis expert
- Nurse Practitioner (Person that removed fluid from my operation site)
- Pain specialist
- District Nurse
- My own doctor (General Practitioner)

Table 8 (Chapter 6): PCI items following consultation with National breast cancer bodies and clinicians

Breast Cancer Specific Patients Concern Inventory-56 items

ou were to attend a clinical consultation today which of the following issues would you wish to discuss with your Breast specialist

1. **General Information**
   - □ Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)
   - □ Information about Breast Cancer (Unable to get or unable to understand)
   - □ Information about personal hygiene (May be related to breast prosthesis or wig)
   - □ Lifestyle (Smoking/ alcohol-started or unable to stop)
   - □ Complementary /Homeopathic Medicines (Problems with or unable to get information about)
   - □ Fertility issues following treatment (Problems with or unable to get information about)
2. **Body Image-related**
   - □ Appearance (Overall physical appearance)
   - □ Arm appearance
   - □ Breast appearance
   - □ Breast Prosthesis / Padding
   - □ Hair loss
   - □ Hair replacement (wig)
   - □ Weight (Unable to control my weight)
   - □ Wound healing (Scar appearance)
   - □ Mastectomy appearance
3. **Physical Functioning and health-related**
   - □ Appetite
   - □ Arm swelling (Lymphoedema)
   - □ Diarrhoea
   - □ Constipation
   - □ Breast texture
   - □ Breast sensitivity /Breast pain
   - □ Cancer Treatment
   - □ Sore mouth / Dry Mouth
   - □ Fatigue / Tiredness (Low energy levels overall)
   - □ Indigestion
   - □ Memory/ Concentration
   - □ Nausea
   - □ Pain in the Breast
   - □ Pain in the arm or shoulder
   - □ Pain elsewhere
   - □ Sleeping
   - □ Swallowing
   - □ Taste
   - □ Vomiting / Sickness
   - □ Hot Flushes
4. **Psychological state and emotional well being-related**
   - □ Angry (why me?, why this treatment)
   - □ Anxiety (Related to the diagnosis or treatment)
   - □ Coping (coping with the disease, the treatment or the side effects of treatment)

- □ Depression
- □ Fear of Cancer coming back
- □ Fear of Cancer spreading
- □ Mood
- □ Self esteem
- □ Temperament and personality
- □ Fear about the future

5. **Sexual Functioning**
   - □ Intimacy
   - □ Relationships
   - □ Sex
6. **Social Functioning/ Family-related**
   - □ Financial issues
   - □ Home care / district nurse support
   - □ Mobility
   - □ Spiritual / Religious aspects
   - □ Support for my family
   - □ Worried about the future of my children
   - □ Unable to go out and enjoy my family
   - □ Unable to go to go to work
7. □ **Other, please state**

.....

Referral Options at consultation:

aff would you like to see or be referred on to:

- □ Breast surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)
- □ Plastic surgeon (This doctor performs your breast reconstruction)
- □ Medical oncologist (This specialist administers anticancer drugs or chemotherapy)
- □ Radiation oncologist (He or she administers radiation therapy)
- □ Breast Care Nurse
- □ Chaplain
- □ Psychologist (He or she may help with anxiety /depression)
- □ Dietician
- □ Lymphoedema specialist /clinic
- □ Hair prosthesis (wig advisor) / Breast prosthesis expert
- □ Nurse Practitioner (Person that removed fluid from my operation site)
- □ Pain specialist
- □ District Nurse
- □ My own doctor (General Practitioner)
- □ Complementary therapies

Table 9 (Chapter 7): Clinical/personal characteristics and survey response

		% Response	Patients	P value*
Age	<50	79	38/48	0.02
	50-9	86	64/74	
	60-9	85	63/74	
	70+	65	34/52	
Gender	Female	80	198/247	Na
	Male	100	2/2	
IMD deprivation: living in area that is one of the 20% most deprived	No	80	148/186	0.40 excl NK
	Yes	73	30/41	
	Not known	100	22/22	
Year of most recent diagnosis	2009/2010	83	108/130	0.04 excl NK
	2011/2012	71	61/86	
	Not known	94	31/33	
Location	Leeds	77	113/146	0.21
	Wakefield	82	64/78	
	Other	92	23/25	
Extent of disease: Primary Local	No	91	99/109	<0.001
	Yes	72	101/140	
Extent of disease: Local recurrent	No	80	197/245	0.59
	Yes	75	¾	
Extent of disease: Metastatic	No	81	191/237	0.71
	Yes	75	9/12	
Extent of disease: Living with cancer	No	81	192/237	0.26
	Yes	67	8/12	
Treatment (known for 242/249)				
Chemotherapy	No	81	100/123	0.63
	Yes	78	93/119	
Radiotherapy	No	70	67/96	0.003
	Yes	86	126/146	
Wide local excision /lumpectomy	No	78	100/128	0.53
	Yes	82	93/114	
Mastectomy	No	79	105/133	0.75
	Yes	81	88/109	
Reconstructive surgery	No	78	168/216	0.04
	Yes	96	25/26	
Anti-oestrogen therapy**	No/NK	87	111/128	0.006
	Yes	72	82/114	
Other treatment: **	No/NK	79	176/224	0.13
	Yes	94	17/18	

*****Fishers exact test or chi-squared test as appropriate

** Anti-oestrogen therapy included: tamoxifen, letrozole, anastrozole, aromasin, arimidex, exemestane;

Other treatment included :Herceptin, lepatinib, trastuzumab, neratinib.

Table 10 (Chapter 7-A): Clinical/personal characteristics and number of PCI ite

			% of 200 patients selecting one or more items within domain						Median (IQR) of total number of PCI items selected	Median (IQR) of total number of health professional staff selected
		Number of patients	General information	Body image related	Physical functioning and health-related	Psychological state and emotional wellbeing	Sexual functioning	Social functioning / family related		
All patients	Total	200	51% (102)	68% (136)	87% (173)	83% (167)	24% (49)	35% (70)	8 (5-13)	2 (1-4)
Age	<50	38	66% (25)	71% (27)	82% (31)	92% (35)	45% (17)	45% (17)	12 (5-17)	2 (1-4)
	50-9	64	45% (29)	73% (47)	88% (56)	89% (57)	27% (17)	39% (25)	7 (5-12)	2 (1-3)
	60-9	63	57% (36)	63% (40)	90% (57)	81% (51)	21% (13)	37% (23)	8 (4-12)	2 (1-4)
	70+	34	35% (12)	62% (21)	82% (28)	68% (23)	6% (2)	15% (5)	6 (2-10)	1 (1-3)
IMD deprivation: living in area that	No	148	52% (77)	72% (106)	90% (133)	82% (122)	29% (43)	34% (50)	8 (5-14)	2 (1-4)
is one of the 20% most deprived	Yes	30	50% (15)	63% (19)	80% (24)	83% (25)	10% (3)	47% (14)	6 (4-11)	2 (1-3)
	Not known	22	45% (10)	50% (11)	73% (16)	91% (20)	14% (3)	27% (6)	6 (1-12)	2 (1-3)
Year of most recent diagnosis	2009/2010	108	58% (63)	66% (71)	87% (94)	85% (92)	26% (28)	35% (38)	8 (5-15)	2 (1-4)
	2011/2012	61	39% (24)	70% (43)	89% (54)	84% (51)	25% (15)	36% (22)	8 (4-12)	2 (1-3)
	Not known	31	48% (15)	71% (22)	81% (25)	77% (24)	19% (6)	32% (10)	6 (4-12)	2 (1-3)
Location	Leeds	113	58% (66)	71% (80)	87% (98)	82% (93)	23% (26)	36% (41)	8 (5-15)	2 (1-4)
	Wakefield	64	39% (25)	67% (43)	88% (56)	86% (55)	28% (18)	36% (23)	7 (3-12)	2 (1-3)
	Other	23	48% (11)	57% (13)	83% (19)	83% (19)	22% (5)	26% (6)	6 (3-12)	1 (1-3)
Extent of disease: Primary Local	Yes	101	45% (45)	67% (68)	86% (87)	78% (79)	23% (23)	34% (34)	7 (3-12)	2 (1-3)
	No	99	58% (57)	69% (68)	87% (86)	89% (88)	26% (26)	36% (36)	8 (6-15)	2 (1-4)
Extent of disease: Local recurrent	Yes	3	67% (2)	100% (3)	67% (2)	100% (3)	67% (2)	100% (3)	15 (-)	2 (-)
	No	197	51% (100)	68% (133)	87% (171)	83% (164)	24% (47)	34% (67)	7 (5-13)	2 (1-4)
Extent of disease: Metastatic	Yes	9	56% (5)	67% (6)	100% (9)	100% (9)	33% (3)	44% (4)	8 (-)	2 (-)
	No	191	51% (97)	68% (130)	86% (164)	83% (158)	24% (46)	35% (66)	7 (4-13)	2 (1-4)
Extent of disease: Living with cancer	Yes	8	50% (4)	63% (5)	100% (8)	88% (7)	13% (1)	38% (3)	6 (-)	2 (-)
	No	192	51 (98)	68 (131)	86% (165)	83% (160)	25% (48)	35% (67)	8 (4-13)	2 (1-4)

Chemotherapy	Yes	93	51% (47)	77% (72)	88% (82)	88% (82)	31% (29)	37% (34)	8 (5-16)	2 (1-4)
	No	100	51% (51)	60% (60)	85% (85)	79% (79)	19% (19)	33% (33)	7 (4-11)	2 (1-3)
Radiotherapy	Yes	126	55% (69)	66% (83)	88% (111)	83% (104)	26% (33)	35% (44)	8 (5-13)	2 (1-4)
	No	67	43% (29)	73% (49)	84% (56)	85% (57)	22% (15)	34% (23)	6 (3-13)	2 (1-3)
Wide local excision/Lumpectomy	Yes	93	53% (49)	59% (55)	86% (80)	83% (77)	22% (20)	37% (34)	8 (4-13)	2 (1-3)
	No	100	49% (49)	77% (77)	87% (87)	84% (84)	28% (28)	33% (33)	7 (5-14)	2 (1-4)
Mastectomy	Yes	88	52% (46)	83% (73)	86% (76)	86% (76)	32% (28)	40% (35)	9 (6-17)	2 (1-4)
	No	105	50% (52)	56% (59)	87% (91)	81% (85)	19% (20)	30% (32)	7 (4-12)	2 (1-3)
Reconstructive surgery	Yes	25	72% (18)	84% (21)	88% (22)	96% (24)	40% (10)	48% (12)	11 (7-17)	3 (2-5)
	No	168	48% (80)	66% (111)	86% (145)	82% (137)	23% (38)	33% (55)	7 (4-13)	2 (1-3)
Anti-oestrogen therapy**	Yes	82	38% (31)	68% (56)	87% (71)	83% (68)	24% (20)	33% (27)	7 (3-11)	2 (1-3)
	No	111	60% (67)	68% (76)	86% (96)	84% (93)	25% (28)	36% (40)	8 (5-16)	2 (1-4)
Other therapy**	Yes	17	59% (10)	59% (10)	71% (12)	82% (14)	41% (7)	35% (6)	8 (2-18)	2 (1-5)
	No	176	50% (88)	69% (122)	88% (155)	84% (147)	23% (41)	35% (61)	7 (5-12)	2 (1-4)

*****Mann-Whitney (2 group comparison) or Kruskall-Wallis test (>2 group comparison) as appropriate using the full distribution of number of items selected, apart from age for which Spearman correlation methods were used. Missing data categories were excluded from the significance tests. Tests for extent of disease and treatment were tested against the absence of each, results of which are not shown. Results were displayed within domains as % with one or more item selected for convenience of presentation - the use of Fishers Exact test or chi-squared test as appropriate with these statistics did not add any further statistically significant results at P<0.01. P values: P <0.001 (yellow highlight), 0.001≤P<0.01 (blue highlight), 0.01≤P<0.05 (grey highlight)
** see footnote to Table 1

Table 11 (chapter 7-A): Correlations (at P<0.001) between number of PCI items / staff selected and summary scores from the EORTC QLQ-C30 and EORTC breast cancer module QLQ-BR23

PCI items / staff	EORTC	Correlation coefficient*
General information	C30 Cognitive functioning	-0.25
Body image-related	BR23 Body image	-0.34
Body image-related	BR23 Systemic therapy side effects	0.32
Body image-related	C30 Fatigue	0.29
Body image-related	C30 Insomnia	0.26
Body image-related	BR23 Arm symptoms	0.26
Body image-related	C30 Cognitive functioning	-0.25
Body image-related	C30 Social functioning	-0.25
Physical functioning and health-related	BR23 Systemic therapy side effects	0.53
Physical functioning and health-related	C30 Fatigue	0.45
Physical functioning and health-related	C30 Insomnia	0.39
Physical functioning and health-related	BR23 Arm symptoms	0.37
Physical functioning and health-related	C30 Cognitive functioning	-0.37
Physical functioning and health-related	C30 Physical functioning	-0.35
Physical functioning and health-related	C30 Pain	0.34
Physical functioning and health-related	C30 Role functioning	-0.33
Physical functioning and health-related	C30 Social functioning	-0.33
Physical functioning and health-related	C30 Constipation	0.32
Physical functioning and health-related	BR23 Breast symptoms	0.32
Physical functioning and health-related	C30 Nausea and vomiting	0.27
Physical functioning and health-related	C30 Dyspnoea	0.25
Psychological state and emotional well-being	C30 Emotional functioning	-0.35
Psychological state and emotional well-being	BR23 Future perspective	0.33
Psychological state and emotional well-being	C30 Cognitive functioning	-0.33
Psychological state and emotional well-being	BR23 Body image	-0.27
Psychological state and emotional well-being	C30 Fatigue	0.26
Social functioning / family related	C30 financial difficulties	0.43
Social functioning / family related	C30 Fatigue	0.31
Social functioning / family related	C30 Social functioning	-0.30
Social functioning / family related	BR23 Systemic therapy side effects	0.29
Social functioning / family related	C30 Role functioning	-0.28
Social functioning / family related	C30 Nausea and vomiting	0.27
Social functioning / family related	C30 Physical functioning	-0.26
Social functioning / family related	C30 Cognitive functioning	-0.26
Social functioning / family related	C30 Appetite	0.25
Total PCI items	BR23 Systemic therapy side effects	0.48
Total PCI items	C30 Fatigue	0.45
Total PCI items	BR23 Upset by hair loss	0.44
Total PCI items	C30 Cognitive functioning	-0.42
Total PCI items	C30 Insomnia	0.40

Total PCI items	C30 Social functioning	-0.36
Total PCI items	BR23 Arm symptoms	0.33
Total PCI items	C30 Role functioning	-0.31
Total PCI items	C30 Pain	0.30
Total PCI items	C30 Physical functioning	-0.30
Total PCI items	BR23 Body image	-0.29
Total PCI items	C30 Emotional functioning	-0.28
Total PCI items	C30 financial difficulties	0.28
Total PCI items	BR23 Breast symptoms	0.28
Total PCI items	C30 Nausea and vomiting	0.26
Total PCI items	C30 Diarrhoea	0.26
Staff: Psychological state and emotional well-being	C30 Emotional functioning	-0.31
Staff: Psychological state and emotional well-being	C30 Cognitive functioning	-0.30
Staff: Psychological state and emotional well-being	BR23 Arm symptoms	0.29
Staff: Psychological state and emotional well-being	C30 financial difficulties	0.28
Staff: Total number	C30 Fatigue	0.26

*Spearman, for which P<0.001

Table 12 (chapter 7-B): Number of PCI domain items selected by number of Fears (of cancer coming back, of spread, about the future) selected

PCI Domain description	Number of Fears selected on PCI	Number of Patients	Number of items selected from PCI Domain				Total Items	Spearman correlation*
			Median	IQR	≥ 1 item	≥ 3 items		
General information (6 items)	3 Fears	36	1	1-2	81% (29)	8% (3)	47	
	2 Fears	50	1	0-1	52% (26)	6% (3)	37	0.26 P<0.001
	1 Fear	57	0	0-1	37% (21)	2% (1)	24	
	0 Fears	57	0	0-1	46% (26)	2% (1)	34	
Body image related (9 items)	3 Fears	36	3	1-5	86% (31)	53% (19)	108	
	2 Fears	50	2	1-2	76% (38)	18% (9)	86	0.34 P<0.001
	1 Fear	57	1	0-2	56% (32)	14% (8)	59	
	0 Fears	57	1	0-2	61% (35)	12% (7)	60	
Physical functioning and health-related (20 items)	3 Fears	36	7	4-9	94% (34)	92% (33)	261	
	2 Fears	50	4	2-6	90% (45)	68% (34)	198	0.34 P<0.001
	1 Fear	57	3	1-4	81% (46)	54% (31)	173	
	0 Fears	57	3	1-5	84% (48)	54% (31)	184	
Psychological state and emotional wellbeing excluding Fear items (10-3=7 items)	3 Fears	36	2	1-3	81% (29)	44% (16)	86	
	2 Fears	50	0	0-1	46% (23)	4% (2)	38	0.25 P<0.001
	1 Fear	57	0	0-1	30% (17)	4% (2)	30	
	0 Fears	57	0	0-2	42% (24)	18% (10)	53	
Sexual functioning (3 items)	3 Fears	36	0	0-1	47% (17)	11% (4)	25	
	2 Fears	50	0	0-1	32% (16)	6% (3)	25	0.31 P<0.001
	1 Fear	57	0	0-0	19% (11)	-	14	
	0 Fears	57	0	0-0	9% (5)	-	7	
Social functioning /	3 Fears	36	1	0-3	72% (26)	25% (9)	59	0.30 P<0.001

family related (8 items)								
	2 Fears	50	0	0-1	28% (14)	6% (3)	29	
	1 Fear	57	0	0-1	30% (17)	5% (3)	27	
	0 Fears	57	0	0-0	23% (13)	4% (2)	23	
		Patients	Median	IQR	≥ 3 item	≥ 5 items	Total Items	
Total: PCI excluding Fear items (56-3=53 items)	3 Fears	36	16	9-21	97% (35)	92% (33)	586	
	2 Fears	50	7	4-11	88% (44)	72% (36)	413	0.38
	1 Fear	57	5	2-7	68% (39)	51% (29)	327	P<0.001
	0 Fears	57	6	3-9	75% (43)	63% (36)	361	
Total: Health professional staff (15 items)	3 Fears	36	5	3-6	78% (28)	40% (18)	177	
	2 Fears	50	2	1-4	34% (17)	16% (8)	128	0.41
	1 Fear	57	1	1-2	21% (12)	4% (2)	98	P<0.001
	0 Fears	57	1	1-3	25% (14)	9% (5)	105	

*between number of items selected and number of fears.

Table 13 (chapter 7-B): Percentage of patients selecting specific PCI items and health professionals, by number of PCI Fear items selected

Body table gives % of column totals	Number of PCI Fear items selected							
	0	1	2	3	P value*	FoR	FOS	FFF
	N=57	N=57	N=50	N=36		N=124	N=78	N=63
GENERAL INFORMATION								
B11 Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)	21	18	22	56	0.002	30	36	43
B12 Information about Breast Cancer (Unable to get or unable to understand)	12	9	18	31	0.02	19	18	29
B13 Information about personal hygiene (May be related to breast prosthesis or wig)	2	2	2	6	0.34	3	4	3
B14 Lifestyle (Smoking/ alcohol-started or unable to stop)	14	4	12	8	0.54	10	9	10
B15 Complementary /Homeopathic Medicines (Problems with or unable to get information about)	9	4	18	28	0.006	17	19	25
B16 Fertility issues following treatment (Problems with or unable to get information about)	2	0	2	3	0.61	2	3	2
BODY IMAGE RELATED								
B21 Appearance (Overall physical appearance)	12	11	16	36	0.008	19	26	29
B22 Arm appearance	11	5	16	22	0.06	15	19	16
B23 Breast appearance	26	25	26	47	0.08	31	37	37
B24 Breast Prosthesis / Padding	9	4	18	33	0.001	19	26	24
B25 Hair loss	0	11	20	31	<0.001	18	26	27
B26 Hair replacement (wig)	0	4	8	14	0.003	8	10	11
B27 Weight (Unable to control my weight)	21	19	34	44	0.007	33	37	37
B28 Wound healing (Scar appearance)	12	9	16	36	0.006	21	26	22
B29 Mastectomy appearance	14	14	18	36	0.02	21	28	27
PHYSICAL FUNCTIONING AND HEALTH RELATED								
B31 Appetite	16	16	10	33	0.18	17	23	25
B32 Arm swelling (Lymphoedema)	14	4	12	33	0.04	16	22	24
B33 Diarrhoea	9	4	8	17	0.32	9	14	13
B34 Constipation	12	9	18	22	0.12	15	19	21
B35 Breast texture	14	11	10	17	0.92	13	14	11
B36 Breast sensitivity /Breast pain	33	39	54	64	0.001	52	58	56
B37 Cancer Treatment	11	9	24	33	0.002	19	26	35

B38 Sore mouth / Dry Mouth	18	11	14	36	0.08	17	26	29
B39 Fatigue / Tiredness (Low energy levels overall)	42	30	48	72	0.005	50	56	59
B310 Indigestion	5	11	4	28	0.01	12	18	17
B311 Memory/ Concentration	23	19	26	50	0.01	31	35	40
B312 Nausea	2	4	8	28	<0.001	12	18	17
B313 Pain in the Breast	19	23	34	44	0.005	35	37	37
B314 Pain in the arm or shoulder	23	21	20	42	0.13	24	35	32
B315 Pain elsewhere	14	16	12	33	0.09	19	21	27
B316 Sleeping	26	16	44	58	<0.001	39	50	46
B317 Swallowing	2	2	2	6	0.34	2	3	6
B318 Taste	2	11	2	25	0.005	10	13	19
B319 Vomiting / Sickness	4	5	4	19	0.02	7	12	16
B320 Hot Flushes	35	40	42	64	0.02	48	51	54
PSYCHOLOGICAL STATE AND EMOTIONAL WELLBEING								
B41 Angry (why me?, why this treatment)	2	5	4	22	0.002	10	10	17
B42 Anxiety (Related to the diagnosis or treatment)	4	4	22	67	<0.001	29	38	48
B43 Coping (coping with the disease, the treatment or the side effects of treatment)	19	11	18	42	0.03	22	28	32
B44 Depression	14	14	12	31	0.13	16	23	24
B45 Fear of cancer coming back	0	70	96	100	NA	NA	85	86
B46 Fear of cancer spreading	0	18	64	100	NA	53	NA	60
B47 Mood	23	9	4	28	0.71	11	17	19
B48 Self esteem	12	4	12	33	0.01	15	19	25
B49 Temperament and personality	16	4	4	17	0.59	9	9	13
B410 Fear about the future	0	12	40	100	NA	44	49	NA
SEXUAL FUNCTIONING								
B51 Intimacy	5	12	12	22	0.03	16	17	16
B52 Relationships	4	2	12	28	<0.001	14	17	21
B53 Sex	4	11	26	19	0..002	21	18	21
SOCIAL FUNCTIONING / FAMILY RELATED								
B61 Financial issues	12	21	14	36	0.03	24	22	29
B62 Home care / district nurse support	0	4	10	14	0.002	9	12	11
B63 Mobility	9	2	6	22	0.07	9	13	16
B64 Spiritual / Religious aspects	4	0	0	8	0.40	2	4	5
B65 Support for my family	4	5	8	28	0.008	12	17	21
B66 Worried about the future of my children	2	4	10	25	0.001	15	12	22
B67 Unable to go out and enjoy my family	4	4	4	17	0.07	7	9	16
B68 Unable to go to go to work	4	2	6	14	0.04	7	8	11
HEALTH PROFESSIONALS								
R1 Breast surgeon (He or she will perform the biopsy of the	42	49	34	64	0.28	49	50	49

breast tumour and the lumpectomy or mastectomy)								
R2 Plastic surgeon (This doctor performs your breast reconstruction)	11	9	8	25	0.13	13	17	17
R3 Medical oncologist (This specialist administers anticancer drugs or chemotherapy)	18	16	34	53	<0.001	31	37	52
R4 Radiation oncologist (He or she administers radiation therapy)	12	2	10	31	0.02	14	21	17
R5 Breast Care Nurse	39	33	48	81	<0.001	52	63	65
R6 Chaplain	2	2	0	6	0.48	2	3	3
R7 Psychologist (He or she may help with anxiety /depression)	12	14	14	50	<0.001	24	26	41
R8 Dietician	16	4	22	25	0.08	18	21	21
R9 Lymphoedema specialist /clinic	4	5	12	19	0.04	11	17	14
R10 Hair prosthesis (wig advisor) / Breast prosthesis expert	4	5	6	25	0.002	10	17	16
R11 Nurse Practitioner (Person that removed fluid from my operation site)	2	0	4	14	0.007	6	9	8
R12 Pain specialist	5	12	12	22	0.03	15	15	19
R13 District Nurse	2	0	4	6	0.17	3	5	3
R14 My own doctor (General Practitioner)	9	11	16	22	0.06	16	15	22
R15 Complementary therapies	5	11	20	50	<0.001	26	32	37

*Mann-Whitney test comparing 0,1,2,3 Fears count distribution for specific PCI items being selected Vs. not selected. NA not applicable as these items make up the Fears count. FoR: Fear of cancer coming back, FoS: Fear of spread of cancer, FFF: Fear about the future. The percentages given in the last three columns are for descriptive purposes only – specific tests of significance for each cell result in relation to absence of that specific fear have not been summarised.

Table 14 (chapter 7-B): Clinical/personal characteristics and selection of Fear items on the PCI

Body table gives % (n) of row totals			Number of Fear items selected							
		Patients	0	1	2	3	P value*	% (n) with FoR	%(n) With FoS	% (n) with FFF
	ALL	200	29 (57)	29 (57)	25 (50)	18 (36)	-			
Age	<55	69	23 (16)	26 (18)	29 (20))	22 (15		74 (51)	38 (26)	38 (26)
	55-64	59	20 (12)	34 (20)	25 (15)	20 (12)	0.04	68 (40)	41 (24)	37 (22)
	65-74	52	37 (19)	29 (15)	19 (10)	15 (8)		50 (26)	38 (20)	25 (13)
	75+	19	53 (10)	16 (3)	26 (5)	5 (1)		32 (6)	42 (8)	11 (2)
Gender	Female	198	28 (56)	28 (56)	25 (50)	18 (36)	-	63 (124)	39 (77)	32 (63)
	Male	2	50 (1)	50 (1)	-	-		0 (0)	50 (1)	0 (0)
IMD deprivation: living in area that is one of the 20% most deprived	No	148	32 (47)	24 (35)	25 (37)	20 (29)	0.90 excl NK	61 (90)	41 (60)	31 (46)
	Yes	30	23 (7)	37 (11)	23 (7)	17 (5)		63 (19)	37 (11)	33 (10)
	Not known	22	14 (3)	50 (11)	27 (6)	9 (2)		68 (15)	32 (7)	32 (7)
Year of most recent diagnosis	2009/2010	108	23 (25)	28 (30)	29 (31)	20 (22)	0.07 excl NK	69 (74)	44 (47)	34 (37)
	2011/2012	61	31 (19)	36 (22)	18 (11)	15 (9)		56 (34)	31 (19)	30 (18)
	Not known	31	42 (13)	16 (5)	26 (8)	16 (5)		52 (16)	39 (12)	26 (8)
Location	Leeds	113	27 (31)	20 (23)	32 (36)	20 (23)	0.07	63 (71)	48 (54)	35 (39)
	Wakefield	64	27 (17)	39 (25)	17 (11)	17 (11)		67 (43)	33 (21)	25 (16)
	Other	23	39 (9)	39 (9)	13 (3)	9 (2)		43 (10)	13 (3)	35 (8)
Extent of disease: Primary Local	No	99	23 (23)	27 (27)	32 (32)	17 (17)	0.13	63 (62)	47 (47)	33 (33)
	Yes	101	34 (34)	30 (30)	18 (18)	19 (19)		61 (62)	31 (31)	30 (30)
Extent of disease: Local recurrent	No	197	29 (57)	28 (56)	25 (50)	17 (34)	-	62 (122)	39 (76)	30 (60)
	Yes	3	0 (0)	33 (1)	0 (0)	67 (2)		67 (2)	67 (2)	100 (3)
Extent of disease: Metastatic	No	191	29 (56)	28 (54)	25 (47)	18 (34)	0.31	62 (119)	39 (75)	29 (56)
	Yes	9	11 (1)	33 (3)	33 (3)	22 (2)		57 (5)	33 (3)	78 (7)
Extent of disease: Living with cancer	No	192	29 (55)	28 (53)	26 (49)	18 (35)	0.61	64 (122)	39 (75)	31 (59)
	Yes	8	25 (2)	50 (4)	13 (1)	13 (1)		25 (2)	38 (3)	50 (4)
Treatment (known for 193/200)										
Chemotherapy	No	100	32 (32)	28 (28)	22 (22)	18 (18)	0.41	57 (57)	36 (36)	33 (33)
	Yes	93	25 (23)	30 (28)	28 (26)	17 (16)		68 (63)	40 (37)	30 (28)
Radiotherapy	No	67	27 (18)	30 (20)	25 (17)	18 (12)	0.79	61 (41)	40 (27)	33 (22)

	Yes	126	29 (37)	29 (36)	25 (31)	17 (22)		63 (79)	37 (46)	31 (39)
Wide local excision /lumpectomy	No	100	29 (29)	27 (27)	26 (26)	18 (18)	0.86	60 (60)	43 (43)	30 (30)
	Yes	93	28 (26)	31 (29)	24 (22)	17 (16)		65 (60)	32 (30)	33 (31)
Mastectomy	No	105	30 (32)	34 (36)	24 (25)	11 (12)	0.04	58 (61)	28 (29)	30 (32)
	Yes	88	26 (23)	23 (30)	26 (23)	25 (22)		67 (59)	50 (44)	33 (29)
Reconstructive surgery	No	168	31 (52)	30 (50)	25 (42)	14 (24)	0.003	59 (99)	35 (58)	29 (49)
	Yes	25	12 (3)	24 (6)	24 (6)	40 (10)		84 (21)	60 (15)	48 (12)
Anti-oestrogen therapy**	No/NK	111	27 (30)	23 (26)	27 (30)	23 (25)	0.05	66 (73)	44 (49)	35 (39)
	Yes	82	30 (25)	37 (30)	22 (18)	11 (9)		57 (47)	29 (24)	27 (22)
Other treatment: **	No/NK	176	29 (51)	31 (54)	24 (42)	16 (29)	0.13	61 (107)	37 (65)	30 (53)
	Yes	17	24 (4)	12 (2)	35 (6)	29 (5)		76 (13)	47 (8)	47 (8)
Mastectomy with chemotherapy	Yes	59	24 (14)	25 (15)	27 (16)	24 (14)	0.10 Yes Vs Not both	73 (43)	49 (29)	29 (17)

***** Mann-Whitney (2 group comparison) or Kruskall-Wallis test (>2 group comparison) as appropriate using the number of Fear items selected; ** Anti-oestrogen therapy included: tamoxifen, letrozole, anastrozole, aromasin, arimidex, exemestane. Other treatment included :Herceptin, lepatinib, trastuzumab, neratinib. FoR: Fear of cancer coming back, FoS: Fear of spread of cancer, FFF: Fear about the future:- Grey shading: P<0.01 Fishers exact test

Table 15 (chapter 7-B): Association between PCI Fear items and summary scores from the EORTC QLQ-C30 and EORTC breast cancer module QLQ-BR23

EORTC	Spearman correlation* Correlation coefficient1	P value	Patients	Mann-Whitney Test** FoR P value	FoS P value	FFF P value
C30 Physical functioning	0.14	0.05	199	0.002	0.06	0.34
C30 Role functioning	0.05	0.52	200	0.10	0.09	0.03
C30 Emotional functioning	-0.10	0.15	195	0.61	0.78	0.001
C30 Cognitive functioning	-0.08	0.26	196	0.99	0.55	0.02
C30 Social functioning	-0.04	0.57	195	0.47	0.84	0.06
C30 Fatigue	0.02	0.74	200	0.45	0.41	0.01
C30 Nausea and vomiting	0.02	0.74	200	0.62	0.99	0.20
C30 Pain	-0.02	0.74	199	0.23	0.60	0.27
C30 Global health status / QOL	0.04	0.56	196	0.19	0.18	0.14
C30 Dyspnoea	-0.06	0.39	200	0.72	0.29	0.67
C30 Insomnia	0.06	0.38	200	0.86	0.86	0.09
C30 Appetite loss	-0.04	0.57	200	0.29	0.34	0.43
C30 Constipation	-0.06	0.41	200	0.28	0.91	0.61
C30 Diarrhoea	0.06	0.44	193	0.74	0.14	0.87
C30 Financial difficulties	0.02	0.74	196	0.41	0.25	0.23
BR23 Body image	-0.12	0.08	195	0.06	0.96	0.04
BR23 Sexual functioning	0.07	0.36	177	0.12	0.87	0.63
BR23 Sexual enjoyment	-0.14	0.25	68	0.24	0.16	0.93
BR23 Future perspective	-0.33	<0.001	195	<0.001	0.28	<0.001
BR23 Systemic therapy side effects	0.06	0.39	197	0.68	0.57	0.06
BR23 Breast symptoms	0.01	0.92	197	0.57	0.99	0.77
BR23 Arm symptoms	0.01	0.93	197	0.48	0.38	0.83
BR23 Upset by hair loss	0.23	0.08	62	0.51	0.95	0.002

* Spearman correlation coefficient between number of PCI Fear items selected (range 0-3) and the EORTC scores

**Mann-Whitney test comparing distribution of EORTC scores in relation to FoR (Fear of cancer coming back), FoS (Fear of spread) or FFF (Fears about the future).

Table 16 (chapter 7-C): Body image –related domain

During the past week have you lost any hair (Sprangers et al, 1996)
During the past week have you felt physically less attractive as a result of your disease or treatment (Sprangers et al,1996)
During the past week have you been feeling less feminine as a result of your disease or treatment (Sprangers et al, 1996)
During the past week did you find it difficult to look at yourself naked (Sprangers et al,1996)
During the past week have you been dissatisfied with your body (Sprangers et al,1996)
I avoid looking at my scars from breast surgery (Baxter et al, 2006)
I am satisfied with the shape of my body (Baxter et al, 2006)
I feel less feminine since cancer (Baxter et al,2006)
I Like my body (Baxter et al, 2006)
I feel comfortable about the way I look when exercise (Baxter et al, 2006)
I would feel comfortable changing in a public change-room (Baxter et al, 2006)
I feel my body has been invaded (Baxter et al, 2006)
I am satisfied with the appearance of my arm (Baxter et al, 2006)
I am satisfied with the appearance of my hips (Baxter et al, 2006)
I am satisfied with the shape of my buttocks (Baxter et al, 2006)
I feel comfortable looking at my mastectomy (Baxter et al, 2006)
I am happy with the position of my nipple (Baxter et al, 2006)
I feel satisfied with the size of my breast (Baxter et al, 2006)
I feel comfortable when other see my breasts (Baxter et al, 2006)
The appearance of my breasts could disturb others (Baxter et al, 2006)
I feel that people are looking at my breasts (Baxter et al, 2006)
How satisfied are you with the way your breast looks (Polivy J, 1977)
Have you been feeling self-conscious about your appearance (Hopwood et al, 2001)
Have you felt less physically attractive as a result of your disease or treatment (Hopwood et al, 2001)
Have you been dissatisfied with your appearance when dressed (Hopwood et al, 2001)
Did you find it difficult to look at your self naked (Hopwood et al, 2001)
Did you avoid people because of the way you felt about your appearance (Hopwood et al, 2001)
Have you been feeling the treatment has left your body less whole (Hopwood et al, 2001)
Have you been dissatisfied with your body (Hopwood et al,2001)
Have you been dissatisfied with the appearance of your scar (Hopewood et al, 2001)

Is there a difference between the treated and untreated areas in terms of Breast size (Stanton et al,2005)

Is there a difference between the treated and untreated areas in terms of breast texture (hardening) (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of nipple appearance (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast shape (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of breast elevation (Stanton et al, 2005)

Is there a difference between the treated and untreated areas in terms of scar tissue (Stanton et al, 2005)

I am self-conscious about the way I dress (Brady et al, 1997)

I am bothered by hair loss (Brady et al, 1997)

How satisfied or dissatisfied have you been with how you look in the mirror clothed (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the shape of your reconstructed breasts when you are wearing a bra (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how normal you feel in your clothes (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the size of your reconstructed breasts (Pusic et al, 2009)

How satisfied or dissatisfied have you been with being able to wear clothing that is more fitted (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your breasts are lined up in relation to each other (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how comfortably your bras fit (Pusic et al, 2009)

How satisfied or dissatisfied have you been with the softness of your reconstructed breasts (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how equal in size your breasts are to each other (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how natural your reconstructed breast looks (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how natural your reconstructed breast sits/hangs (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your reconstructed breast feels to touch (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how much your reconstructed breast feels like a natural part of your body (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how closely matched your breasts are to each other (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how your reconstructed breast look now compared to before you had any surgery (Pusic et al, 2009)

How satisfied or dissatisfied have you been with how you look in the mirror unclothed (Pusic et al, 2009)

Table 17 (chapter 7-C): Body image related items selected on the PCI

Body table gives % (n) of column totals	Number of body Image related items					
	0 N=64	1 N=56	2 N=37	3 N=17	4-8 N=26	ALL N=200
BODY IMAGE RELATED items:						
B21 Appearance (Overall physical appearance)	0	4 (2)	22 (8)	47 (8)	62 (16)	17 (34)
B22 Arm appearance	0	5 (3)	22 (8)	29 (5)	35 (9)	13 (25)
B23 Breast appearance	0	18 (10)	43 (16)	59 (10)	88 (23)	30 (59)
B24 Breast Prosthesis / Padding	0	4 (2)	22 (8)	18 (3)	65 (17)	15 (30)
B25 Hair loss	0	7 (4)	19 (7)	24 (4)	46 (12)	14 (27)
B26 Hair replacement (wig)	0	0	3 (1)	12 (2)	31 (8)	6 (11)
B27 Weight (Unable to control my weight)	0	46 (26)	30 (11)	24 (4)	58 (15)	28 (56)
B28 Wound healing (Scar appearance)	0	9 (5)	16 (6)	47 (8)	54 (14)	17 (33)
B29 Mastectomy appearance	0	7 (4)	24 (9)	41 (7)	69 (18)	19 (38)

Table 18 (chapter 7-C): Median (IQR) and total number of items selected on the PCI, by number of body image related items selected.

Body table gives median (IQR), total number of items in other domains	N of body Image related items* 0 N=64	1 N=56	2-3 N=54	4-8 N=26
General information (6 items)	0 (0-0), 19	1 (0-1), 37	1 (0-1), 48	1 (1-2), 38
Physical functioning and health-related (20 items)	2 (0-4), 155	3 (2-4), 166	5 (3-7), 279	7 (5-11), 216
Psychological state and emotional wellbeing (10 items)	1 (1-2), 101	1 (1-2), 88	3 (2-4), 159	5 (3-6), 124
Sexual functioning (3 items)	0 (0-0), 10	0 (0-0), 11	0 (0-1), 28	1 (0-1), 22
Social functioning / family related (8 items)	0 (0-0), 16	0 (0-1), 21	0 (0-2), 52	2 (1-3), 49
Total number of other PCI items (range 0-47 after excluding the 9 body image related items)	4 (2-6), 301	6 (4-7), 323	10 (5-14), 566	17 (10-23), 449
Health professionals (15 staff)	1 (1-2), 92	2 (1-3), 110	3 (2-4), 174	5 (3-6), 132

*Spearman correlation was significant at P<0.001 between the number of body image related items (range 0-9) and the number of items in each other domain, and also with total number of other items and with the number of health professionals selected.

Table 19 (chapter 7-C): Percentage selecting other specific PCI items and health professionals, by number of PCI body image related items selected

Body table gives % of column totals	N of body Image related items				P Value*
	0 N=64	1 N=56	2-3 N=54	4-8 N=26	
GENERAL INFORMATION					
B11 Activity	9	29	31	54	<0.001
B12 Information about Breast Cancer (Unable to get or unable to understand)	9	14	15	38	0.005
B13 Information about personal hygiene (Maybe related to breast prosthesis/wig)	0	2	0	15	0.007
B14 Lifestyle (Smoking/ alcohol-started or unable to stop)	6	11	13	15	0.10
B15 Complementary /Homeopathic Medicines (information about)	3	11	26	23	0.001
B16 Fertility issues following treatment (information about)	2	0	4	0	0.93
PHYSICAL FUNCTIONING AND HEALTH RELATED					
B31 Appetite	8	16	19	42	0.001
B32 Arm swelling (Lymphoedema)	6	5	24	38	<0.001
B33 Diarrhoea	6	7	11	19	0.06
B34 Constipation	9	5	20	35	0.002
B35 Breast texture	0	12	20	27	<0.001
B36 Breast sensitivity /Breast pain	28	39	61	69	<0.001
B37 Cancer Treatment	16	4	22	42	0.004
B38 Sore mouth / Dry Mouth	13	13	19	42	0.004
B39 Fatigue / Tiredness (Low energy levels overall)	33	43	50	73	0.001
B310 Indigestion	3	4	20	23	<0.001
B311 Memory/ Concentration	16	23	35	50	<0.001
B312 Nausea	2	4	11	31	<0.001
B313 Pain in the Breast	17	25	37	46	0.001
B314 Pain in the arm or shoulder	17	11	35	54	<0.001
B315 Pain elsewhere	19	13	15	31	0.36
B316 Sleeping	17	21	52	62	<0.001
B317 Swallowing	0	2	4	8	0.03
B318 Taste	2	2	9	38	<0.001
B319 Vomiting / Sickness	3	2	6	31	<0.001
B320 Hot Flushes	28	46	46	69	0.001
PSYCHOLOGICAL STATE AND EMOTIONAL WELLBEING					
B41 Angry (why me?, why this treatment)	2	4	7	27	<0.001
B42 Anxiety (Related to the diagnosis or treatment)	8	13	30	50	<0.001
B43 Coping (coping with the disease, the treatment or the side effects of treatment)	16	9	28	42	0.005
B44 Depression	11	11	19	38	0.006
B45 Fear of Cancer coming back	55	57	67	81	0.02
B46 Fear of Cancer spreading	25	27	52	73	<0.001
B47 Mood	8	7	20	38	<0.001
B48 Self esteem	8	4	17	42	<0.001
B49 Temperament and personality	6	5	13	27	0.004
B410 Fear about the future	20	21	43	58	<0.001
SEXUAL FUNCTIONING					
B51 Intimacy	5	5	19	31	<0.001
B52 Relationships	3	2	17	27	<0.001

B53 Sex	8	12	17	27	0.01
SOCIAL FUNCTIONING / FAMILY RELATED					
B61 Financial issues	8	16	30	35	<0.001
B62 Home care / district nurse support	0	0	11	23	<0.001
B63 Mobility	5	2	15	19	0.008
B64 Spiritual / Religious aspects	2	2	4	4	0.38
B65 Support for my family	0	5	11	46	<0.001
B66 Worried about the future of my children	5	5	15	19	0.01
B67 Unable to go out and enjoy my family	5	4	7	19	0.04
B68 Unable to go to go to work	2	4	4	23	0.002
HEALTH PROFESSIONALS					
R1 Breast surgeon	50	41	41	58	0.99
R2 Plastic surgeon	0	2	24	38	<0.001
R3 Medical oncologist	14	23	35	54	<0.001
R4 Radiation oncologist	5	7	17	31	<0.001
R5 Breast Care Nurse	30	39	65	69	<0.001
R6 Chaplain	0	2	2	8	0.04
R7 Psychologist	13	13	26	42	0.002
R8 Dietician	9	18	15	27	0.08
R9 Lymphoedema specialist /clinic	0	9	17	23	<0.001
R10 Hair prosthesis (wig advisor) / Breast prosthesis expert	0	4	9	38	<0.001
R11 Nurse Practitioner	0	0	8	15	<0.001
R12 Pain specialist	5	7	17	31	0.001
R13 District Nurse	0	0	7	4	0.03
R14 My own doctor (General Practitioner)	11	16	15	12	0.70
R15 Complementary therapies	8	16	26	35	0.001

*Mann-Whitney test comparing the full distribution (range 0-9) of body image related items for specific PCI items being selected Vs. not selected.

Table 20 (chapter 7-C): Clinical/personal characteristics and selection of PCI body image related items

Body table gives % (n) of row totals			Number of Body image related items selected				
		Patients	0	1	2-3	4-8	P value*
	ALL	200	32 (64)	28 (56)	27 (54)	13 (26)	-
Age	<55	69	28 (19)	23 (16)	36 (25)	13 (9)	0.04**
	55-64	59	25 (15)	34 (20)	24 (14)	17 (10)	
	65-74	52	42 (22)	31 (16)	15 (8)	12 (6)	
	75+	19	42 (8)	16 (3)	37 (7)	5 (1)	
Gender	Female	198	32 (64)	28 (56)	27 (53)	13 (25)	-
	Male	2	0	0	50 (1)	50 (1)	
IMD deprivation: living in area that is one of the 20% most deprived	No	148	28 (42)	30 (44)	28 (41)	14 (21)	0.38 excl NK
	Yes	30	37 (11)	27 (8)	23 (7)	13 (4)	
	Not known	22	50 (11)	18 (4)	27 (6)	5 (1)	
Year of most recent diagnosis	2009/2010	108	34 (37)	26 (28)	26 (28)	14 (15)	0.84 excl NK
	2011/2012	61	30 (18)	31 (19)	28 (17)	11 (7)	
	Not known	31	29 (9)	29 (9)	29 (9)	13 (4)	
Location	Leeds	113	29 (33)	26 (29)	31 (35)	14 (16)	0.21
	Wakefield	64	33 (21)	34 (22)	17 (11)	16 (10)	
	Other	23	43 (10)	22 (5)	35 (8)	0	
Extent of disease: Primary Local	No	99	31 (31)	24 (24)	30 (30)	14 (14)	0.48
	Yes	101	33 (33)	32 (32)	24 (24)	12 (12)	
Extent of disease: Local recurrent	No	197	32 (64)	28 (55)	27 (53)	13 (25)	-
	Yes	3	0	33 (1)	33 (1)	33 (1)	
Extent of disease: Metastatic	No	191	32 (61)	28 (54)	27 (52)	13 (24)	0.84
	Yes	9	33 (3)	22 (2)	22 (2)	22 (2)	
Extent of disease: Living with cancer	No	192	32 (61)	28 (53)	28 (53)	13 (25)	0.55
	Yes	8	38 (3)	38 (3)	13 (1)	13 (1)	
Treatment (known for 193/200)							
Chemotherapy	No	100	40 (40)	30 (30)	21 (21)	9 (9)	0.002
	Yes	93	23 (21)	28 (26)	31 (29)	18 (17)	
Radiotherapy	No	67	27 (18)	28 (19)	28 (19)	16 (11)	0.24
	Yes	126	34 (43)	29 (37)	25 (31)	12 (15)	
Wide local excision /lumpectomy	No	100	23 (23)	30 (30)	30 (30)	17 (17)	0.005
	Yes	93	41 (38)	28 (26)	22 (20)	10 (9)	
Mastectomy	No	105	44 (46)	30 (31)	22 (23)	5 (5)	<0.001
	Yes	88	17 (15)	28 (25)	31 (27)	24 (21)	
Reconstructive surgery	No	168	34 (57)	31 (52)	23 (38)	13 (21)	0.006
	Yes	25	16 (4)	16 (4)	48 (12)	20 (5)	
Anti-oestrogen therapy***	No/NK	111	32 (35)	23 (25)	28 (31)	18 (20)	0.08
	Yes	82	32 (26)	38 (31)	23 (19)	7 (6)	
Other treatment: ***	No/NK	176	31 (54)	30 (53)	27 (47)	13 (22)	0.92
	Yes	17	41 (7)	18 (3)	18 (3)	24 (4)	

***** Mann-Whitney (2 group comparison) or Kruskall-Wallis test (>2 group comparison) as appropriate using the number of body image related items selected (range 0-9)

** Spearman correlation between age in years and number of body image related items (range 0-9)

*** Anti-oestrogen therapy included: tamoxifen, letrozole, anastrozole, aromasin, arimidex, exemestane;

Other treatment included :Herceptin, lepatinib, trastuzumab, neratinib.

Table 21 (chapter 7-C): Number of body image related items by treatment

Wide local excision or lumpectomy surgery	Reconstructive surgery	Chemotherapy	Mastectomy	Number of Body image-related items				Total
				0	1	2-3	4-8	
No	No	No	No	8	2	3	-	13
No	No	No	Yes	1	6	7	4	18
No	No	Yes	No	1	4	3	-	8
No	No	Yes	Yes	10	14	7	10	41
No	Yes	No	Yes	-	2	4	-	6
No	Yes	Yes	Yes	3	2	6	3	14
Yes	No	No	No	31	19	6	2	58
Yes	No	No	Yes	-	1	1	2	4
Yes	No	Yes	No	6	6	10	3	25
Yes	No	Yes	Yes	-	-	1	-	1
Yes	Yes	No	Yes	-	-	-	1	1
Yes	Yes	Yes	No	-	-	1	-	1
Yes	Yes	Yes	Yes	1	-	1	1	3
Treatment not known				3	-	4	-	7

Table 22 (chapter 7-C): Number of PCI Body image related items and summary scores from the EORTC QLQ-C30 and EORTC breast cancer module QLQ-BR23

	Spearman correlation*			Number of PCI body image related items			
				0	1	2-3	4-8
EORTC	Correlation coefficient1	P value	Patients	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
C30 Physical functioning	-0.23	0.001	199	85.3 (2.4)	81.3 (2.7)	77.5 (3.2)	76.8 (3.5)
C30 Role functioning	-0.18	0.01	200	82.6 (3.0)	77.1 (3.9)	70.7 (4.2)	69.9 (6.0)
C30 Emotional functioning	-0.13	0.08	195	73.8 (2.8)	75.3 (2.7)	66.2 (3.5)	62.7 (6.0)
C30 Cognitive functioning	-0.25	<0.001	196	84.1 (2.5)	77.8 (3.2)	65.4 (3.8)	69.2 (6.2)
C30 Social functioning	-0.25	<0.001	195	86.6 (2.9)	76.2 (3.7)	70.1 (3.9)	70.5 (6.2)
C30 Fatigue	0.29	<0.001	200	22.6 (3.1)	32.1 (2.7)	38.5 (3.3)	41.0 (5.5)
C30 Nausea and vomiting	0.18	0.01	200	3.4 (1.0)	5.4 (2.1)	10.2 (2.4)	11.5 (4.4)
C30 Pain	0.17	0.02	199	19.3 (2.6)	23.3 (3.4)	34.3 (4.4)	30.8 (6.0)
C30 Global health status / QOL	-0.06	0.39	196	67.2 (2.6)	66.2 (2.5)	61.7 (3.1)	63.5 (4.6)
C30 Dyspnoea	0.22	0.002	200	9.4 (2.6)	16.7 (3.3)	14.2 (3.2)	26.9 (5.2)
C30 Insomnia	0.26	<0.001	200	22.9 (3.3)	37.5 (4.7)	54.3 (4.9)	37.2 (7.0)
C30 Appetite loss	0.09	0.23	200	8.9 (2.7)	8.9 (2.8)	18.5 (4.3)	10.3 (4.8)
C30 Constipation	0.11	0.13	200	14.6 (3.4)	13.1 (2.9)	17.9 (3.7)	19.2 (5.0)
C30 Diarrhoea	0.22	0.002	193	2.8 (1.4)	8.6 (3.2)	10.7 (2.8)	14.1 (5.3)
C30 Financial difficulties	0.15	0.03	196	12.0 (3.0)	15.8 (3.4)	25.3 (4.4)	21.8 (7.1)
BR23 Body image	-0.34	<0.001	195	78.8 (3.3)	74.4 (3.3)	53.8 (4.4)	60.3 (5.5)
BR23 Sexual functioning	-0.01	0.87	177	21.5 (3.2)	15.4 (2.4)	18.8 (3.2)	24.3 (5.9)
BR23 Sexual enjoyment	-0.05	0.69	68	57.3 (5.3)	47.1 (5.8)	47.1 (7.6)	59.3 (10.8)
BR23 Future perspective	0.01	0.95	195	41.9 (4.1)	51.2 (4.5)	43.4 (4.7)	42.3 (6.6)
BR23 Systemic therapy side effects	0.32	<0.001	197	14.0 (1.6)	18.7 (1.7)	23.8 (2.2)	30.8 (4.8)
BR23 Breast symptoms	0.19	0.007	197	15.8 (1.9)	20.9 (2.4)	29.6 (3.2)	21.5 (3.8)
BR23 Arm symptoms	0.26	<0.001	197	13.1 (2.0)	16.9 (2.4)	23.5 (3.8)	32.9 (5.5)
BR23 Upset by hair loss	0.41	0.001	62	15.8 (5.3)	64.4 (10.0)	62.2 (9.1)	56.4 (8.8)

* Spearman correlation coefficient between the number of PCI Body image related items selected (range 0-9) and the EORTC scores
SE: Standard Error of mean

Table 23 (Chapter 8): Clinical/personal characteristics of patients in the two cohorts of the study

		Cohort 1 N=24	Cohort 2 N=29	P value*
Age	Mean (SD) Age	59 (17)	62 (15)	0.58
	Age ≥75 years	33% (8)	45% (13)	0.41
IMD deprivation: living in area that	Living in area described as one of IMD most 20% deprived	33% (8)	24% (7)	0.55
Year of most recent diagnosis	2008/2009	54% (13)	34% (10)	
	2010	21% (5)	24% (7)	0.25
	2011	13% (3)	34% (10)	using actual
	2012/2013	13% (3)	7% (2)	Year
Overall tumour staging	Tis (0)	13% (3)	14% (4)	
	1	38% (9)	38% (11)	0.96
	2	46% (11)	41% (12)	
	3	4% (1)	7% (2)	
Treatment	Chemotherapy	25% (6)	18% (5/28)	0.74
	Radiotherapy	58% (14)	50% (14/28)	0.59
	Wide local excision	46% (11)	36% (10/28)	0.57
	Mastectomy	33% (8)	29% (8/28)	0.77
	Reconstructive surgery	8% (2)	4% (1/28)	0.59
	Anti-oestrogen therapy**	58% (14)	79% (22/28)	0.14
	Other treatment: **	17% (4)	0% (0/28)	0.04

*****Fishers exact test apart from two-sample t test (to compare ages) and Mann-Whitney test (year of diagnosis and tumour staging)

** Anti-oestrogen therapy included: tamoxifen, letrozole, anastrozole (ARIMIDEX), aromasin, arimidex, exemestane;

Other treatment included :Herceptin, lepatinib, trastuzumab, neratinib.

Table 24 (Chapter 8): Results of the consultation questionnaire, by study cohort

1	To what extent was your main problem(s) discussed today?		Completely	Mostly	A little	Not at all	P value
		Cohort 1	67% (16)	29% (7)	4% (1)	-	
		Cohort 2	34% (10)	55% (16)	7% (2)	3% (1)	0.02
2	How satisfied were you with the discussion of your problem(s)?		Very satisfied	Satisfied	Somewhat satisfied	Not satisfied	
		Cohort 1	54% (13)	42% (10)	-	4% (1)	
		Cohort 2	34% (10)	45% (13)	21% (6)	-	0.08
3	To what extent did the doctor listen to what you had to say?		Completely	Mostly	A little	Not at all	
		Cohort 1	58% (14)	38% (9)	4% (1)	-	
		Cohort 2	62% (18)	38% (11)	-	-	0.70
4	To what extent did the doctor explain your problem(s) to you?		Completely	Mostly	A little	Not at all	
		Cohort 1	58% (14)	38% (9)	4% (1)	-	
		Cohort 2	38% (11)	45% (13)	14% (4)	3% (1)	0.09
5	To what extent did you and the doctor discuss your respective roles? (Who is responsible for making decisions and who is responsible for what aspects of your care?)		Completely	Mostly	A little	Not discussed	
		Cohort 1	38% (9)	17% (4)	4% (1)	42% (10)	
		Cohort 2	18% (5)	18% (5)	11% (3)	54% (15)	0.40
6	To what extent did the doctor explain treatment?		Very well	Well	Somewhat	Not at all	
		Cohort 1	46% (11)	50% (12)	4% (1)	-	
		Cohort 2	28% (8)	55% (16)	17% (5)	-	0.09
7	To what extent did the doctor explore how manageable this (treatment) would be for you? He/she explored this…		Completely	Mostly	A little	Not at all	
		Cohort 1	58% (14)	33% (8)	8% (2)	-	
		Cohort 2	24% (7)	59% (17)	10% (3)	7% (2)	0.02
8	How well do you think your doctor understood you today?		Very well	Well	Somewhat	Not at all	
		Cohort 1	50% (12)	50% (12)	-	-	
		Cohort 2	38% (11)	62% (18)	-	-	0.38
9	To what extent did the doctor discuss personal or family issues that might affect your health?		Completely	Mostly	A little	Not at all	
		Cohort 1	25% (6)	29% (7)	13% (3)	33% (8)	
		Cohort 2	34% (10)	41% (12)	7% (2)	17% (5)	0.16

P Value from Mann-Whitney test comparing Cohort 1 (no PCI) and Cohort 2 (with PCI) patients in distribution of responses to ordinal questions, except for the chi-squared test for question 5.

Table 25 (Chapter 8): PCI items / health professionals selected by the 29 patients in Cohort 2 of the study

	%	Patients
GENERAL INFORMATION		
B11 Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)	3	1
B12 Information about Breast Cancer	10	3
B13 Information about personal hygiene	-	-
B14 Lifestyle (Smoking/ alcohol-started or unable to stop)	-	-
B15 Complementary /Homeopathic Medicines (Problems with or unable to get information about)	-	-
B16 Fertility issues following treatment (Problems with or unable to get information about)	-	-
BODY IMAGE RELATED		
B21 Appearance (Overall physical appearance)	-	-
B22 Arm appearance	-	-
B23 Breast appearance	21	6
B24 Breast Prosthesis / Padding	3	1
B25 Hair loss	7	2
B26 Hair replacement (wig)	-	-
B27 Weight (Unable to control my weight)	7	2
B28 Wound healing (Scar appearance)	-	-
B29 Mastectomy appearance	3	1
PHYSICAL FUNCTIONING AND HEALTH RELATED		
B31 Appetite	7	2
B32 Arm swelling (Lymphoedema)	7	2
B33 Diarrhoea	-	-
B34 Constipation	-	-
B35 Breast texture	10	3
B36 Breast sensitivity /Breast pain	3	1
B37 Cancer Treatment	7	2
B38 Sore mouth / Dry Mouth	-	-
B39 Fatigue / Tiredness (Low energy levels)	7	2
B310 Indigestion	3	1
B311 Memory/ Concentration	3	1
B312 Nausea/ Vomiting / Sickness	14	4
B313 Pain in the Breast	14	4
B314 Pain in the arm or shoulder	10	3
B315 Pain elsewhere	14	4
B316 Sleeping	10	3
B317 Swallowing	-	-
B318 Taste	-	-
B320 Hot Flushes	10	3
PSYCHOLOGICAL STATE AND EMOTIONAL WELLBEING		
B41 Angry (why me? Why this treatment)	-	-
B42 Anxiety (Related to the diagnosis or treatment)	38	11
B43 Coping (coping with the disease, the treatment, the side effects of treatment)	10	3
B44 Depression	7	2
B45 Fear of Cancer coming back	28	8
B46 Fear of Cancer spreading	14	4
B47 Mood	7	2
B48 Self esteem	-	-
B49 Temperament and personality	3	1
B410 Fear about the future	48	14

SEXUAL FUNCTIONING		
B51 Intimacy	-	-
B52 Relationships	-	-
B53 Sex	-	-
SOCIAL FUNCTIONING / FAMILY RELATED		
B61 Financial issues	-	-
B62 Home care / district nurse support	-	-
B63 Mobility	-	-
B64 Spiritual / Religious aspects	-	-
B65 Support for my family	-	-
B66 Worried about the future of my children	-	-
B67 Unable to go out and enjoy my family	3	1
B68 Unable to go to go to work	-	-
HEALTH PROFESSIONALS		
R1 Breast surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)	100	29
R2 Plastic surgeon (This doctor performs your breast reconstruction)	10	3
R3 Medical oncologist (This specialist administers anticancer drugs or chemotherapy)	-	-
R4 Radiation oncologist (He or she administers radiation therapy)	-	-
R5 Breast Care Nurse	3	1
R6 Chaplain	-	-
R7 Clinical psychologist (He or she may help with anxiety /depression)	3	1
R8 Dietician	3	1
R9 Lymphoedema specialist /clinic	3	1
R10 Hair prosthesis (wig advisor) / Breast prosthesis expert	-	-
R11 Nurse Practitioner (Person that removed fluid from my operation site)	-	-
R12 Pain specialist	-	-
R13 District Nurse	-	-
R14 General Practitioner	3	1
R15 Complementary therapies	3	1
R16 Physiotherapist	-	-

Table 26 (Chapter 8): Number of items selected from PCI domains by the 29 patients in cohort 2 of the study

	Median	IQR	Range	≥ 1 item	≥ 3 items	Total items
General information (6 items)	0	0-0	0-2	10% (3)	-	4
Body image related (9 items)	0	0-1	0-2	31% (9)	-	12
Physical functioning and health-related (19 items)	1	0-2	0-6	62% (18)	14% (4)	35
Psychological state and emotional wellbeing (10 items)	1	0-3	0-6	59% (17)	24% (7)	45
Sexual functioning (3 items)	0	0-0	0-0	-	-	0
Social functioning / family related (8 items)	0	0-0	0-1	3% (1)	-	1
Total: PCI (55 items)	2	2-4	1-17	100% (29)	41% (12)	97
Total: Health professional staff (16 items)	1	1-2	1-2	100% (29)	-	38

Table 27 (Chapter 8): Items selected in detail in cohorts 1 and 2 and during consultation

	Cohort 1: during consultation (N=24) %	Cohort 2: during consultation (N=29) %	Cohort 2: PCI (N=29) %
B11 Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)	17	14	3
B12 Information about Breast Cancer	25	3	10
B13 Information about personal hygiene	0	0	0
B14 Lifestyle (Smoking/ alcohol-started or unable to stop)	4	0	0
B15 Complementary /Homeopathic Medicines (Problems with or unable to get information about)	17	17	0
B16 Fertility issues following treatment (Problems with or unable to get information about)	0	0	0
B21 Appearance (Overall physical appearance)	0	0	0
B22 Arm appearance	0	0	0
B23 Breast appearance	50	31	21
B24 Breast Prosthesis / Padding	13	10	3
B25 Hair loss	0	3	7
B26 Hair replacement (wig)	0	0	0
B27 Weight (Unable to control my weight)	13	3	7
B28 Wound healing (Scar appearance)	29	24	0
B29 Mastectomy appearance	0	0	3
B31 Appetite	4	0	7
B32 Arm swelling (Lymphoedema)	8	3	7
B33 Diarrhoea	0	0	0
B34 Constipation	0	0	0
B35 Breast texture	21	10	10
B36 Breast sensitivity /Breast pain	13	10	3
B37 Cancer Treatment	8	0	7
B38 Sore mouth / Dry Mouth	4	0	0
B39 Fatigue / Tiredness (Low energy levels)	29	3	7
B310 Indigestion	0	0	3
B311 Memory/ Concentration	0	0	3
B312 Nausea/ Vomiting / Sickness	13	3	14
B313 Pain in the Breast	8	10	14
B314 Pain in the arm or shoulder	0	0	10
B315 Pain elsewhere	25	21	14
B316 Sleeping	17	7	10
B317 Swallowing	0	0	0
B318 Taste	0	0	0
B320 Hot Flushes	29	14	10
B41 Angry (why me? Why this treatment)	4	21	0
B42 Anxiety (Related to the diagnosis or treatment)	46	48	38
B43 Coping (coping with the disease, the treatment, the side effects of treatment)	21	0	10
B44 Depression	17	7	7

B45 Fear of Cancer coming back	8	7	28
B46 Fear of Cancer spreading	8	3	14
B47 Mood	4	3	7
B48 Self esteem	8	0	0
B49 Temperament and personality	8	0	3
B410 Fear about the future	4	21	48
B51 Intimacy	0	0	0
B52 Relationships	0	0	0
B53 Sex	0	0	0
B61 Financial issues	0	0	0
B62 Home care / district nurse support	0	0	0
B63 Mobility	0	0	0
B64 Spiritual / Religious aspects	4	0	0
B65 Support for my family	0	0	0
B66 Worried about the future of my children	4	0	0
B67 Unable to go out and enjoy my family	0	0	3
B68 Unable to go to go to work	4	0	0

Table 28 (Chapter 8): Consultation duration in minutes. The first 24 patients are before the introduction of the PCI, and just the use of the consultation satisfaction scale. The rest involve the use of the PCI with the consultation satisfaction scale.

Patient number	Duration (mins)
Cohort 1	
1	**7.36**
2	**19.99**
3	**7.87**
4	**5.18**
5	**8.88**
6	**22.89**
7	**26.65**
8	**28.19**
9	**11.88**
10	**7.58**
11	**9.27**
12	**7.31**
13	**8.16**
14	**20.83**
15	**11.16**
16	**11.76**
17	**4.45**
18	**7.66**
19	**19.99**
20	**20.59**
21	**19.52**
22	**14.24**
23	**11.18**
24	**11.32**
Mean	**13.50 minutes**
Cohort 2	
25	**10.0**
26	**4.3**
27	**4.0**
28	**8.8**
29	**9.85**

30	**5.21**
31	**6.95**
32	**7.32**
33	**7.54**
34	**5.38**
35	**8.3**
36	**6.15**
37	**10.55**
38	**18.3**
39	**17.2**
40	**8.85**
41	**28.01**
42	**14.7**
43	**14.55**
44	**10.1**
45	**12.01**
46	**6.15**
47	**7.59**
48	**28.87**
49	**6.05**
50	**7.61**
51	**22.83**
52	**19.2**
53	**21.33**
Mean	**11.6 minutes**

Table 29 (Chapter 8): Mean , median and interquartile range of the cconsultation duration (based on the data from Table 28).

	Number of patients	Median	Interquartile range (IQR)	Mean	Standard Deviation (SD)
Cohort 1	**24**	**11.3**	**7.7-20.0**	**13.5**	**7.0**
Cohort 2	**29**	**8.9**	**6.6-16.9**	**11.6**	**6.9**

Mean-Whitney test P=0.21

APPENDIX SECTION 2: SUPPLEMENTAL STUDY MATERIAL (LETTERS, FORMS AND OTHER DOCUMENTS)

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Appendix 2-A -Clinical staff Consent Form for audio recording of semi structured interviews

Study Title: Development of a breast cancer specific Patients Concerns Inventory (PCI)

This is an observational study involving

· Audio-recordings of consultations

.....

· I agree to participate in this study

· I give my permission for the researchers to audio-tape the consultation

· I have read the Information Sheet and this consent form and have had the opportunity to ask questions about them

· I understand that the information collected during the study will be treated strictly confidentially. None of the data collected during the study will ever be given to a third party or used for any other purposes except the analysis of this project.

· I am happy for the contribution I have already made to be used in the analysis if I choose to withdraw from the study

Name of Clinician.....

Signature of Clinician:.....

Signature of Researcher:.....

Date:.....

If you would like any further information, want to see the full protocol or have any comments, please contact Mr A Kanatas

Tel:07769946105 e-mail:a.kanatas@doctors.org.uk

Galina Velikova, Professor of Psychosocial and Medical Oncology

/Consultant Medical Oncology, Level 4, Bexley Wing, St James's Institute of Oncology, St James's Hospital, Beckett street, Leeds LS9 7TF, UK. Tel: +44 113 2067917 Fax: +44 113 2068512 e-mail: g.velikova@leeds.ac.uk

Appendix 2-B-Questions to clinicians

The following questions will be asked to the clinicians:

1. What are the common problems that patients needs advice/support one year post diagnosis

3. What are the common problems that patients need advice /support with after the first year and up to three years post diagnosis?

4. What concerns do you think may be missed during a consultation?

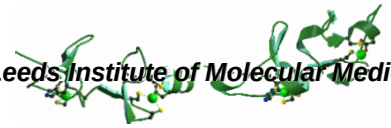
5. What specialists are available to provide support in the MDT?

6. What is their role?

7. What specialist clinics are there for breast cancer patients?

Appendix 2-C -Study information Phase 1

The Leeds Teaching Hospitals NHS
NHS Trust



Institute of Oncology

We would like to invite you to take part in a RESEARCH study that will involve the formation of a group of 8-10 people. Once a group is formed it would involve a meeting at a convenient time for all the members of the group. During the meeting we would ask you questions about problems you experienced after your diagnosis and treatment. The meeting would involve non-identifiable audio recordings.Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves. Please take time to read the following information carefully. Talk to others about the study if you wish, and ask the researcher if you have any questions at all.

Purpose of the study

The aim of the study is to gain an understanding of standard practice in oncology with respect to how patients discuss problems with their doctor and how decisions are being made. This is needed for the following reason:

- In the near future we will aim to introduce a new approach to detecting patient problems, by asking patients to respond to brief questionnaires on touch-screen computers and giving this to their doctors. This initial period of assessment will provide the research team with information that will be used for the development of the brief questionnaire.

Why have I been chosen?

We are inviting patients who had treatment for breast cancer and are between one year and three years post diagnosis. We are hoping to recruit about 40 patients for this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep. Then you will be asked to sign a consent form. Even after signing the consent form, you are free to decide not to take part and you do not have to give us a reason for doing so. A decision not to take part will not affect the standard of medical care you receive.

If you prefer not to take part in the study, we would like to ask for your permission to keep a record of your initials, age, gender and diagnosis for the purposes of the study, so that we know who we have approached.

What is involved?

Once 8-10 people agree to participate, on your next clinic appointment we will approach you again and give you details about a meeting. During this meeting all the patients invited would be in a room together. We would start by introducing out first names only. This meeting would be audio recorded in order for us to be able to process the information. Then we would ask you to tell us about specific problems that you experienced after your diagnosis and treatment. Then we would give you a list of problems that people may experience and we would appreciate your opinion about the frequency of these problems.

Will my taking part in this study be kept confidential?

All information is confidential. The recordings will be kept securely and will only be available to the research team. It will not be shared with the clinical team looking after you. Any analysis or publication of results will not name or identify individual patients.

What are the possible benefits of taking part?

We hope the information you provide will contribute to improving the support we can offer patients in the future and been able to identify specific problems at every consultation.

Thank you for taking the time to read this information sheet and consider this study.

Would you inform my Family Doctor?

Once we have your consent to participate in the study we will send a letter to your doctor. We would do this to ensure that at all times there would be support for you if you need it.

If at any point you have questions or concerns regarding this study, please contact

the researchers below:

1. **Mr A Kanatas** Tel:07769946105

Specialist Registrar

e-mail:a.kanatas@doctors.org.uk

2. **Galina Velikova** BMBS(MD) PhD FRCP

Professor of Psychosocial and Medical Oncology

/Consultant Medical Oncology

Level 4, Bexley Wing; St James's Institute of Oncology; St James's Hospital; Beckett street; Leeds LS9 7TF, UK; Tel: +44 113 2067917; Fax: +44 113 2068512; e-mail: g.velikova@leeds.ac.uk

Appendix 2-D – Patient Consent Form for the Focus Groups.

The Leeds Teaching Hospitals NHS Trust

Centre Number:
Patient Identification Number for this trial:

Patient Initials:

Title of Project: Further Development of The Patients Concerns Inventory (PCI) to help reveal patients concerns in Head and Neck and Breast Oncology clinics

Name of Researcher: A Kanatas

Please tick to confirm

- I confirm that I have read and understand the information sheet dated .....) for the above study. • □
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. • □
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical or legal rights being affected. • □
- I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the NHS, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. • □
- I agree to my GP being informed of my participation in the study. □ •
- I agree to take part in the above research study**, and I agree for the interview to be recorded** • □
- I give permission for anonymised direct quotes to be included in a written report and publications □ •
- I give permission to the research team to contact me with relation to the study □

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Researcher	Date	Signature

When complete, 1 copy for patient: 1 (original) to be kept in medical notes.

Appendix 2-E: Study reply slip

The Leeds Teaching Hospitals NHS Trust

Leeds Institute of Molecular Medicine

Title of project: **Development of a breast cancer specific Patients Concerns Inventory (PCI)**

Please read the statements below and tick the one that applies to you:

I do not wish to take part in this study □

I am interested in taking part in this study and would be happy to speak to researchers again at my next clinic appointment □

Name

Date

Which clinic are you currently attending?

Breast clinic

(Monday morning) □

Please use the freepost envelope provided to return completed forms to:

Anastasios Kanatas
Psychosocial Oncology and Clinical Practice Research Group
St James's Institute of Oncology
Level 3, Bexley Wing
Beckett StreetLeeds, LS9 7TF If you have any queries please contact Anastasios Kanatas
Tel:07769946105 e-mail:a.kanatas@doctors.org.uk

Appendix 2-F: EORTC 30 and - BR23 module

EORTC QLQ-C30 (version 3)

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

Please fill in your initials: _____

Your birthdate (Day, Month, Year): _____

Today's date (Day, Month, Year): 31 _____

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

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?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle 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

EORTC QLQ - BR23

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	Not at All	A Little	Quite a Bit	Very Much
31. Did you have a dry mouth?	1	2	3	4
32. Did food and drink taste different than usual?	1	2	3	4
33. Were your eyes painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	1	2	3	4
36. Did you feel ill or unwell?	1	2	3	4
37. Did you have hot flushes?	1	2	3	4
38. Did you have headaches?	1	2	3	4
39. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
40. Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
41. Did you find it difficult to look at yourself naked?	1	2	3	4
42. Have you been dissatisfied with your body?	1	2	3	4
43. Were you worried about your health in the future?	1	2	3	4

During the past <u>four</u> weeks:	Not at All	A Little	Quite a Bit	Very Much
44. To what extent were you interested in sex?	1	2	3	4
45. To what extent were you sexually active? (with or without intercourse)	1	2	3	4
46. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
47. Did you have any pain in your arm or shoulder?	1	2	3	4
48. Did you have a swollen arm or hand?	1	2	3	4
49. Was it difficult to raise your arm or to move it sideways?	1	2	3	4
50. Have you had any pain in the area of your affected breast?	1	2	3	4
51. Was the area of your affected breast swollen?	1	2	3	4
52. Was the area of your affected breast oversensitive?	1	2	3	4
53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	1	2	3	4

Appendix 2- G: Patient Information Sheet

The Leeds Teaching Hospitals NHS
NHS Trust

Leeds Institute of Molecular Medicine

Institute of Oncology

We would like to invite you to take part in a RESEARCH study that will involve the completion of two questionnaires. We will also ask you to complete two questionnaires and return them in the SAE provided. Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves. Please take time to read the following information carefully. Talk to others about the study if you wish, and ask the researcher if you have any questions at all.

Purpose of the study

The aim of the study is to gain an understanding of standard practice in oncology with respect to how patients discuss problems with their doctor and how decisions are being made. This is needed for several reasons:

1) In the near future we will aim to introduce a new approach to detecting patient problems, by asking patients to respond to brief questionnaires on touch-screen computers and giving this to their doctors. This initial period of assessment will provide the research team with information that will be used for the development of the brief questionnaire.

3) The information from the consultations and the questionnaires will help to develop and individualise the consultation to the specific patient needs.

Why have I been chosen?

We are inviting patients who had treatment for breast cancer and are between one year and three years post diagnosis. We are hoping to recruit about 200 patients for this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep. Then you will be asked to sign a consent form. Even after signing the consent form, you are free to decide not to take part and you do not have to give us a reason for doing so. A decision not to take part will not affect the standard of medical care you receive.

If you prefer not to take part in the study, we would like to ask for your permission to keep a record of your initials, age, gender and diagnosis for the purposes of the study, so that we know who we have approached.

What is involved?

If you agree to take part in the study, please complete the two questionnaires provided.The questionnaires cover issues relating to doctor-patient communication, and those such as symptoms, emotions, coping, and family life. You are not obliged to answer any question that you are not comfortable with. Questionnaires should take no longer than 20 minutes to complete in total, and you can either complete them before you leave the clinic or take them home to complete and return in a pre-paid addressed envelope.

When would I take part?

Please take the time to read all the information provided and if you wish discuss with the researchers, clinic staff and your carer(s).

If you decide you would like to take part in this study, please inform the researcher present in clinic. You will be asked to read and sign the consent form (a copy is shown overleaf).

You can keep this information sheet and a copy of the signed consent form.

Will my taking part in this study be kept confidential?

All information from the questionnaires is confidential. The questionnaire data will be kept securely and will only be available to the research team. It will not be shared with the clinical team looking after you. Any analysis or publication of results will not name or identify individual patients. We will ask for your permission to look at your medical records for information about the treatment you are receiving and for details of your disease condition. All information that we collect during the study will be kept anonymous and confidential.

What are the possible benefits of taking part?

We hope the information you provide will contribute to improving the support we can offer patients in the future and been able to identify specific problems at every consultation.

Would you inform my Family Doctor?

Once we have your consent to participate in the study we will send a letter to your doctor. We would do this to ensure that at all times there would be support for you if you need it.

Thank you for taking the time to read this information sheet and consider this study.

If at any point you have questions or concerns regarding this study, please contact

the researchers below:

1).**Mr A Kanatas** Tel:07769946105

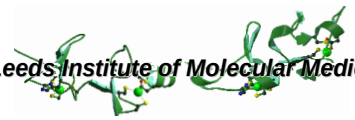
e-mail:a.kanatas@doctors.org.uk

2).**Galina Velikova,** Professor of Psychosocial and Medical Oncology

/Consultant Medical Oncology, Level 4, Bexley Wing, St James's Institute of Oncology, St James's Hospital, Beckett street, Leeds LS9 7TF, UK. Tel: +44 113 2067917 Fax: +44 113 2068512 e-mail: g.velikova@leeds.ac.uk

Appendix 2- H: Patient Consent Form for the Cross-Sectional Study

The Leeds Teaching Hospitals NHS
NHS Trust



Centre Number:
Patient Identification Number for this trial:

Title of Project: Further Development of The Patients Concerns Inventory (PCI) to help reveal patients concerns in Head and Neck and Breast Oncology clinics

Name of Researcher: A Kanatas

Please tick to confirm

- I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study. □ •
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. □ •
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical or legal rights being affected. □ •
- I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from the NHS, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. □ •
- I agree to my GP being informed of my participation in the study. □ •
- I agree to take part in the above research study □ •
- I give permission for anonymised direct quotes to be included in a written report and publications □ •
- I give permission to the research team to contact me with relation to the study □

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Researcher	Date	Signature

When complete, 1 copy for patient: 1 (original) to be kept in medical notes.

Appendix 2- I: Study reply slip

The Leeds Teaching Hospitals NHS Trust

Leeds Institute of Molecular Medicine

Title of project: **Development of a breast cancer specific Patients Concerns Inventory (PCI)**

Please read the statements below and tick the one that applies to you:

I do not wish to take part in this study □

I am interested in taking part in this study and would be happy to speak to researchers again at my next clinic appointment □

Name

Date

Which clinic are you currently attending?

Breast clinic

(Monday morning) □

Please use the freepost envelope provided to return completed forms to:

Anastasios Kanatas
Psychosocial Oncology and Clinical Practice Research Group
St James's Institute of Oncology
Level 3, Bexley Wing
Beckett StreetLeeds, LS9 7TF

If you have any queries please contact Anastasios Kanatas
Tel:07769946105 e-mail:a.kanatas@doctors.org.uk

Appendix 2-J : -Letter to GP

The Leeds Teaching Hospitals NHS
NHS Trust

Leeds Institute of Molecular Medicine

AAnastasios Kanatas, BSc (Hons), BDS, MBChB (Hons), MFDSRCS, MRCSRCS, PhD, PGC. Specialty Registrar, Leeds Teaching Hospitals and St James Institute of Oncology

a.kanatas@doctors.org.uk

Tel: 07769946105

Dear Mr....

RE:NAME OF PATIENT

Date of Birth

Address

This is to inform you that the above patient has agreed to participate in the Questionnaire study with a title: Development of a breast cancer specific Patients Concerns Inventory (PCI).

This study is carried out by Mr A Kanatas (Specialist Registrar) under the supervision of Prof Galina Velikova and Mr Kieran Horgan in Leeds General Infirmary.

For further information please do not hesitate to contact us.

Yours sincerely

A Kanatas

Appendix 2- K: Form Collecting Socio-demographic data

Date of birth:

Post-code:

Hospital:

Appendix 2-L: Clinical Background information

A. Background

AGE:

POSTCODE:

B. Clinical information

Diagnosis:

Stage (TNM or cancer site-specific staging):

Extent of disease:

1. Primary local □

2.Local recurrent □

3.Metastatic □

4.Disease free □

Treatment :

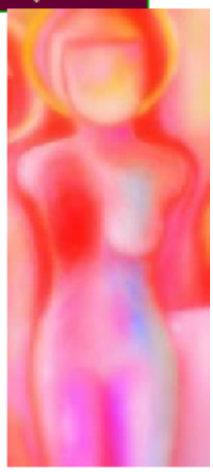
Chemotherapy □

Radiotherapy □

Surgery □

Appendix 2-M: Information leaflet that was included in the information pack

Development of a breast cancer specific Patients Concerns Inventory (PCI)



Breast Cancer Support Centres

We would like to invite you to take part in a **RESEARCH** study that will involve the completion of a questionnaire **(PINK PAPER)**. We will ask you to complete the questionnaire, which will take about 2 minutes, and return it in the **SAE** provided. This study is held in the **St James's Institute of Oncology in Leeds**.

Purpose of the study
The aim of the study is to gain an understanding of standard practice in oncology with respect to how patients discuss issues with their doctor and how decisions are being made.

Why have I been chosen?
We will welcome the contribution of all the National bodies and centres with significant and specific expertise towards the management of patients with breast cancer.

Will my taking part in this study be kept confidential?
All information from the questionnaires will be kept confidential. The questionnaire data will be kept securely and will only be available to the research team.

What are the possible benefits of taking part?
We hope the information you provide will contribute to improving the support we can offer patients in the future and enable us to identify specific problems during consultations.

If at any point you have questions or concerns regarding this study, please contact the researchers below:

1).**Mr A Kanatas** Tel:07769946105
e-mail:a.kanatas@doctors.org.uk

2).**Galina Velikova,** Professor of Psychosocial and Medical Oncology
Consultant Medical Oncology, Level 4, Bexley Wing, St James's Institute of Oncology, St James's Hospital, Beckett street, Leeds LS9 7TF, UK. Tel: +44 113 2067917 Fax: +44 113 2068512 e-mail: g.velikova@leeds.ac.uk

Thank You very much for your help

Appendix 2-N: Breast specific Patient Concerns Inventory

Breast Cancer Specific Patients Concern Inventory-56 items

Patients who have had breast cancer usually report issues in the following areas. If you were to attend a clinical consultation today which of the following issues would you wish to discuss with your Breast specialist

1. **General Information**

- □ Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)
- □ Information about Breast Cancer (Unable to get or unable to understand)
- □ Information about personal hygiene (May be related to breast prosthesis or wig)
- □ Lifestyle (Smoking/ alcohol-started or unable to stop)
- □ Complementary /Homeopathic Medicines (Problems with or unable to get information about)
- □ Fertility issues following treatment (Problems with or unable to get information about)

2. **Body Image-related**

- □ Appearance (Overall physical appearance)
- □ Arm appearance
- □ Breast appearance
- □ Breast Prosthesis / Padding
- □ Hair loss
- □ Hair replacement (wig)
- □ Weight (Unable to control my weight)
- □ Wound healing (Scar appearance)
- □ Mastectomy appearance

3. **Physical Functioning and health-related**

- □ Appetite
- □ Arm swelling (Lymphoedema)
- □ Diarrhoea
- □ Constipation
- □ Breast texture
- □ Breast sensitivity /Breast pain
- □ Cancer Treatment
- □ Sore mouth / Dry Mouth

- □ Fatigue / Tiredness (Low energy levels overall)
- □ Indigestion
- □ Memory/ Concentration
- □ Nausea
- □ Pain in the Breast
- □ Pain in the arm or shoulder
- □ Pain elsewhere
- □ Sleeping
- □ Swallowing
- □ Taste
- □ Vomiting / Sickness
- □ Hot Flushes

4. Psychological state and emotional well being-related

- □ Angry (why me?, why this treatment)
- □ Anxiety (Related to the diagnosis or treatment)
- □ Coping (coping with the disease, the treatment or the side effects of treatment)
- □ Depression
- □ Fear of Cancer coming back
- □ Fear of Cancer spreading
- □ Mood
- □ Self esteem
- □ Temperament and personality
- □ Fear about the future

5. Sexual Functioning

- □ Intimacy
- □ Relationships
- □ Sex

6. Social Functioning/ Family-related

- □ Financial issues
- □ Home care / district nurse support
- □ Mobility
- □ Spiritual / Religious aspects
- □ Support for my family

□ Worried about the future of my children

□ Unable to go out and enjoy my family

□ Unable to go to go to work

7. □ **Other, please state**

.....

Referral Options at consultation:

If you were to attend a clinical consultation today which of the following members of staff would you like to see or be referred on to:

□ Breast surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)

□ Plastic surgeon (This doctor performs your breast reconstruction)

□ Medical oncologist (This specialist administers anticancer drugs or chemotherapy)

□ Radiation oncologist (He or she administers radiation therapy)

□ Breast Care Nurse

□ Chaplain

□ Psychologist (He or she may help with anxiety /depression)

□ Dietician

□ Lymphoedema specialist /clinic

□ Hair prosthesis (wig advisor) / Breast prosthesis expert

□ Nurse Practitioner (Person that removed fluid from my operation site)

□ Pain specialist

□ District Nurse

□ My own doctor (General Practitioner)

□ Complementary therapies

Appendix 2-O: Breast cancer specific patient concerns inventory following formatting to be consistent with the Head and Neck PCI

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Breast Cancer

Patient Concerns Inventory

Please choose from the list of issues you would specifically like to talk about in your consultation in clinic today. You can choose more than one option: (Tick the box ☑)

GENERAL INFORMATION	
Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)	
Complementary / Homeopathic Medicines (Problems with or unable to get information about)	
Fertility issues following treatment (Problems with or unable to get information about)	
Lifestyle (Smoking / Alcohol-started or unable to stop)	
Information about Breast cancer	
Information about personal hygiene	

BODY IMAGE-RELATED	
Appearance (Overall physical appearance)	
Arm appearance	
Breast appearance	
Breast prosthesis / Padding	
Hair loss	
Hair replacement (wig)	
Mastectomy appearance	
Weight (Unable to control my weight)	
Wound healing (Scar appearance)	

PHYSICAL FUNCTIONING AND HEALTH-RELATED	
Appetite	
Arm swelling (Lymphoedema)	
Breast texture	
Breast sensitivity /Breast pain	
Cancer treatment	
Constipation	
Diarrhoea	
Fatigue / Tiredness (Low energy levels)	
Hot flushes	
Indigestion	
Memory / Concentration	
Nausea/ Vomiting / Sickness	
Pain in the breast	
Pain in the arm or shoulder	
Pain elsewhere	
Sleeping	
Sore mouth / Dry mouth	
Swallowing	
Taste	

PSYCHOLOGICAL STATE AND EMOTIONAL WELL BEING	
Angry (Why me? Why this treatment?)	
Anxiety (Related to the diagnosis or treatment)	
Coping (with the disease, the treatment, the side effects of treatment)	
Depression	
Fear about the future	
Fear of cancer coming back	
Fear of cancer spreading	
Mood	
Self esteem	
Temperament and personality	

SEXUAL FUNCTIONING	
Intimacy	
Relationships	
Sex	

SOCIAL FUNCTIONING / FAMILY-RELATED	
Financial issues	
Home care / district nurse support	
Mobility	
Spiritual / Religious aspects	
Support for my family	
Unable to go out and enjoy my family	
Unable to go to work	
Worried about the future of my family	

OTHER	

More next page ➔

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Breast Cancer
Patient Concerns Inventory

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Tick the box ☑)

TREATMENT-RELATED	
Breast Surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)	
Complementary therapies	
Medical Oncologist (This specialist administers anticancer drugs or chemotherapy)	
Plastic surgeon (This doctor performs your breast reconstruction)	
Radiation oncologist (He or she administers radiation therapy)	
Pain specialist	
Breast care nurse	

PHYSICAL & FUNCTIONAL WELL-BEING	
Dietician	
Lymphoedema specialist / Clinic	
Hair prosthesis wig advisor / Breast prosthesis expert	
Nurse practitioner (Person that removed fluid from my operation site)	
Physiotherapist	

PSYCHOLOGICAL, EMOTIONAL & SPIRITUAL WELL-BEING	
Chaplain	
Clinical psychologist (He or she may help with anxiety / depression)	

SOCIAL CARE & SOCIAL WELL-BEING	
General practitioner	
District Nurse	

OTHERS	

Appendix 2-P: Patient Information Sheet—Revision 1

The Leeds Teaching Hospitals NHS
NHS Trust

Anastasios Kanatas, BSc (Hons), BDS, MBChB (Hons), MFDSRCS, MRCSRCS, PhD, PGC. Specialty Registrar in Surgery, Leeds Teaching Hospitals and St James Institute of Oncology

a.kanatas@doctors.org.uk

Tel:07769946105

Institute of Oncology

We would like to invite you to take part in a RESEARCH study that will involve the completion of a maximum of two questionnaires. Some people will only receive one questionnaire after their consultation with the clinical team whilst other patients will receive one before and a further questionnaire after their consultation. The patients that will agree to take part will be divided into two groups. In the first group patients will complete the questionnaire after their appointment with the clinical team. In the second group patients will be asked to complete a questionnaire before they see their doctor and one just after. The allocation of patients into the two groups will be based on a number randomly generated from a computer program. **Your consultation will be recorded anonymously**. Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves. Please take time to read the following information carefully. Talk to others about the study if you wish, and ask the researcher if you have any questions at all.

What is the purpose of the study?

Treating cancer is still based on three options-surgery, radiotherapy, and chemotherapy. However, these may simply treat the disease, rather than the person. It is recognised that every patient has different issues at different times after a diagnosis of cancer. There can be unmet needs that may be difficult to identify in a busy clinic. There are barriers to an effective patient with cancer and carer consultation. There is reliance on verbal communication but certain patient issues could be considered taboo. The aim of the study is to gain an understanding of standard practice in oncology with respect to how patients discuss problems with their doctor and how decisions are made. This is needed for several reasons:

1) In the near future we will aim to introduce a new approach in detecting patient problems, by asking patients to respond to brief questionnaires on touch-screen computers and giving them to their doctors. This initial period of assessment will provide the research team with information that will be used for the development of the brief questionnaire.

2) The information from the consultations and the questionnaires will help to develop and individualise the consultation to the specific patient needs.

Why have I been invited?

We are inviting patients who have had treatment for breast cancer and are between one year and three years post diagnosis. We are hoping to recruit about 100 patients in this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep. Then you will be asked to sign a consent form. Even after signing the consent form, you are free to decide not to take part and you do not have to give us a reason for doing so. A decision not to take part will not affect the standard of medical care you receive.

What will happen to me if I take part?

All suitable patients will be identified by the treating consultant (Mr Horgan) and the Clinical Nurse Specialists. (CPN). During your routine clinic appointment you will be asked if you would like to participate in this study, starting at the next appointment. This will be at least 4 weeks in advance. If you wish to consider this, you will be given the study information pack by the clinical team. This will include the study details and a consent form. If you wish to take part, the study will take place at your next appointment.

One group will attend for their clinic appointment as normal. Their consultation will be recorded by the principal investigator (Mr Kanatas). After the consultation, they will be asked to fill in a brief questionnaire about their satisfaction with the consultation.

The second group will be asked to complete a questionnaire whilst in the waiting room prior to their clinic appointment. Then they will see their doctor as normal. Their consultation will be recorded. After the consultation they will be asked to fill in a brief questionnaire about their satisfaction with the consultation.

The questionnaires cover issues relating to doctor-patient communication, symptoms, emotions, coping, and family life. You are not obliged to answer any question that you are not comfortable with.

Why will my consultation be audio recorded?

Part of this research will be to develop ways to identify patients with problems when they attend in the clinic. This may be difficult due to the busy nature of out-patient clinics. A large volume of information may be presented during a consultation and in order to ensure accurate collection the most efficient way is to audio record the consultation. Your consultation will be recorded but will be anonymised before analysis. **Also, if you feel uncomfortable at any point you can ask for the recording to be stopped.**

When would I take part?

Please take the time to read all the information provided and if you wish you can discuss with the researchers, clinic staff and your carer(s).

If you decide you would like to take part in this study, please inform the researcher present in clinic. You will be asked to read and sign the consent form (a copy is shown overleaf).

You can keep this information sheet and a copy of the signed consent form.

Will my taking part in this study be kept confidential?

All information from the questionnaires is confidential. The questionnaire data will be kept securely and will only be available to the principal investigator (Mr A Kanatas) and to your Breast Surgeon (Mr Horgan).

What are the possible disadvantages of taking part?

The questionnaires may take about 8 minutes of your time to complete. We have looked at alternative methods but at present this is the best way to collect the information required for this research. Also we will ensure that you will not be disadvantaged with respect to the timing of your appointment or any parking arrangements.

What are the possible benefits of taking part?

We hope the information you provide will contribute to improving the support we can offer patients in the future and be able to identify specific problems at every consultation.

Thank you for taking the time to read this information sheet and consider this study.

If at any point you have questions or concerns regarding this study, please contact

the researchers below:

1).**Mr A Kanatas** Tel:07769946105

e-mail:a.kanatas@doctors.org.uk

2).**Galina Velikova,** Professor of Psychosocial and Medical Oncology

/Consultant Medical Oncology, Level 4, Bexley Wing, St James's Institute of Oncology, St James's Hospital, Beckett street, Leeds LS9 7TF, UK. Tel: +44 113 2067917 Fax: +44 113 2068512 e-mail: g.velikova@leeds.ac.uk

Appendix 2-Q: –Patient Consent Form for focus group-Version 2.1

The Leeds Teaching Hospitals NHS
NHS Trust

Anastasios Kanatas, BSc (Hons), BDS, MBChB (Hons), MFDSRCS, MRCSRCS, PhD, PGC. Specialty Registrar in Surgery, Leeds Teaching Hospitals and St James Institute of Oncology

a.kanatas@doctors.org.uk

Tel:07769946105

Centre Number:

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Further Development of The Patients Concerns Inventory (PCI) to help reveal patients concerns in Breast Oncology clinics

Name of Researcher: A Kanatas

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **08/07/2012** (version **2.1-Revision 1**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that the meeting will be audio recorded. ☐

5. I agree to take part in the above study. ☐

6. I give permission for anonymised direct quotes to be included in a written report and publications. ☐

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

Appendix 2-R: Consultation satisfaction questionnaire

Consultation Questionnaire

Please think about the consultation you had at the oncology clinic today. Look at the questions below and tick a box on each line to indicate your response.

1. To what extent was your main problem(s) discussed today?

   Completely □ Mostly □ A little □ Not at all □

2. How satisfied were you with the discussion of your problem(s)?

   Very satisfied □ Satisfied □ Somewhat satisfied □ Not satisfied □

3. To what extent did the doctor listen to what you had to say?

   Completely □ Mostly □ A little □ Not at all □

4. To what extent did the doctor explain your problem(s) to you?

   Completely □ Mostly □ A little □ Not at all □

5. To what extent did you and the doctor discuss your respective roles? (Who is responsible for making decisions and who is responsible for what aspects of your care?)

   Completely □ Mostly □ A little □ Not discussed □

6. To what extent did the doctor explain treatment?

   Very well □ Well □ Somewhat □ Not at all □

7. To what extent did the doctor explore how manageable this (treatment) would be for you? He/she explored this…

   Completely □ Mostly □ A little □ Not at all □

8. How well do you think your doctor understood you today?

   Very well □ Well □ Somewhat □ Not at all □

9. To what extent did the doctor discuss personal or family issues that might affect your health?

Completely □ Mostly □ A little □ Not at all □

Thank you for completing these questionnaire.

Appendix 2-S: Thematic framework used in the identification of issues from the consultation recordings

ITEM CHECKLIST					
Items of concern	**Phrase/terms used**	**Assessor 1**	**Assessor 2**	**Items missed**	**Item resolved**
GENERAL INFORMATION					
Activity	Information about exercise; unable to do exercise or problems returning to my daily routine / Job/duties/work/travelling/holidays				
Complementary / Homeopathic Medicines	Problems with or unable to get information, reflexology, Relaxation techniques, Acupuncture, Bio-oil, Primore oil, E45				
Fertility issues following treatment	(Problems with or unable to get information about)				
Lifestyle	Smoking / Alcohol-started or unable to stop, dependence, addiction, habit, nicotine patches				
Information about Breast cancer					
Information about personal hygiene	Prosthesis related such as wig /padding				
BODY IMAGE-RELATED					
Appearance (Overall physical appearance	Ugly, disfigurement, 'does not look right'				
Arm appearance	Ugly, disfigurement, 'does not look right'				
Breast appearance	Ugly, disfigurement, 'does not look right'				

Breast Prosthesis / Padding					
Hair Loss					
Hair replacement (wig)					
Mastectomy appearance					
Weight	Unable to control my weight, putting on weight, losing weight, 'fat', 'thin'.				
Wound healing	Scar appearance, infection, scars, dressing				
PHYSICAL FUNCTIONING AND HEALTH-RELATED					
Appetite	Fancy food, desire to eat, hungry, enjoy food				
Arm swelling	Lymphoedema				
Breast texture	Hard, firm, skin feels different				
Breast sensitivity /	Breast pain				
Cancer treatment					
Constipation	Hard stools, difficulties passing stools				
Diarrhoea	Runny stools				
Fatigue / Tiredness	Low energy levels, lethargic, lacking energy, tiredness, exhausted, weary 'creased'				
Hot flushes	Feeling hot, hot sweats				
Indigestion	Acid reflux, heartburn				
Memory / concentration	Forgetfulness, poor memory, absent-minded				
Nausea / Vomiting/ Sickness	Feel ill, poorly, nausea, 'being sick', 'being ill' ,'throw-up'.				

Pain in the breast					
Pain in the arm or shoulder	Stiff shoulder, Can't lift arm				
Pain elsewhere	Pain, sore, ache, discomfort in other parts of the body, joint stiffness				
Sleeping	Insomnia, can't get to sleep, awake at night				
Sore mouth / Dry mouth	Parched mouth				
Swallowing	Food stuck, painful swallowing				
Taste	Can't taste food, food tastes awful / different				
PSYCHOLOGICAL STATE AND EMOTIONAL WELL BEING					
Angry	Annoyed, angry, frustrated, furious, irritated				
Anxiety	Worry, nervous, concern, fear, scared, panic, shock				
Coping	Dealing with issues, putting-up, struggling				
Depression	Feeling down /low, despair, sadness, worthlessness				
Fear about the future	Worry about the future				
Fear of cancer coming back	Worry about the cancer returning				
Fear of cancer spreading	Worry about cancer spreading				
Mood	Mood, loss of motivation, feeling emotional, tearful				
Self-esteem	Emotional assessment of self-worth, attitude toward self, feel a nuisance				

Temperament and personality	Shy, quite, character, pessimistic, feeling emotional				
SEXUAL FUNCTIONING					
Intimacy					
Relationships	Connected, lonely, isolation				
Sex	Sex drive, libido, fertility				
SOCIAL FUNCTIONING / FAMILY RELATED					
Financial issues	Compensation, pay, money.				
Home care/ district nurse support	Help at home				
Mobility	Limp, Hobbling, balance issues				
Spiritual / Religious aspects	Beliefs / faith, sense of peace/ purpose, meaning of life, prayer, concerns about death				
Support of my family	Help for my family, housing				
Unable to go out and enjoy my family					
Unable to go to work					
Worried about the future of my family	Worried about my children				
TOTAL					

PROFESSIONALS					
	Phrase/terms used	**Assessor 1**	**Assessor 2**	**Items mi**	**Item resolved**

				ss ed	
TREATMENT-RELATED					
Surgeon	Breast surgeon, Plastic surgeon				
Radiation oncologist	Radiotherapy doctor				
Medical Oncologist	Chemotherapy doctor				
Pain specialist					
Breast cancer nurse	Macmillan nurse, case worker, diabetic nurse, wound care nurse				
Complementary therapies	Acupuncture, relaxation				
SOCIAL CARE AND WELL-BEING					
General practitioner	Family doctor				
District nurse	Home nurse support				
PHYSICAL AND FUNCTIONAL WELL-BEING					
Dietician					
Lymphoedema specialist /clinic					
Hair / Breast prosthesis / advisor	Wig / Breast pudding				
Physiotherapist					
PSYCHOLOGICAL, EMOTIONAL AND SPIRITUAL WELL-BEING					
Chaplain	Priest, 'somebody from church', temple, imam				
(Clinical) Psychologist	Psychologist				
TOTAL					

CLINICAL ACTION/DECISION TAKEN

Medical action	Phrase/terms used	Assessor 1	Assessor 2	Items missed	Item resolved
Placement on waiting list for rehabilitative-related surgery	Implant placement, scar excision, Breast reconstruction				
Placement on waiting list for cancer-related surgery	Core biopsy				
Symptomatic /supportive medical treatment	Analgesia, antibiotics, topical analgesic gel, change of anti-oestrogen tablets				
Investigations	Mammogram, Blood tests, ultrasound, CT scan, MRI scan				
Referrals	Write referral letter, telephone referral, Write letter to the GP				
Other	Discharge from clinic				
TOTAL					

Non-medical action	Phrase/terms used	Assessor 1	Assessor 2	Items missed	Item resolved
Provision of information	Explanation regarding concern item, information regarding cancer prognosis, information regarding progress of healing, reconstruction onformation Provide leaflet/video				
Lifestyle advice	Smoking cessation, alcohol cessation, exercise, dietary intake				
Coping	Suggestions for how to handle or manage concerns, Suggestion to meet/join support group				

Reassurance	Encouragement, comfort, assurance, gives hope				
Further surveillance	New follow up appointment, mammogram				
Others	Provide letter of support for patient, provide medical certificate, GP letter				
TOTAL					

Appendix 2-T: Thematic Framework development

Steps	Definition	Process
Familiarisation	The process through which the researcher becomes familiarised with the data	Listened to audio-recordings Read through transcripts
Identification of thematic framework	Identification of issues, themes and concepts from the data. They can also be based on previous knowledge At this stage the framework can be tentative and open to further changes for refinement based on logical and intuitive thinking	Previous knowledge of the themes was gained from the Head and Neck PCI. Themes were structured according to a collection of words, terms, and expressions considered to be of the same type. This provided a standardised list for reference during evaluation
Indexing	Identification of portions or sections of data that correspond to a particular theme	Transcripts were analysed by two assessors using thematic coding Portions of data that represented a theme were highlighted in the text, and the corresponding theme annotated in the margin for the purpose of indexing
Charting	Organisation of indexed data into charts	Both assessors met to agree the codes. For each transcript assessed by both, the items were considered as "item agreed" or "missed". Those missed were discussed and ultimately resolved. Some items were missed because they had been overlooked, misclassified, or the theme was not included on the thematic framework. They were carefully considered to create new themes to refine the existing framework
Mapping and interpretation	Analysis of key characteristics as set out in the tables	The indexed themes from the transcript were tabled according to type This was contrasted against another table consisting of the items identified by patients on the PCI before consultation

Appendix 2-U: Thematic framework and consultation interviews

ITEMS OF CONCERN	INTERVIEW PART
GENERAL INFORMATION	
Activity	
Complementary / Homeopathic Medicines	**Patient 17**: *' I have tried massaging with a...bio-oil, its like a moisturiser thing..'*
Fertility issues following treatment	
Lifestyle	
Information about Breast cancer	**Patient 33: '***My breast cancer...is it dangerous?...what type is it? Please let me know more..*
Information about personal hygiene	
BODY IMAGE-RELATED	
Appearance (Overall physical appearance	
Arm appearance	**Patient 5:**...*'This side of my arm...I think is getting bigger'*
Breast appearance	**Patient 2: '** *I just don't like it as it is now, obviously because there is a massive difference. I don't expect them to be exactly the same size anyway, because they weren't anyway. So its just...*'
Breast Prosthesis / Padding	**Patient 19:** *' the only thing I don't like is you can't wear anything low because if you bend forwards, even though you've got these, it goes forward'*
Hair Loss	**Patient 35**: *' doc: Arimidex. How are you managing with those? Are they alright for you?* *pat: yeah, yeah. I think I do get, as it says, hair loss... erm... you know, but other than... I just take them and that's it'*
Hair replacement (wig)	
Mastectomy appearance	**Patient 25**: ' *... so obviously after the surgery the breast size is different one side compared to the other...'*

Weight	**Patient 7**: *' Are you having any bother with the tamoxifen in terms of...* *Pat: no. I've put weight on definitely, I know that's...common yeah...'*
Wound healing	**Patient 2**: *' well I had, I don't know if he didn't mention that one, twisted the first implant I had in so they had to take that out and put another one in. So that one had been fine, this one. And obviously then my skin decided to split instead...'*
PHYSICAL FUNCTIONING AND HEALTH-RELATED	
Appetite	**Patient 21***: ' I just don't feel well* *Doc: how is your appetite?* *Pat: I don't eat much at all* *Doc: are you losing weight?* *Pat: yeah..'*
Arm swelling	**Patient 5***: ' So its a bit better than it was...but it does flare up occasionally (lymphoedema), but its one of these things that I've come to...You have to live with it really, there is not a lot you can do about it...'*
Breast texture	**Patient 2***: ' no I don't...because I can tell what this feels like, I don't mean like firmer, I mean like it never moved. So I didn't know if it was too big compares to...so I thought if it was smaller there might be more room in it'*
Breast sensitivity /	**Patient 14***: ' and there, it feels funny...pulling sensation. It sometimes feel like there is something tickling inside...'*
Cancer treatment	**Patient 2***: ' Doc: it takes multiple goes of doing fat injections* *Pat: I'd rather have a mastectomy then having one of them again* *Doc: yeah* *Pat: its painful'*
Constipation	
Diarrhoea	
Fatigue / Tiredness	**Patient 8**: '*... its just that my whole body wants to lie down... the problem is, will my body will stand all this? Quite honestly...because I could just flop quite quickly...* *' if you don't have the strength you can't fight really'*
Hot flushes	**Patient 20**: ' *... if you said to be it would stop the flushes, then...like a shot I would swap...'*
Indigestion	

Memory / concentration	
Nausea / Vomiting/ Sickness	**Patient 39**: *' are you managing alright with Letrozole? yes,...I feel sick in the morning so I started taking it at night.'*
Pain in the breast	**Patient 7**: *' it is actually, I was really lucky it didn't go so hard, but its still quite tender where the lump was taken out...'*
Pain in the arm or shoulder	
Pain elsewhere	**Patient 11***: ' The joint pains..is joint pains and stiffness you are getting as well, isn't it?* *Pat: its shooting pains in joints and stiffness and my neck is very bad, erm, I was diagnosed during the summer with that and that's partly, my skin because of the pain...My skin tends to open and then I get a pain...so its a vicious circle.'*
Sleeping	**Patient 9**: ' *...so I am not sleeping brilliantly...laying awake in the middle of the night...'*
Sore mouth / Dry mouth	**Patient 6***: ' Letrozole didn't do me any good at all. In fact it gave me a very dry mouth...'*
Swallowing	
Taste	
PSYCHOLOGICAL STATE AND EMOTIONAL WELL BEING	
Angry	**Patient 48**: *' I get... I get snappy coming up to medical appointments..* *Doc: due to stress probably* *Pat: yeah probably...but apart from that, I am not snappy, am I?* *Husband: no'*
Anxiety	**Patient 9**: *' I've got these, like two heads...you know; sensible head which is quite logical most of the time and then laying awake in the middle of the night...'*
Coping	**Patient 8**: *' I don't think I can stand anything. Quite honestly I don't know if I could stand it'*
Depression	**Patient 7***:' I don't know if you can tell from my notes, its been quite a journey I've been down with all this. With the...initially I had been told to have a double mastectomy..'*
Fear about the future	**Patient 40**: ' *it's just that I've had the comfort of a mammogram every year and all of a sudden nothing. It*

	stops. And I think it's the fear of it stopping that... you know...'
Fear of cancer coming back	**Patient 9**: *' The sensible bit was like, you know, its fine, its going to be absolutely nothing, erm, but just a little bit at the back of your mind is there all the time, that is like: oh it could be again.'*
Fear of cancer spreading	**Patient 48**: *' erm...does this tablet stop cancer forming in another part of my body..?*
Mood	
Self-esteem	
Temperament and personality	**Patient 6*:*** *' this is making me very, very emotional. I was never like that..'*
	' I can't go to anybody without a cry..'
SEXUAL FUNCTIONING	
Intimacy	
Relationships	
Sex	
SOCIAL FUNCTIONING / FAMILY RELATED	
Financial issues	
Home care/ district nurse support	
Mobility	
Spiritual / Religious aspects	**Patient 6**: *' I pray for them each morning that I won't get any. But we are not talking just a flush we are talking one after the other, after the other...'*
Support of my family	
Unable to go out and enjoy my family	**Patient 6**: '*...you can't get ready to go anywhere because the sweat (hot sweats) is coming through...*
Unable to go to work	
Worried about the future of my family	**Patient 19*:*** *' because the thought of not eing able to pick up my grandkids would kill me...'*
TOTAL	

Appendix 2-V: Breast cancer specific PCI following input from the study

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Edge Hill University

Aintree University Hospitals NHS
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Where quality matters

Breast Cancer
Patient Concerns Inventory

Please choose from the list of issues you would specifically like to talk about in your consultation in clinic today. You can choose more than one option: (Tick the box ☑)

GENERAL INFORMATION	
Activity (Conflicting information about exercise; unable to do exercise or problems returning to my daily routine)	
Complementary / Homeopathic Medicines (Problems with or unable to get information about)	
Fertility issues following treatment (Problems with or unable to get information about)	
Lifestyle (Smoking / Alcohol-related	
Information about Breast cancer	
Information about personal hygiene	

BODY IMAGE-RELATED	
Appearance (Overall physical appearance)	
Arm appearance	
Breast appearance	
Breast prosthesis / Padding	
Hair loss	
Hair replacement (wig)	
Mastectomy appearance	
Weight (Unable to control my weight)	
Skin changes /appearance	
Wound healing (Scar appearance)	

PHYSICAL FUNCTIONING AND HEALTH-RELATED	
Appetite	
Arm swelling (Lymphoedema)	
Breast texture	
Breast sensitivity /Breast pain	
Cancer treatment	
Constipation	
Diarrhoea	
Fatigue / Tiredness (Low energy levels)	
Hot flushes	
Indigestion	
Memory / Concentration	
Nausea/ Vomiting / Sickness	
Pain in the breast	
Pain in the arm or shoulder	
Pain elsewhere	
Sleeping	
Sore mouth / Dry mouth	
Swallowing	
Taste	

PSYCHOLOGICAL STATE AND EMOTIONAL WELL BEING	
Angry (Why me? Why this treatment?)	
Anxiety (Related to the diagnosis or treatment)	
Coping (with the disease or the treatment)	
Depression	
Fear about the future	
Fear of cancer coming back	
Fear of cancer spreading	
Mood	
Self esteem	
Temperament and personality	

SEXUAL FUNCTIONING	
Intimacy	
Relationships	
Sex	

SOCIAL FUNCTIONING / FAMILY-RELATED	
Financial issues	
Home care / district nurse support	
Mobility	
Spiritual / Religious aspects	
Support for my family	
Unable to go out and enjoy my family	
Unable to go to work	
Worried about the future of my family	
Bereavement	

OTHER	

More next

EPRC
Evidence-based Practice Research Centre
Edge Hill University

Aintree University Hospitals NHS
NHS Foundation Trust
Where quality matters

Breast Cancer
Patient Concerns Inventory

Please indicate the people you would specifically like to talk with either in clinic or by referral. You can indicate more than one person. (Tick the box ☑)

TREATMENT-RELATED

Breast Surgeon (He or she will perform the biopsy of the breast tumour and the lumpectomy or mastectomy)	
Complementary therapies	
Medical Oncologist (This specialist administers anticancer drugs or chemotherapy)	
Plastic surgeon (This doctor performs your breast reconstruction)	
Radiation oncologist (He or she administers radiation therapy)	
Pain specialist	
Breast care nurse	

PHYSICAL & FUNCTIONAL WELL-BEING

Dietician	
Lymphoedema specialist / Clinic	
Hair prosthesis wig advisor / Breast prosthesis expert	
Nurse practitioner (Person that removed fluid from my operation site)	
Physiotherapist	

PSYCHOLOGICAL, EMOTIONAL & SPIRITUAL WELL-BEING

Chaplain	
Clinical psychologist (He or she may help with anxiety / depression)	

SOCIAL CARE & SOCIAL WELL-BEING

General practitioner	
District Nurse	

OTHERS

APPENDIX SECTION 3: Publications in Support of Thesis

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Appendix 3-A Summary of Publications related to the PCI:

1. A Kanatas, N Ghazali, D Lowe, M Udberg, J Heseltine, E O'Mahony, SN Rogers. Issues patients would like to discuss at their review consultation: variation by early and late stage oral, oropharyngeal and laryngeal subsites. European Archives of Oto-Rhino-Laryngology 270 (3), 1067-1074
2. A Kanatas, N Ghazali, D Lowe, SN Rogers. The identification of mood and anxiety concerns using the patients concerns inventory following head and neck cancer. International journal of oral and maxillofacial surgery 41 (4), 429-436
3. Kanatas A, Velikova G, Roe B, Horgan K, Ghazali N, Shaw RJ, Rogers SN. Patient-reported outcomes in breast oncology: a review of validated outcome instruments. Tumori. 2012 Nov;98(6):678-88.
4. N Ghazali, A Kanatas, B Scott, D Lowe, A Zuydam, SN Rogers. Use of the Patient Concerns Inventory to identify speech and swallowing concerns following treatment for oral and oropharyngeal cancer. The Journal of Laryngology & Otology 1 (1), 1-9
5. N Ghazali, A Kanatas, F Bekiroglu, B Scott, D Lowe, SN Rogers. The Patient Concerns Inventory: A Tool to Uncover Unmet Needs in a Cancer Outpatient Clinic. Bulletin of The Royal College of Surgeons of England 95 (3), 1-6

Appendix 3-B Poster presentations related to the breast cancer specific PCI:

A. Development Of A Breast Cancer Specific PatientsConcerns Inventory (PCI). Kanatas A, Velikova G, Roe B, Horgan K, Lowe. Psycho-Oncology 03/2012;21:1-20
B. Integrating Quality Of Life And Patient Concerns Into Routine Out-Patients Clinics As A Tool To Promote Intervention. Rogers S, Ghazali N, Kanatas A, Roe B. Psycho-Oncology 03/2012; 21(Suppl. 2):1–20
C. Uncovering patients' concerns using the patient concerns inventory (PCI) in routine head and neck and breast oncology follow up clinics: a comparative study. Kanatas A, Velikova G, Lowe D, Roe B, Horgan K, Ghazali N,Shaw RJ and Rogers SN BAHNO 04/2013.

Appendix 3-C: Issues patients would like to discuss at their review consultation in Breast Cancer clinics-a cross-sectional survey

A Kanatas[1], D Lowe[2], G Velikova[3], B Roe[4], K Horgan[5], RJ Shaw[6] and SN Rogers[7]

Abstract

Introduction:

In breast cancer (BC) there are different therapies available with different side-effects affecting the health-related quality of life (HRQOL). The Patient Concerns Inventory (PCI) for head and neck cancer patients was used as the basis to develop a PCI instrument for BC patients. Here we report the concerns that BC patients would like to discuss in the outpatient clinic and also their choice of multidisciplinary team (MDT) members they would like to see.

Methods:

Cross-sectional survey, using the BC specific PCI, of patients who had completed their initial treatment and attending a review outpatient clinic. 249 patients were recruited from February to July 2012.

Results:

Survey responses were obtained from 80% (200/249). The three most frequent items were Fear of Cancer coming back (62%, 124), Breast sensitivity/pain (46%, 92), Fatigue/tiredness- low energy levels overall (46%, 92). The most frequently selected members of the MDT that patients wished to see were the Breast care nurse (46%, 92), Medical oncologist (28%, 55) and Psychologist (20%, 40).

Conclusions:

The PCI may empower patients to raise issues that otherwise could be missed. It provides the opportunity for multiprofessional engagement across a range of issues specific to BC thus allowing for additional support which might help resolve more symptoms and improve HRQOL. The BC specific PCI is a practical tool that may assist in the holistic needs assessment of patients during the cancer journey.

Appendix 3-D: Fear of recurrence (FOR)-a cross sectional study using the breast cancer (BC) specific Patient Concerns Inventory (PCI)

A Kanatas, D Lowe, G Velikova, B Roe, RJ Shaw, G Humphris and SN Rogers

Abstract

Introduction:

Fear of recurrence (FOR) is an issue that is present to varying degrees in almost all cancer survivors. Fear of cancer recurrence (FOR) is a well recognised challenge in BC patients and is often an unmet need. This study aimed to explore the role of the BC specific PCI in the identification of those patients who report the wish to discuss FOR.

Methods:

Cross-sectional survey, using the BC specific PCI with an established breast cancer HRQOL measure [EORTC C30 (European Organisation for Research and Treatment of Cancer) with BR23] , of patients that had completed their initial treatment and attending in a review outpatient clinic. 249 patients were recruited.

Results:

Survey responses were obtained from 80% (200) of the 249 patients. 49% (122), wanted to discuss fear of recurrence, 31% (77) fear of cancer spreading and 25% (62) fear about the future, with 57% (141) one or more of these.

Conclusions:

The PCI may empower patients to raise the issue of FOR that otherwise could be missed. BC survivors may use the PCI to convey their concerns to their clinicians. FOR is a difficult subject to approach in a routine outpatient clinic. The PCI is tool that provides an opportunity to broach and to address this issue early, rather than patients dwelling on their fear and potentially adopting negative coping.

Appendix 3-E: The breast cancer specific Patient Concerns Inventory (PCI) as a means to assist the identification of body image concerns in routine follow up clinics

A Kanatas[1], D Lowe[2], G Velikova[3], B Roe[4], J P White[5], RJ Shaw[6] and SN Rogers[7]

Introduction

Many changes to our appearance may occur through life. These may be planned or unplanned, desired or not (1). There are several definitions of body image in the literature based on body size estimation, evaluation of body attractiveness, feelings associated with body size and shape (2). The definition we use relates body image to a person's perceptions, feelings and thoughts about his or her body (2,3).

Women treated for breast cancer endure scars and disfigurement of the breast, skin changes related to radiotherapy and/or hair loss due to chemotherapy (4,5). These effects from the disease and its treatment are life changing and can lead to a significant alteration in body image (5,6). In turn this effect on body image can result in undesirable Health-Related-Quality-of Life (HRQOL) changes that affect the transition from patient to breast cancer survivor (7-12). Younger patients may be more susceptible to stress related to change in body image and report greater changes in HRQOL scores (11-16). Brunet et al (2013) (17) reported that women with breast cancer experienced various physical changes that negatively affected, their perceptions, thoughts, attitudes, feelings, and beliefs about their bodies. Based on these findings they highlighted the need to recognise body image concerns that could have a long lasting effect on the HRQOL.

The link between body image disturbance, lower self-compassion and an increase level of distress has been recognised by Przezdziecki et al (2012) (18). Specific treatment options, such as mastectomy, may adversely affect specific aspects of body image such as problems related to sexual intimacy (19). Mastectomy may alter body image so much that can obliterate sexual relationships for a period of time (30). Support in relation to sexuality and body image could improve relationships by modifying perceptions with a direct improvement in patients' and spouses' HRQOL (31). Clinicians do not always elicit such concerns from patients. One way of improving recognition of these problems is to develop tools to improve clinicians' communication with patients. Cohen et al (2012) suggested that patients want honesty, openness, and directness from their physicians during the discussion of breast-related body image issues (20). Breast cancer patients rate the information on physical changes, sexual response and body image as very important (21). However, Ussher et al (2013) reported that only 41% of their patients obtained such information, hence only 34% of patients claimed to be satisfied with this aspect of their consultation.

Body image can affect a woman's treatment decisions with respect to surgical options such as mastectomy versus breast conserving surgery (22). A multidisciplinary approach to address the impact of body image, with specific medical and psychosocial interventions has been analysed (23). Younger patients take longer to make treatment decisions and require enhanced levels of support compared to older adults. The availability of breast reconstruction only partially ameliorates this effect (24).

Body image changes associated with mastectomy, chemotherapy and radiotherapy are well recognised (25,26,27). Up to a third of women report moderate or marked breast, arm, and shoulder symptoms over 5 years of follow-up after radiotherapy, and skin changes related to radiotherapy are well document in the literature (28). However, these appear to have little impact on body image. As expected, adjuvant treatments (chemotherapy and radiotherapy) are associated with decrease in overall HRQOL, an increase in physical problems and adverse effects on the body image (29,30).

Tools to evaluate changes in body image following breast cancer exist and may be used in both research and clinical settings (32). A number of HRQOL instruments in use in breast oncology have incorporated body image questions (32-40) (Table 1). HRQOL questionnaires are designed as outcome measures to compare groups of patients. Although some studies have described their use in clinical practice, they are not specifically designed for this context. While it is tempting to use the scores derived from such tools to screen patients from problems relating to body image, thresholds to trigger specific interventions are not currently defined in breast cancer care. Furthermore, these tools are time-consuming to use and hence may not be practical in a busy clinical environment.

In other types of cancer, HRQOL tools have been used as a trigger for discussion of patients' problems of appearance (41). HRQOL tools can help focus the consultation and are a suitable means of screening for appearance issues (42). In head and neck cancer the Patient Concerns Inventory (PCI) has been used with HRQOL tool and its role has been defined (43).

The PCI enables holistic evaluation of body image concerns in the breast cancer outpatient clinic (44). The aim of this work is to assess the role of the breast cancer specific PCI in the identification of body image concerns in breast cancer patients and compare this against an establish HRQOL such as the European Organization for Research and Treatment of Cancer breast cancer-specific quality of life questionnaire module (BR23).

Materials and methods

We have performed a cross-sectional survey, using the BC specific PCI with an established breast cancer HRQOL measure [EORTC C30 (European Organisation for Research and Treatment of Cancer) with BR23]. A convenience sample of 249 breast cancer patients was

recruited prospectively from February to July 2012. The patients had completed their initial treatments and were attending an outpatient clinic for review. Patients were recruited by the clinical team at the outpatient clinic but participants completed the questionnaires at home. Prospective study participants received a study information pack containing details about the study and the BC specific PCI. The BC specific PCI (44) has two parts and includes 55 items that are divided into six groups. In the first part the groups include general information, body image- related, physical functioning and health-related, psychological state and emotional well being, sexual functioning and social functioning / family-related. In the second part there is a list of the members of the breast cancer MDT that the patients are given the option to consult, either in the clinic or by referral. The Body image -specific domains include overall physical appearance, arm appearance, breast appearance, breast prosthesis / padding, hair loss, hair replacement (wig), mastectomy appearance, weight and wound healing (scar appearance).

Also the pack included a consent form and a reply slip. Study participants also gave consent for the principal investigator to collect social and treatment-related data from their clinical files. Approval for this study was granted by the Leeds Central Ethics Committee.

Statistical analysis was performed using SPSS version 19. The distribution of PCI body image related items (range 0-9) was analysed using the Mann-Whitney test. Patient/clinical subgroups was compared by the number of body image related items selected using the Kruskal-Wallis or Mann-Whitney test as appropriate. The association of number of PCI Body image related items with number of other PCI items selected overall or within domain and with number of health professionals selected, and with EORTC scores was assessed using Spearman rank correlation methods. In view of the multiple tests performed, statistical significance was taken as $P<0.01$.

Results

Survey responses were obtained from 80% (200/249) of participants. Response was lowest from patients aged ≥75 (63%), with primary local disease (72%), having anti-oestrogen therapy (72%), without radiotherapy (70%), and was higher after reconstructive surgery (96%). Median (IQR) age of responders was 59 (52-68) years, and the overwhelming majority were female (198), only two were male. The most recent breast cancer diagnosis was 2009/2010 for 54% (108), 2011/2012 for 31% (61), unknown 16% (31). Patients with all stages of disease were represented: 51% (101) primary local, 2% (3) local recurrent, 5% (9) metastatic and 4% (8) living with cancer (includes patients with hormonal or biological treatment as the only modality). The multimodal nature of breast cancer management was

reflected in the range of treatments received by participants: 47% (93) chemotherapy, 63% (126) radiotherapy, 47% (93) wide local excision / lumpectomy, 44% (88) mastectomy, 13% (25) reconstructive surgery, 41% (82) anti-oestrogen therapy. Responders were mainly from Leeds 57% (113), or Wakefield 32% (64), and 17% (30/178) lived in one of the 20% most deprived areas as defined by Indices of Multiple Deprivation (IMD).

Two-thirds (68%, 136) of patients selected one or more of the nine PCI items within the Body-image-related domain, with 28% (56) selecting 1 item, 27% (54) selecting 2-3 items and 13% (26) selecting 4-8 items (Table 2). In descending order of frequency the items selected were breast appearance 30%, weight- unable to control weight 28%, mastectomy appearance 19%, overall physical appearance 17%, wound healing – scar appearance 17%, breast prosthesis/padding 15%, hair loss 14%, arm appearance 13% and hair replacement-wig 6%. Those who selected hair replacement-wig were a subset of those who selected hair-loss. Nearly half (26/56) of those selecting just one item selected weight.

There was significant correlation between the number of body image related items selected and the number of PCI items selected in other PCI domains, the total number of other PCI items selected and the total number of health professionals selected (Table 3). Those selecting four or more body image related items also selected a median (IQR) of 17 (10-23) other items and there was a clear gradient in the increase in numbers of other items across the PCI and in the number of health professionals selected as the number of body image related items increased. This is reflected also in the analysis of specific PCI items (Table 4) and there were associations at $P<0.01$ for 37 of the 46 non-body image related items. There were associations at $P<0.001$ with wanting to discuss activity, arm swelling, breast texture, breast sensitivity/pain, indigestion, memory/concentration, nausea, pain in arm or shoulder, sleeping, taste, vomiting/sickness, anger, anxiety, fear of cancer spreading, mood, self-esteem, fear about the future, and with wanting to see the plastic surgeon, medical oncologist, radiation oncologist, breast care nurse, lymphoedema specialist, hair prosthesis advisor/ breast prosthesis expert and nurse practitioner.

The number of body image related items was significantly associated with treatment by chemotherapy, wide local excision/lumpectomy, mastectomy and reconstructive surgery (Table 5), with an increase in items related to chemotherapy and mastectomy and reconstructive surgery and the absence of wide local excision/lumpectomy. There was also a tendency for fewer items to be selected by older patients aged 65 years and over, but no notable differences in regard to the IMD deprivation measure and time of most recent diagnosis. A fuller stratification by treatment combination is shown in Table 6.

Correlations between the number of PCI body image related items and summary scores from

the EORTC QLQ-C30 and the EORTC breast cancer QLQ-BR23 are summarised in Table 7. These correlations were generally quite weak, the strongest of these being with the QLQ-BR23 Body image score and the QLQ BR23 systemic therapy side effects score.

Discussion

To our knowledge this is the first study in which the BR23 questionnaire and the PCI have been used in combination to screen for body image problems in patients with breast cancer. Although several important points have been raised we must recognise that there are limitation to this study. The study involved a relatively small sample of patients from one area in the United Kingdom, thus the results may reflect the beliefs and practice of this group and caution must be applied before extrapolating our findings to other settings. The present study is limited by the cross-sectional nature of the data. Future longitudinal studies need to focus on body image and could to examine whether body image state eventually returns to values similar to those before the breast cancer diagnosis. Body image should not be seen in isolation. There is a need to examine any possible associations with sexual function and quality of life. In this study there were weak correlations between the number of PCI body image items and the EORTC tool. Another limitation of this study is that a specific body image scale would have been appropriate (4). Items such as change in self-consciousness with appearance, less sexually attractive, less feminine, dissatisfaction with appearance when dressed, and body feeling less whole that are present in the QOL BR23 were not assessed in our study.

The body can be viewed as a symbol of social expression (45). Breast cancer diagnosis and treatment can result in a sustained disturbance of that view at 12 months post-diagnosis and beyond (46). This is reflected in our study since 54% of patients were diagnosed at least two years prior to enrolment. Body image is clearly an important issue since 68% of patients selected an item from the body-image domain. In this study the number of body image related items was significantly associated with chemotherapy and mastectomy and reconstructive surgery. Some previous studies showed that chemotherapy, hormonal therapy and radiotherapy do not have a negative effect on body image (47). In contrast, the findings from this study are consistent with, Schover et al. (48) who concluded that chemotherapy do have a negative impact on body image, while hormonal and radiation therapy do not. Breast appearance was the item most frequently selected followed by weight and mastectomy appearance. This is not unexpected since the physical effects of breast cancer treatment on the body serve not only as a personal reminder of the disease but also as an 'announcement' to others (49). Yurek et al (2000) (50) reported that those patients who underwent a lumpectomy faced less body change stress than women with a modified radical mastectomy with breast reconstruction or just a modified radical mastectomy.

In this work only 14% of patients selected hair loss. This low incidence may be explained because most participants completed the PCI several months after their chemotherapy by which point hair-loss had recovered for the majority.

As it can be seen on table 3, those patients selecting body image related items selected a median of 17 other items. The effect of breast cancer on body image should not be under-estimated, and this is widely reflected in the literature. Fallowfield et al. (51) found that the incidence of anxiety and/or depression was as high as 38% in patients with a surgical intervention. Age was negatively correlated with the items detected.

We found that older patients tended to select fewer items and this is consistent with Al-Ghazal et al (2000) (52) who compared the psychological outcome and satisfaction of patients undergoing wide local excision, mastectomy alone or mastectomy with breast reconstruction. This study reported that while women of all age groups face body image issues after breast cancer surgery, women between 40 and 59 years of age report more body image issues after breast cancer surgery.

The head and neck PCI has been used before as a tool to identify appearance-related concerns (53). Appearance was highlighted as a problem on the PCI at 9% (42/454) of questionnaires, and was indicated as a serious problem on 10% (47/454) of UW-QoL questionnaires. Concerns about appearance were raised on the inventory or were shown to be a serious problem on the UW-QoL in 14% (64/454) of patients. One must be cautious comparing our findings with that work since appearance was related to the face, and the participants included male patients and patients with different socioeconomic characteristics.

The routine use of the PCI in breast cancer patients facilitates a holistic approach to management. It identifies the need for interventions; this can have a bearing on resource allocation and should provide a direction for future research. The role of interventions such as body beauty treatments to body image (54) and exercise need (55) in breast cancer patients needs to be evaluated further.

Conclusions

The breast cancer specific PCI can empower women to engage in an honest conversation about their cancer related body image issues. It can be use as a screening tool for body image in order to identify a subgroup of patients that would benefit from focus interventions.

Conflict of interest: The authors have no conflict of interest to report

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Table 1:Body image –related domain

During the past week have you lost any hair (Sprangers et al) (35)

During the past week have you felt physically less attractive as a result of your disease or treatment (Sprangers et al) (35)

During the past week have you been feeling less feminine as a result of your disease or treatment (Sprangers et al) (35)

During the past week did you find it difficult to look at yourself naked (Sprangers et al) (35)

During the past week have you been dissatisfied with your body (Sprangers et al) (35)

I avoid looking at my scars from breast surgery (Baxter et al) (36)

I am satisfied with the shape of my body (Baxter et al) (36)

I feel less feminine since cancer (Baxter et al) (36)

I Like my body (Baxter et al) (36)

I feel comfortable about the way I look when exercise (Baxter et al) (36)

I would feel comfortable changing in a public change-room (Baxter et al) (36)

I feel my body has been invaded (Baxter et al) (36)

I am satisfied with the appearance of my arm (Baxter et al) (36)

I am satisfied with the appearance of my hips (Baxter et al) (36)

I am satisfied with the shape of my buttocks (Baxter et al) (36)

I feel comfortable looking at my mastectomy (Baxter et al) (36)

I am happy with the position of my nipple (Baxter et al) (36)

I feel satisfied with the size of my breast (Baxter et al) (36)

I feel comfortable when other see my breasts (Baxter et al) (36)

The appearance of my breasts could disturb others (Baxter et al) (36)

I feel that people are looking at my breasts (Baxter et al) (36)

How satisfied are you with the way your breast looks (Polivy J) (37)

Have you been feeling self-conscious about your appearance (Hopwood et al) (32)

Have you felt less physically attractive as a result of your disease or treatment (Hopwood et al) (32)

Have you been dissatisfied with your appearance when dressed (Hopwood et al) (32)

Did you find it difficult to look at your self naked (Hopwood et al) (32)

Did you avoid people because of the way you felt about your appearance (Hopwood et al) (32)

Have you been feeling the treatment has left your body less whole (Hopwood et al) (32)

Have you been dissatisfied with your body (Hopwood et al) (32)

Have you been dissatisfied with the appearance of your scar (Hopewood et al) (32)

Is there a difference between the treated and untreated areas in terms of Breast size (Stanton et al) (38)

Is there a difference between the treated and untreated areas in terms of breast texture (hardening) (Stanton et al) (38)

Is there a difference between the treated and untreated areas in terms of nipple appearance (Stanton et al) (38)

Is there a difference between the treated and untreated areas in terms of breast shape (Stanton et al) (38)

Is there a difference between the treated and untreated areas in terms of breast elevation (Stanton et al) (38)

Is there a difference between the treated and untreated areas in terms of scar tissue (Stanton et al) (38)

I am self-conscious about the way I dress (Brady et al) (39)

I am bothered by hair loss (Brady et al) (39)
How satisfied or dissatisfied have you been with how you look in the mirror clothed (Pusic et al) (40)
How satisfied or dissatisfied have you been with the shape of your reconstructed breasts when you are wearing a bra (Pusic et al) (40)
How satisfied or dissatisfied have you been with how normal you feel in your clothes (Pusic et al) (40)
How satisfied or dissatisfied have you been with the size of your reconstructed breasts (Pusic et al) (40)
How satisfied or dissatisfied have you been with being able to wear clothing that is more fitted (Pusic et al) (40)
How satisfied or dissatisfied have you been with how your breasts are lined up in relation to each other (Pusic et al) (40)
How satisfied or dissatisfied have you been with how comfortably your bras fit (Pusic et al) (40)
How satisfied or dissatisfied have you been with the softness of your reconstructed breasts (Pusic et al) (40)
How satisfied or dissatisfied have you been with how equal in size your breasts are to each other (Pusic et al) (40)
How satisfied or dissatisfied have you been with how natural your reconstructed breast looks (Pusic et al) (40)
How satisfied or dissatisfied have you been with how natural your reconstructed breast sits/hangs (Pusic et al) (40)
How satisfied or dissatisfied have you been with how your reconstructed breast feels to touch (Pusic et al) (40)
How satisfied or dissatisfied have you been with how much your reconstructed breast feels like a natural part of your body (Pusic et al) (40)
How satisfied or dissatisfied have you been with how closely matched your breasts are to each other (Pusic et al) (40)
How satisfied or dissatisfied have you been with how your reconstructed breast look now compared to before you had any surgery (Pusic et al) (40)
How satisfied or dissatisfied have you been with how you look in the mirror unclothed (Pusic et al) (40)

Table 2 Body image related items selected on the PCI

Body table gives % (n) of column totals	Number of body Image related items					
	0 N=64	1 N=56	2 N=37	3 N=17	4-8 N=26	ALL N=200
BODY IMAGE RELATED items:						
B21 Appearance (Overall physical appearance)	0	4 (2)	22 (8)	47 (8)	62 (16)	17 (34)
B22 Arm appearance	0	5 (3)	22 (8)	29 (5)	35 (9)	13 (25)
B23 Breast appearance	0	18 (10)	43 (16)	59 (10)	88 (23)	30 (59)
B24 Breast Prosthesis / Padding	0	4 (2)	22 (8)	18 (3)	65 (17)	15 (30)
B25 Hair loss	0	7 (4)	19 (7)	24 (4)	46 (12)	14 (27)
B26 Hair replacement (wig)	0	0	3 (1)	12 (2)	31 (8)	6 (11)
B27 Weight (Unable to control my weight)	0	46 (26)	30 (11)	24 (4)	58 (15)	28 (56)
B28 Wound healing (Scar appearance)	0	9 (5)	16 (6)	47 (8)	54 (14)	17 (33)
B29 Mastectomy appearance	0	7 (4)	24 (9)	41 (7)	69 (18)	19 (38)

Table 3 Median (IQR) and total number of items selected on the PCI, by number of body image related items selected.

Body table gives median (IQR), total number of items in other domains	N of body Image related items* 0 N=64	1 N=56	2-3 N=54	4-8 N=26
General information (6 items)	0 (0-0), 19	1 (0-1), 37	1 (0-1), 48	1 (1-2), 38
Physical functioning and health-related (20 items)	2 (0-4), 155	3 (2-4), 166	5 (3-7), 279	7 (5-11), 216
Psychological state and emotional wellbeing (10 items)	1 (1-2), 101	1 (1-2), 88	3 (2-4), 159	5 (3-6), 124
Sexual functioning (3 items)	0 (0-0), 10	0 (0-0), 11	0 (0-1), 28	1 (0-1), 22
Social functioning / family related (8 items)	0 (0-0), 16	0 (0-1), 21	0 (0-2), 52	2 (1-3), 49
Total number of other PCI items (range 0-47 after excluding the 9 body image related items)	4 (2-6), 301	6 (4-7), 323	10 (5-14), 566	17 (10-23), 449
Health professionals (15 staff)	1 (1-2), 92	2 (1-3), 110	3 (2-4), 174	5 (3-6), 132

*Spearman correlation was significant at P<0.001 between the number of body image related items (range 0-9) and the number of items in each other domain, and also with total number of other items and with the number of health professionals selected.

Table 4. Percentage selecting other specific PCI items and health professionals, by number of PCI body image related items selected

Body table gives % of column totals	N of body Image related items 0 N=64	1 N=56	2-3 N=54	4-8 N=26	P Value*
GENERAL INFORMATION					
B11 Activity	9	29	31	54	<0.001
B12 Information about Breast Cancer (Unable to get or unable to understand)	9	14	15	38	0.005
B13 Information about personal hygiene (Maybe related to breast prosthesis/wig)	0	2	0	15	0.007
B14 Lifestyle (Smoking/ alcohol-started or unable to stop)	6	11	13	15	0.10
B15 Complementary /Homeopathic Medicines (information about)	3	11	26	23	0.001
B16 Fertility issues following treatment (information about)	2	0	4	0	0.93
PHYSICAL FUNCTIONING AND HEALTH RELATED					
B31 Appetite	8	16	19	42	0.001
B32 Arm swelling (Lymphoedema)	6	5	24	38	<0.001
B33 Diarrhoea	6	7	11	19	0.06
B34 Constipation	9	5	20	35	0.002
B35 Breast texture	0	12	20	27	<0.001
B36 Breast sensitivity /Breast pain	28	39	61	69	<0.001
B37 Cancer Treatment	16	4	22	42	0.004
B38 Sore mouth / Dry Mouth	13	13	19	42	0.004
B39 Fatigue / Tiredness (Low energy levels overall)	33	43	50	73	0.001
B310 Indigestion	3	4	20	23	<0.001
B311 Memory/ Concentration	16	23	35	50	<0.001
B312 Nausea	2	4	11	31	<0.001
B313 Pain in the Breast	17	25	37	46	0.001
B314 Pain in the arm or shoulder	17	11	35	54	<0.001
B315 Pain elsewhere	19	13	15	31	0.36
B316 Sleeping	17	21	52	62	<0.001
B317 Swallowing	0	2	4	8	0.03
B318 Taste	2	2	9	38	<0.001
B319 Vomiting / Sickness	3	2	6	31	<0.001
B320 Hot Flushes	28	46	46	69	0.001
PSYCHOLOGICAL STATE AND EMOTIONAL WELLBEING					
B41 Angry (why me?, why this treatment)	2	4	7	27	<0.001
B42 Anxiety (Related to the diagnosis or treatment)	8	13	30	50	<0.001
B43 Coping (coping with the disease, the treatment or the side effects of treatment)	16	9	28	42	0.005
B44 Depression	11	11	19	38	0.006
B45 Fear of Cancer coming back	55	57	67	81	0.02
B46 Fear of Cancer spreading	25	27	52	73	<0.001
B47 Mood	8	7	20	38	<0.001
B48 Self esteem	8	4	17	42	<0.001
B49 Temperament and personality	6	5	13	27	0.004
B410 Fear about the future	20	21	43	58	<0.001
SEXUAL FUNCTIONING					
B51 Intimacy	5	5	19	31	<0.001
B52 Relationships	3	2	17	27	<0.001
B53 Sex	8	12	17	27	0.01
SOCIAL FUNCTIONING / FAMILY RELATED					

B61 Financial issues	8	16	30	35	<0.001
B62 Home care / district nurse support	0	0	11	23	<0.001
B63 Mobility	5	2	15	19	0.008
B64 Spiritual / Religious aspects	2	2	4	4	0.38
B65 Support for my family	0	5	11	46	<0.001
B66 Worried about the future of my children	5	5	15	19	0.01
B67 Unable to go out and enjoy my family	5	4	7	19	0.04
B68 Unable to go to go to work	2	4	4	23	0.002
HEALTH PROFESSIONALS					
R1 Breast surgeon	50	41	41	58	0.99
R2 Plastic surgeon	0	2	24	38	<0.001
R3 Medical oncologist	14	23	35	54	<0.001
R4 Radiation oncologist	5	7	17	31	<0.001
R5 Breast Care Nurse	30	39	65	69	<0.001
R6 Chaplain	0	2	2	8	0.04
R7 Psychologist	13	13	26	42	0.002
R8 Dietician	9	18	15	27	0.08
R9 Lymphoedema specialist /clinic	0	9	17	23	<0.001
R10 Hair prosthesis (wig advisor) / Breast prosthesis expert	0	4	9	38	<0.001
R11 Nurse Practitioner	0	0	8	15	<0.001
R12 Pain specialist	5	7	17	31	0.001
R13 District Nurse	0	0	7	4	0.03
R14 My own doctor (General Practitioner)	11	16	15	12	0.70
R15 Complementary therapies	8	16	26	35	0.001

*Mann-Whitney test comparing the full distribution (range 0-9) of body image related items for specific PCI items being selected Vs. not selected.

Table 5: Clinical/personal characteristics and selection of PCI body image related items

Body table gives % (n) of row totals			Number of Body image related items selected				
		Patients	0	1	2-3	4-8	P value*
	ALL	200	32 (64)	28 (56)	27 (54)	13 (26)	-
Age	<55	69	28 (19)	23 (16)	36 (25)	13 (9)	0.04**
	55-64	59	25 (15)	34 (20)	24 (14)	17 (10)	
	65-74	52	42 (22)	31 (16)	15 (8)	12 (6)	
	75+	19	42 (8)	16 (3)	37 (7)	5 (1)	
Gender	Female	198	32 (64)	28 (56)	27 (53)	13 (25)	-
	Male	2	0	0	50 (1)	50 (1)	
IMD deprivation: living in area that is one of the 20% most deprived	No	148	28 (42)	30 (44)	28 (41)	14 (21)	0.38 excl NK
	Yes	30	37 (11)	27 (8)	23 (7)	13 (4)	
	Not known	22	50 (11)	18 (4)	27 (6)	5 (1)	
Year of most recent diagnosis	2009/2010	108	34 (37)	26 (28)	26 (28)	14 (15)	0.84 excl NK
	2011/2012	61	30 (18)	31 (19)	28 (17)	11 (7)	
	Not known	31	29 (9)	29 (9)	29 (9)	13 (4)	
Location	Leeds	113	29 (33)	26 (29)	31 (35)	14 (16)	0.21
	Wakefield	64	33 (21)	34 (22)	17 (11)	16 (10)	
	Other	23	43 (10)	22 (5)	35 (8)	0	
Extent of disease: Primary Local	No	99	31 (31)	24 (24)	30 (30)	14 (14)	0.48
	Yes	101	33 (33)	32 (32)	24 (24)	12 (12)	
Extent of disease: Local recurrent	No	197	32 (64)	28 (55)	27 (53)	13 (25)	-
	Yes	3	0	33 (1)	33 (1)	33 (1)	
Extent of disease: Metastatic	No	191	32 (61)	28 (54)	27 (52)	13 (24)	0.84
	Yes	9	33 (3)	22 (2)	22 (2)	22 (2)	
Extent of disease: Living with cancer	No	192	32 (61)	28 (53)	28 (53)	13 (25)	0.55
	Yes	8	38 (3)	38 (3)	13 (1)	13 (1)	
Treatment (known for 193/200)							
Chemotherapy	No	100	40 (40)	30 (30)	21 (21)	9 (9)	0.002
	Yes	93	23 (21)	28 (26)	31 (29)	18 (17)	
Radiotherapy	No	67	27 (18)	28 (19)	28 (19)	16 (11)	0.24
	Yes	126	34 (43)	29 (37)	25 (31)	12 (15)	
Wide local excision /lumpectomy	No	100	23 (23)	30 (30)	30 (30)	17 (17)	0.005
	Yes	93	41 (38)	28 (26)	22 (20)	10 (9)	
Mastectomy	No	105	44 (46)	30 (31)	22 (23)	5 (5)	<0.001
	Yes	88	17 (15)	28 (25)	31 (27)	24 (21)	
Reconstructive surgery	No	168	34 (57)	31 (52)	23 (38)	13 (21)	0.006
	Yes	25	16 (4)	16 (4)	48 (12)	20 (5)	
Anti-oestrogen therapy***	No/NK	111	32 (35)	23 (25)	28 (31)	18 (20)	0.08

	Yes	82	32 (26)	38 (31)	23 (19)	7 (6)	
Other treatment: ***	No/NK	176	31 (54)	30 (53)	27 (47)	13 (22)	0.92
	Yes	17	41 (7)	18 (3)	18 (3)	24 (4)	

***** Mann-Whitney (2 group comparison) or Kruskall-Wallis test (>2 group comparison) as appropriate using the number of body image related items selected (range 0-9)
** Spearman correlation between age in years and number of body image related items (range 0-9)
*** Anti-oestrogen therapy included: tamoxifen, letrozole, anastrozole, aromasin, arimidex, exemestane; Other treatment included :Herceptin, lepatinib, trastuzumab, neratinib.

Table 6. Number of body image related items by treatment

Wide local excision or lumpectomy surgery	Reconstructive surgery	Chemotherapy	Mastectomy	Number of Body image-related items				Total
				0	1	2-3	4-8	
No	No	No	No	8	2	3	-	13
No	No	No	Yes	1	6	7	4	18
No	No	Yes	No	1	4	3	-	8
No	No	Yes	Yes	10	14	7	10	41
No	Yes	No	Yes	-	2	4	-	6
No	Yes	Yes	Yes	3	2	6	3	14
Yes	No	No	No	31	19	6	2	58
Yes	No	No	Yes	-	1	1	2	4
Yes	No	Yes	No	6	6	10	3	25
Yes	No	Yes	Yes	-	-	1	-	1
Yes	Yes	No	Yes	-	-	-	1	1
Yes	Yes	Yes	No	-	-	1	-	1
Yes	Yes	Yes	Yes	1	-	1	1	3
Treatment not known				3	-	4	-	7

Table 7. Number of PCI Body image related items and summary scores from the EORTC QLQ-C30 and EORTC breast cancer module QLQ-BR23

	Spearman correlation*			Number of PCI body image related items			
	Correlation coefficient1	P value	Patients	0	1	2-3	4-8
EORTC				Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
C30 Physical functioning	-0.23	0.001	199	85.3 (2.4)	81.3 (2.7)	77.5 (3.2)	76.8 (3.5)
C30 Role functioning	-0.18	0.01	200	82.6 (3.0)	77.1 (3.9)	70.7 (4.2)	69.9 (6.0)
C30 Emotional functioning	-0.13	0.08	195	73.8 (2.8)	75.3 (2.7)	66.2 (3.5)	62.7 (6.0)
C30 Cognitive functioning	-0.25	<0.001	196	84.1 (2.5)	77.8 (3.2)	65.4 (3.8)	69.2 (6.2)
C30 Social functioning	-0.25	<0.001	195	86.6 (2.9)	76.2 (3.7)	70.1 (3.9)	70.5 (6.2)
C30 Fatigue	0.29	<0.001	200	22.6 (3.1)	32.1 (2.7)	38.5 (3.3)	41.0 (5.5)
C30 Nausea and vomiting	0.18	0.01	200	3.4 (1.0)	5.4 (2.1)	10.2 (2.4)	11.5 (4.4)
C30 Pain	0.17	0.02	199	19.3 (2.6)	23.3 (3.4)	34.3 (4.4)	30.8 (6.0)
C30 Global health status / QOL	-0.06	0.39	196	67.2 (2.6)	66.2 (2.5)	61.7 (3.1)	63.5 (4.6)
C30 Dyspnoea	0.22	0.002	200	9.4 (2.6)	16.7 (3.3)	14.2 (3.2)	26.9 (5.2)
C30 Insomnia	0.26	<0.001	200	22.9 (3.3)	37.5 (4.7)	54.3 (4.9)	37.2 (7.0)
C30 Appetite loss	0.09	0.23	200	8.9 (2.7)	8.9 (2.8)	18.5 (4.3)	10.3 (4.8)
C30 Constipation	0.11	0.13	200	14.6 (3.4)	13.1 (2.9)	17.9 (3.7)	19.2 (5.0)
C30 Diarrhoea	0.22	0.002	193	2.8 (1.4)	8.6 (3.2)	10.7 (2.8)	14.1 (5.3)
C30 Financial difficulties	0.15	0.03	196	12.0 (3.0)	15.8 (3.4)	25.3 (4.4)	21.8 (7.1)
BR23 Body image	-0.34	<0.001	195	78.8 (3.3)	74.4 (3.3)	53.8 (4.4)	60.3 (5.5)
BR23 Sexual functioning	-0.01	0.87	177	21.5 (3.2)	15.4 (2.4)	18.8 (3.2)	24.3 (5.9)
BR23 Sexual enjoyment	-0.05	0.69	68	57.3 (5.3)	47.1 (5.8)	47.1 (7.6)	59.3 (10.8)
BR23 Future perspective	0.01	0.95	195	41.9 (4.1)	51.2 (4.5)	43.4 (4.7)	42.3 (6.6)
BR23 Systemic therapy side effects	0.32	<0.001	197	14.0 (1.6)	18.7 (1.7)	23.8 (2.2)	30.8 (4.8)
BR23 Breast symptoms	0.19	0.007	197	15.8 (1.9)	20.9 (2.4)	29.6 (3.2)	21.5 (3.8)
BR23 Arm symptoms	0.26	<0.001	197	13.1 (2.0)	16.9 (2.4)	23.5 (3.8)	32.9 (5.5)
BR23 Upset by hair loss	0.41	0.001	62	15.8 (5.3)	64.4 (10.0)	62.2 (9.1)	56.4 (8.8)

* Spearman correlation coefficient between the number of PCI Body image related items selected (range 0-9) and the EORTC scores
SE: Standard Error of mean

APPENDIX SECTION 4: Letters and Approvals from the Research Ethics Committee and the Leeds Teaching Hospitals Research and Development Departments

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Appendix 4-A: Ethical Opinion

NHS
National Research Ethics Service

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25 July 2011

Mr Anastasios Kanatas
Specialist Registar in Oral and Maxillofacial surgery
Leeds Teaching Hospitals NHS Trust
Oral and Maxillofacial Department
Leeds General Infirmary
Great George Street
LS1 3EX

Dear Mr Kanatas

Study title:	**Development of a breast cancer specific Patients Concerns Inventory (PCI)**
REC reference:	**11/YH/0245**
Protocol number:	**n/a**

The Research Ethics Committee reviewed the above application at the meeting held on 15 July 2011. Thank you for attending to discuss the study.

Ethical opinion

The Committee asked you to explain the two phases of the study. You explained that overall you are trying to identify patients concerns of living with breast cancer. You stated that phase 1 will involve listing over 200 items that may be a concern to breast cancer patients. You stated that you will then hold focus groups to identify common problems and reduce the number of items to something more manageable.

You explained that phase 2 will involve 200 patients who will be asked to complete a questionnaire. This will allow the format to be tested to ensure it is user-friendly.

The Committee asked you if you intend to audio-record the focus groups. You stated that you will be recording the groups for you MD degree. Members explained that a clause must be included in the consent form to allow participants to consent to being audio-recorded.

Members asked you why you need to collect demographic data. You explained that you will need the data to establish who the instrument will be developed for and allow you to compare it with other instruments. Members acknowledged the need for age and postcode, but explained that using full address and date of birth was not necessary for the study.

The Committee asked you how carers will be involved in the study. You explained that participants may want a carer to attend the focus group with them for support. The Committee expressed concern that the careers may be involved in the focus group. You explained that they will not be taking part in the focus group and perhaps they could wait in a room nearby. Members agreed that other participants may feel uncomfortable if carers are

present and it would be more appropriate for them to wait in a room nearby.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

1. The consent form should include initial boxes.

2. The consent form should include a clause allowing participants to consent to the focus group being audio-recorded.

3. The researcher should revise the clinical background information sheet to ensure that only age and postcode is collected in section A and that date of birth and full address is removed.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		14 June 2011
GP/Consultant Information Sheets	1.1	16 June 2011
Investigator CV		14 June 2011
Other: Questions to Clinicians	1.1	16 June 2011
Other: Study reply slip - Phase 1	1.1	16 June 2011
Other: Study reply slip - Phase 2	1.1	16 June 2011
Other: Socio-demographic data	1.1	16 June 2011
Other: Clinical Background Information sheet	1.1	16 June 2011
Other: CV - G Velikova (Supervisor)		14 May 2011
Other: CV - S Rogers (Supervisor)		11 June 2011
Participant Consent Form: Clinical Staff Consent form - Audio recording	1.1	16 June 2011
Participant Consent Form: Phase 1	1.1	16 June 2011
Participant Consent Form: Phase 2	1.1	16 June 2011
Participant Information Sheet: Study Information Phase 1	1.1	16 June 2011
Participant Information Sheet: Study Information Phase 2	1.1	16 June 2011
Protocol	1.1	16 June 2011
Questionnaire: EORTC C30 & BR23 module		
REC application		14 June 2011
Referees or other scientific critique report		08 March 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/YH/0245	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Margaret L Faull
Chair

Email: nicola.mallender-ward@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Mrs Anne Gowing, The Leeds Teaching Hospitals NHS Trust*

NRES Committee Yorkshire & The Humber - Leeds Central

Attendance at Committee meeting on 15 July 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Chris Bennett	Consultant Clinical Geneticist	Yes	
Mr Mick Burns	Senior Commissioning Manager	Yes	
Mr Michael Davidson	Retired Senior Personnel Manager	Yes	
Dr Margaret L Faull	Chair	No	
Mr Mark Godley	IT Consultant	No	
Dr Janet Holt	Senior Lecturer	No	
Ms Sarah Kirkland	Learning Disability Services Directorate	Yes	
Mr Vernon Long	Consultant Ophthalmologist	Yes	
Mrs Claire M Ramsden	Health visitor	Yes	
Dr Jinous Tahmassebi	Senior Lecturer and Specialist in Paediatric Dentistry	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Nicola Mallender-Ward	REC Co-ordinator
Mr Marc Neal	Assistant Co-ordinator

Appendix 4-B: Confirmation of Ethical

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds East
Yorkshire and Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 3050108
Facsimile:

12 July 2012

Mr Anastasios Kanatas
Specialist Registar in Oral and Maxillofacial surgery
Leeds Teaching Hospitals NHS Trust
Oral and Maxillofacial Department
Leeds General Infirmary
Great George Street
LS1 3EX

Dear Mr Kanatas

Study title:	**Further development of the Breast cancer specific Patient Concerns Inventory (PCI)**
REC reference:	**12/YH/0215**
Protocol number:	**N/A**

Thank you for your letter of 08 July 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to

Appendix 4-C: Permission Letter 1

The Leeds Teaching Hospitals NHS
NHS Trust

Ref: Clare Mclernon

19/10/2011

Research & Development
Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 2878
Fax: 0113 392 6397

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

Dr Anastasios Kanatas
Oral and Maxillofacial Department
Leeds General Infirmary
Leeds
LS1 3EX

Dear Dr Kanatas

Re: NHS Permission at LTHT for: Development of a breast cancer specific patients concerns inventory
LTHT R&D Number: GS11/9766

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/sites/research_and_development/.

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust

only accepts liability for research activity that has been managerially approved by the R&D Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as investigator and the researchers listed on the Site Specific Information form. Should there be any changes to the research team please ensure that you inform the R&D Department and that s/he obtains an appropriate contract, or letter of access, with the Trust if required.

Yours sincerely

Dr D R Norfolk
Associate Director of R&D

Approved documents
The documents reviewed and approved are listed as follows

Document	*Version*	*Date of document*
NHS R&D Form	3.1	09.06.11
SSI Form	3.1	06.10.11
Directorate Approval		28.09.11
Protocol	1.1	Undated
REC Letter confirming favourable opinion		25.07.11
Study reply slip (phase 1)	1.1	Undated
GP letter	1.1	Undated
Patient information sheet (REC Approved)	1.1	16.06.11
Consent form (REC Approved)	1.1	16.06.11
Questions to clinicians	1.1	Undated
Study reply slip (phase 2)	1.1	Undated
Sociodemographic data	1.1	Undated
Clinical background information sheet	1.1	Undated
Consent form (clinical staff)	1.1	Undated
Consent form (audio)	1.1	Undated
Consent form (phase 1)	1.1	Undated
Consent form (phase 2)	1.1	Undated
Study info sheet (phase 1)	1.1	Undated
Study info sheet (phase 2)	1.1	Undated
Questionnaire EORTC C30 BR23 module		Undated
Referees/Scientific Critique Report		08.03.11

Appendix 4-D: Permission Letter 2

The Leeds Teaching Hospitals
NHS Trust

Research & Development

Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 2878
Fax: 0113 392 6397

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

29/08/2012

Dr Anastasios Kanatas
Department of Oral & Maxillofacial Surgery
Leeds General Infirmary
LS2 9JX

Dear Dr Kanatas

Re: **NHS Permission at LTHT for: 'The Further Development of the breast cancer specific PGI-**
LTHT R&D Number: GS12/10222
REC: 12/YH/0215

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/sites/research_and_development/.

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval .

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme