UNIVERSITY OF SOUTHAMPTON

Providers and recipients of breast cancer follow-up: addressing needs and optimising service delivery

Emma Pennery, RGN, MSc

Submitted for the degree of Doctor of Philosophy

School of Nursing and Midwifery
Faculty of Medicine, Health and Biological Sciences

01/06/2005

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF MEDICINE, HEALTH AND BIOLOGICAL SCIENCES
SCHOOL OF NURSING AND MIDWIFERY

Doctor of Philosophy

PROVIDERS & RECIPIENTS OF BREAST CANCER FOLLOW-UP: ADDRESSING NEEDS & OPTIMISING SERVICE DELIVERY

By Emma Pennery

Increasing numbers of people attend follow-up after treatment for breast cancer. This constitutes a significant workload and involves costly and time-consuming procedures with questionable, undefined efficacy. Conflicting opinions exist among professionals with regard to the duration and purpose of follow-up. Breast cancer can be conceptualised as a chronic disease where people have multiple needs that change over time. Nevertheless, the current system is traditionally routinised and lacks an individualised approach. There is no evidence that the practice of follow-up is associated with a more favourable prognosis or improved well-being and very little data exist on its effects on health related quality of life.

Opportunities for change lie in formulating a more effective intervention. There were three phases to this study, using multiple methods. The first phase ascertains women's perceptions of follow-up care using semi-structured, taped interviews and qualitative analysis. The second phase describes a focus group held with doctors who regularly provide follow-up to explore and describe their views. The third phase consists of a randomised-controlled trial designed to establish the benefits resulting from nurse-led or medical follow-up. The findings contribute to knowledge of caring for people attending for breast cancer follow-up in several ways. Firstly by eliciting the views of users and providers to ensure compatibility between their collective needs and perceptions. Secondly by clearly identifying specific areas requiring improvement. Thirdly by making recommendations for future research as well as restructuring of breast cancer follow-up to facilitate optimum care in the future.

Providers and recipients of breast cancer follow-up: addressing needs and optimising service delivery

List of Contents

Page numbers

List of Figures & Graphs

Page numbers

List of Tables

Page numbers

List of Appendices

ACKNOWLEDGEMENTS

My very deep and sincere thanks go firstly to Professor Jessica Corner. Jessica is an inspiring and truly motivational supervisor and has hung in there with me through thick and thin, self doubt, evasiveness and many work related trials and tribulations over the last eight years.

Professor Sian Maslin-Prothero arrived later on the supervisor scene but what a contribution she made. I really enjoyed her style and approach and she probably doesn't realise how much of an influence she had on me carrying on at times of doubt, as well as her practical and logistical input that was quite invaluable.

Doctor Jane Mallett was instrumental in getting the whole project going and her knowledge in areas such as submitting to research ethics committees was inestimable, as was her excellent editorial eye.

Jo Havilland contributed her knowledge of statistics with patience, humour and kindness. This was one area I really could not have done without her input.

Mr Gerald Gui advised and encouraged and graciously entrusted his patients to my care.

My team of clinical nurse specialist colleagues, who I also regard as friends, supported me, advised me, covered for me, and I will always treasure my memories of working along side them. Thank you Sheila, Margaret, Betti, Gay, Sheena, Laura, Angie, Lisa, Charmaine, Suzannah and Mary.

My adorable husband Tony has given me practical, emotional, financial and intellectual support for so many years, has never once doubted I would succeed and is unfailingly proud of me even when I am less proud of myself.

And finally my patients. I have cared for literally thousands of women and men with breast cancer over the years. I remember many of them and their loved ones intimately and thank them for letting me into their lives. Jo, Emma, Lee and Heidi specifically, we shared more laughter than tears and I miss you.

Definitions and Abbreviations

Primary breast cancer: cancer originating in and confined to the breast, with no spread elsewhere in surrounding tissues or within the body

Secondary breast cancer: breast cancer that has spread to other parts of the body

Metastases: the name given to cancer cells that have migrated from the original local site and have spread to other parts of the body

Follow-up: a system of routine hospital surveillance commenced after treatment for breast cancer, the primary purpose being to monitor recovery and to check for signs and symptoms of recurrent disease

Clinical Nurse Specialist (CNS): experienced nurses who have developed specialist knowledge within a chosen clinical area

Nurse Practitioner (NP): a nursing role that involves expansion of nursing tasks especially related to domains traditionally regarded as medical, such as cannulation and taking biopsies

Advanced Nurse Practitioner (ANP): an umbrella title that encompasses within it the roles of Clinical Nurse Specialists (CNS), Nurse Practitioners (NP) and Nurse Consultants (NC)

Chapter 1. SETTING THE SCENE

1.1 Introduction

As a senior clinical nurse specialist working in breast cancer care for nearly fifteen years I have noticed discrepancies in the quality, frequency and depth of care given to women (and men[1]) with breast cancer at different times during their progress through diagnosis, treatment and after care. Much of the emphasis of care delivery for people with breast cancer remains on the impact of the diagnosis and coping with subsequent treatment modalities, such as surgery, chemotherapy and radiotherapy. It became apparent to me that much less attention is paid to the longer-term needs of breast cancer survivors (those that remain free of recurrent disease) over the months and years after finishing treatment. It is standard practice in the United Kingdom that, following completion of the various treatments, women (and the small number of men) diagnosed with breast cancer are entered into a system of routine surveillance, known as 'follow-up care'. This involves visits to the hospital outpatient department, which lessen in frequency as time progresses. The purpose is to monitor each woman's recovery and to check for signs and symptoms that might herald recurrent disease that has not been eradicated by the treatment.

However provision of follow-up has proven increasingly problematic over recent years, not least because the number of women receiving this care is substantially increasing. This is because ongoing advancements in medical knowledge and more effective treatments have enabled detection of the disease at an earlier stage for the majority and an improved likelihood of survival from breast cancer compared to twenty or thirty years ago. Consequently more women attend follow-up for longer periods of time, resulting in a greater demand for rationalisation and cost-effective use of resources as hospitals struggle to cope with the burden that this area of care engenders. In my experience breast cancer follow-up clinics have come to represent an unsatisfactory area of care for women, doctors and specialist nurses. Women have

---

[1] Whilst breast cancer predominantly occurs in women, approximately 250 men are also diagnosed with the disease in the UK each year. This thesis refers to women with breast cancer throughout, but it is recognised that many of the issues discussed will also affect men. Optimum care for people with breast cancer will always ensure the needs of men and women are considered and there is no intention to imply the needs of males with breast cancer are any less significant.

expressed that the clinics are impersonal and hurried. I have frequently heard doctors lamenting about the monotony of follow-up consultations and about how time consuming they have become. As a specialist nurse I have also struggled with the time involved in attending such clinics (there were sixteen such clinics a week in the hospital in which this study took place). Furthermore, I have experienced an increasing sense of impotency because my input with women in this setting is inevitably brief (or omitted altogether) for many because of competing demands, such as the necessity to see women receiving bad news when newly diagnosed with primary or secondary breast cancer.

In recent years doubts have emerged about the clinical effectiveness of the current follow-up system (Heys et al 2005) and its impact for the women attending, specifically in terms of improved outcome (prognosis and quality of life), is highly controversial. Yet ongoing concerns about the possibility of the breast cancer recurring and ongoing morbidity arising from treatments may remain a reality for women for months or years after treatment has ended. In light of this I have retained an assertion that breast cancer follow-up is an important and necessary aspect of care. Such clinics, if appropriately conceived and delivered, could be instrumental in enhancing women's ability to recover from the experience of breast cancer and also prove rewarding and worthwhile for health professionals providing this service.

I wanted, therefore to undertake a study that represented a detailed analysis of the practice of breast cancer follow-up from the perspectives of the women who attend and the doctors who deliver it. As well as considering the quite different perspectives of these two groups, it seemed pertinent to also evaluate delivery of breast cancer follow-up provided by a specialist nurse (myself), in comparison to doctors, with a view to highlighting if there are any ways in which the experiences of people requiring such care and the professionals delivering such care could be improved in the future.

1.2 Research Questions

The specific questions posed by the researcher were:

1) What are the pros, cons and essential facets of routine follow-up care initiated after completion of adjuvant treatment for breast cancer, from the perspective of:
    a) The women who attend?
    b) The doctors who provide it?
2) What are the disadvantages and the benefits to individual quality of life and satisfaction with care resulting from nurse-led or traditional medical breast cancer follow-up?

The three studies described in this thesis address these questions, thus enabling ideas for alternative strategies of breast cancer follow-up to be presented that are responsive to the key issues raised by women and health professionals and the finite resources available.

1.3 Outline of the thesis

The thesis is comprised of a further ten chapters. Literature is presented within Chapters 2 to 4 on the perceptions and needs of women who survive breast cancer, the clinical efficacy and value of routine breast cancer follow-up, extended nursing roles and therapeutic relationships. Thus the case is made for the necessity of maintaining some model of breast cancer follow-up provision, of rethinking the current biomedical focus of follow-up and of the hypothetical merits of follow-up being undertaken by specialist nurses. Chapters 5 to 10 present three consecutive studies comprising the three phases of the thesis. Chapter 5 presents an overview of the study design and overall aims. Chapter 6 describes the research design and the paradigmatic underpinning of this approach for the first two studies that explore current follow-up practices. Interviews were conducted with women who attend for routine breast cancer follow-up and a focus group was held with doctors who regularly conduct breast cancer follow-up consultations. Chapter 7 presents the results of these two qualitative studies, which together enable identification of parity and divergence between the views of providers and users of breast cancer follow-up and gaps in care (as perceived by both parties). Chapter 8 describes the preparation and training undertaken in order to establish nurse-led provision of breast cancer follow-up. Chapters 9 and 10 outline the design, paradigmatic underpinning and the results of the final phase, a randomised controlled trial designed to compare provision of follow-up by specialist nurses and doctors in terms of quality of life and satisfaction as reported by the users. Finally, Chapter 11 discusses the findings of all three phases in conjunction with each other, highlighting the contribution of the work to new knowledge. Conclusions are drawn, recommendations made and suggestions for further research are put forward.

1.4 The search strategy for gathering literature

Chapters 2 to 4 provide background information with a review of literature that serves to explore issues that are pertinent to the research questions and to demonstrate the context and relevance of this work to the provision of follow-up care. For each of these chapters a critical review of the literature was deemed essential for the researcher to uncover existing conceptual knowledge in relation to breast cancer follow-up, to determine gaps, consistencies and inconsistencies, and to reveal unanswered questions. The chapters represent a broad and in depth (although inevitably not exhaustive) review and evaluation of published and unpublished material. In this respect, the review represents an attempt at cataloguing pertinent research rather than a systematic review or an assignment of quality scores exercise.

Key search domains were generated with the purpose of refining the search parameters and the literature gathered was divided into three groups (see Table 1.1).

Table 1.1 Key search domains and search terms applied

Search Domain & Grouping	Search terms (applied alone and in combination)
1. Surviving (breast) cancer and ongoing needs	Cancer, breast cancer, survivorship, chronic illness, needs, rehabilitation, follow-up, treatment effects,
2. Clinical efficacy of (breast) cancer follow-up	Cancer, breast cancer, follow-up, surveillance, detection, recurrence, metastasis, symptoms, advanced disease, investigations,
3. Advanced nursing practice and nurse-led follow-up	Nurse-led, extended roles, advanced practice, clinical nurse specialists, nurse practitioners, nurse consultants, follow-up, cancer, breast cancer

The first group covered issues regarding surviving cancer and specifically breast cancer and the ongoing needs for women that this might generate. This was important to expose current knowledge on the experience of living after breast cancer treatment and the ethos of this population of women. The second group pertained to the clinical efficacy of breast cancer follow-up and thus the potential flaws of the conventional model of delivery. This was relevant to appraise current thinking on the traditional biomedical approaches to breast cancer surveillance. The third group related to the advantages and disadvantages of extending and expanding nursing practice and the potential for nurses to deliver breast cancer follow-up. This was relevant to consideration of the possibility of follow-up being undertaken by health professionals other than doctors. Inevitably some overlap between groups was noted and hence some papers are cited in more than one chapter but with reference to different issues each time. The numbers and authorship of the papers included for each group is presented in the relevant chapters.

Initially searches were conducted on established databases such as the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Medical Literature Analysis and Retrieval System On Line (MEDLINE). A further database used was The Cochrane Library, an established and respected resource for information on the effectiveness of healthcare interventions and contains multiple systematic reviews. A systematic review is a comprehensive, unbiased, objective and reliable search of primary studies (Forward and Hobby 2002), which contains an explicit statement of objectives, materials and methods. Such reviews enable results from different studies to be compared to establish generalizability and consistency of findings (lack of heterogeneity) (Greenhalgh 1997). The key advantage of systematic reviews is their objectivity, in that they avoid the researcher finding out what they believe the answer ought to be. A systematic review of follow-up strategies for women treated for early breast cancer was not performed as two such systematic reviews were already available, those conducted by the Cochrane Review group (Cochrane Library 2001), and the American Society of Clinical Oncology (ASCO) (Smith et al 1999). It was therefore considered unnecessary and poor use of time to repeat the same analysis. These systematic reviews together included searches on MEDLINE from January 1975 to September 1999, EMBASE from January 1988 to September 1999, the Cochrane Controlled Trials register, the Breast Cancer Groups Specialised Register and the National Surgical Adjuvant Breast and Bowel Project (NSABP) collaborative research group register. Search words included ‘breast’, neoplasms’, ‘follow-up’ and ‘surveillance’. Both reviews report on randomised controlled trials assessing the effectiveness of different policies of follow-up after primary treatment for breast cancer.

The critical review was necessarily selective and included work that underpinned the approach and clinical focus of this study. Searches were made from 1980 to present day (2005) to capture the last twenty years. Earlier work was not included unless considered seminal and authoritative. Only articles published in English were obtained. Reference lists from work accessed were also checked for additional relevant citations. Initially abstracts of all the literature sources identified in the search were reviewed to elicit the usefulness of each paper in turn. Full copies were then obtained and reviewed of all papers deemed relevant to the search parameters and any for which the abstract was not clear enough to determine overall relevance. All material gathered was then critically analysed and scrutinised for flaws in their design that could threaten internal and external validity. An informal checklist was used including items such as whether methods are presented clearly; whether the research design is appropriate with a clear account of the sampling and analysis processes; whether the findings are presented comprehensively and clearly; the extent of generalisability and the likelihood of random errors. Following this a final decision was made regarding which papers to retain and include in the review. During the analysis themes were noted as they appeared.

The literature presented in the following three chapters establishes the necessity for undertaking further research in the area of breast cancer follow-up, for drawing on the experiences of women who attend and doctors that provide follow-up and for considering alternative health care professionals and strategies that might improve service delivery within this complex and arguably necessary area of care.

Chapter 2. LIFE AFTER BREAST CANCER

2.1 Introduction

This chapter places follow-up within the context of the journey that women (and men) with breast cancer travel through. Prior to consideration of the clinical and technical aspects of follow-up, the focus is the recipient of care and their experiences of life after treatment for breast cancer. This is seen as a crucial starting point to appreciate what the experience of life after breast cancer may mean for women because this will inevitably influence their expectations and needs during follow-up. Thus the concepts of survivorship and chronic illness are explored in the context of living after a diagnosis of breast cancer and women are also considered in terms of their potential ongoing physical, emotional, informational, social and spiritual needs at this time. As a specialist nurse I wanted to learn what was good and bad about the system within which I worked and to understand the nature of any gaps in care that failed to successfully meet the needs of women.

For this section of the review 133 citations were accessed, of which 126 appear in the review. The remaining work was excluded because the content were deemed irrelevant to the focus of the review or because they represented repetition of material already retrieved. The literature used dates between 1977 and 2003. They originate from the United States of America, Canada, Australia, the United Kingdom and Europe. The material reported is derived mainly from literature reviews, government reports and papers, editorials, commentaries, and unpublished academic work. (88 citations). These have not been presented in a table because of their largely descriptive nature which means they do not conform to the subheadings on typical evidence tables (that is they do not include samples or lack specific outcome measures). Research studies, including randomised controlled trials, prospective research studies and retrospective audits represented the minority of the material found (38 in total) and 21 of these, with their countries of origin, are presented in appendix A. The remaining seventeen either applied to experiences of life after a variety of cancers and were omitted from the table because of their lack of breast cancer specific focus or were largely repetitions of another paper (the same authors published in another journal) and so were also omitted to avoid repetitiveness. Papers appearing in appendix A have been allocated a corresponding number within the text to allow the reader to cross-reference accordingly. Of note the lead authors are from a variety of clinical backgrounds, including doctors, nurses, psychologists, sociologists and lay people who have had a diagnosis of cancer themselves and have written about their experiences.

Breast cancer remains the most commonly occurring cancer in women worldwide and it is estimated that one woman in 9 will develop breast cancer at some time in her life. This represents 40,470 newly diagnosed cases in the United Kingdom every year (Cancer Research UK 2004). But whilst incidence rates continue to rise, death rates are decreasing (McPherson et al 2000), resulting in an ever increasing population of survivors and a resultant worsening socio-economic burden from the disease (Tomiak and Piccart 1993). On average 74-84 percent of those diagnosed with breast cancer will survive at least five years, and overall five year survival has increased from just 52% in 1975 to 77% in 2002 (Cancer Research UK 2004).

Treatment for primary breast cancer involves various combinations of surgery, chemotherapy, radiotherapy and endocrine therapy, depending on the disease type and variables and the individual's wishes. Most women will undergo several of these treatments and many will have all four (Fisher et al 2001). On completion of treatment (with the exception of ongoing endocrine therapy such as Tamoxifen, as this is taken for a further five years), women are deemed disease free and commence a schedule of monitoring and routine surveillance known as follow-up care. This involves clinic visits for a check-up, usually by a doctor, within the hospital outpatient department, which lessen in frequency as time progresses. The consultation consists of a brief history taking and a clinical examination, with the purpose of monitoring each woman's recovery and checking for signs and symptoms that might herald recurring disease that has not been eradicated by treatment.

An appreciation of the profound and evolving needs resulting from breast cancer and its treatment is essential when planning optimum care of women for prolonged periods of time in the follow-up setting. Women can continue to experience multi-dimensional problems, even years after treatment has been completed and this has implications for the duration that hospital follow-up visits should last. It also raises the question as to how follow-up schedules can best address these problems. Government policy suggests ceasing follow-up surveillance sooner than ever, but notably only on the grounds of the poor likelihood of clinical efficacy over time, rather than on the individual needs of those who attend. The National Institute of Clinical Excellence (NICE 2002) recently produced the updated document on breast cancer service guidance (after this study was planned and executed). It reiterates that long-term follow-up has not been shown to offer any *clinical* benefit to women and thus check ups should continue for only two to three years (except if clinical trial protocols require longer). Such proposals for breast cancer follow-up pay scant attention to detailing what women may want and need at this time and there is little evidence on effective and appropriate strategies for meeting need. The increase in the sheer numbers of women joining follow-up schedules each year, coupled with shorter periods of professional input over time, renders the success of the current system, in terms of delivering best care to women, debatable and highlights the necessity for re-examination of current surveillance practices (Heys et al 2005).

During discussions with the women in my clinical practice I noted their common belief that the current system poorly addressed need and retained a largely medical focus, that is the purpose of detecting new disease. All too often women commented that other areas of need, such as addressing anxieties and coping with the ongoing effects of cancer treatments were negated. Furthermore many of the women noted the increasing size and workload of follow-up clinics and made reference to the 'cattle market' ethos surrounding them. Inevitably, ensuring any model of follow-up care is designed to focus on the needs of the women who access it necessitates a sound appreciation of what those needs actually are. The following literature attempts to elicit the potential needs of women who receive breast cancer follow-up.

2.2 Cancer Survivorship

Cancer survivorship is a concept that encompasses the multi-dimensional aspects of quality of life and the experiences that follow cancer (good and bad) for those who remain free of recurrent disease. It is important that health care professionals do not assume that the individual has returned to normal, with no subsequent needs, because their cancer treatment has been successful. It is increasingly being recognised that living longer after cancer does not necessarily mean living better (Dow 1992) and affected individuals can be surviving without necessarily also thriving (Hassey-Dow 1990).

Continuing, and often unremitting, uncertainty regarding future development of disease is the overriding concern in the majority of people after treatment for cancer. Literature indicates that breast cancer survivorship is dominated by fear of the possibility of the disease returning (and ultimately proving fatal) and this can persist long after completion of adjuvant treatment, becoming almost a way of life for some (Welch-McCaffrey et al 1989, Carter 1993, Ferrans 1994[5], Palsson and Norberg 1995). Such fears are not necessarily irrational as breast cancer can recur locally or systemically many years after treatment and figures suggest that it will, at some point sooner or later, in up to half of all women who are diagnosed with the disease (Smith and de Boer 2000).

Uncertainty, at least to some degree, about potentially disastrous and poorly predictable future health after breast cancer is almost universal and the ambiguity regarding outcome can, consequentially, become a disruptive force to one's coping (Northouse 1981[15], Hilton 1988, Gaudine et al 2003), leading to intense vulnerability. It might be supposed that the severity of uncertainty and fear of recurrence an individual experiences would be linked to prognosis. Nevertheless Northhouse (1981)[15] in attempting to determine the relationship between significant others and fear of recurrent disease, did not find evidence to support this supposition. Instead they exposed a strong relationship between significant others and fear of recurrence, in that those with fewer significant others had greater fears, whilst those with more significant others had the least fears. This was especially so when the significant others were perceived by the women as people who understood their health concerns and fears. In this study significant others proved to be the only determinant of the magnitude of fear. Interestingly age, marital status, extent of disease, type of treatments, and the amount of time elapsed since treatment were all unrelated to significantly fearing recurrent disease.

Uncertainty commonly manifests itself as an over preoccupation with any physical symptoms experienced, no matter how routine (Ferrans 1994)[5]. Morse et al (1995) eloquently adopt the term the 'deceiving body' to encapsulate the idea of a body that is outwardly in normal health but may contain asymptomatic disease progressing silently. In the absence of pain or symptoms its presence is unknown for some time and may only be detected too late, in that breast cancer that has spread to other parts of the body is no longer curable. If and when recurrence is detected the person may perceive their body has deceived them in some way, such that the trust in their own bodies is lost. Clearly if women lose trust in themselves, they are more likely to seek out investigations to reassure themselves that all is well. But sadly the irony with this is that the biomedical and scientific imaging (discussed in chapter 3) which aims to 'transcend this hidden aspect of disease is', of course, not entirely reliable (Fosket 2000 p28).

This provides some explanation of the overwhelming, sometimes irrational, need of women for reassurance. Cancer, it has been proposed, with its precarious prognosis and unpredictable course, generates uncertainty, making it an inextricable part of surviving the disease (Molleman et al 1984). Uncertainty is recognised as contributing to poor coping, and people who are finding coping difficult will naturally seek reassurance, notably from perceived experts in the field. In a study of the significance of their relationship with doctors to coping, people with cancer (n=418), reported that contact with experts was perceived as the only effective means of reducing uncertainty about the cancer and its after effects (Molleman et al 1984). However replication of this study now might elicit different findings because of vastly improved patient information and wide spread access to knowledge and opinion via the Internet.

Interestingly, predominant concerns for the individuals affected, may be the ones they are most reluctant to share with their health care professionals. A study of 77 women diagnosed with breast cancer (Pistrang and Barker 1992) explored whom they turned to for emotional support and the nature of these interactions with regards to what concerns they disclosed. Women were, predictably, most concerned about the uncertainty of recurrence and related thoughts about death and dying. The concerns that were of least priority were those relating to appearance and desirability. Yet, the most significant concerns transpired to be also those ones that the women talked about the least, whilst less significant ones were commonly broached. This implies that some issues are seen as more threatening or less socially acceptable and hence these topics are more commonly avoided. Another reason cited for failing to disclose key concerns is a reluctance to see significant others suffering, especially as emotional pain reflected on the faces of others accentuates the reality of the situation for the individual as well. This desire to protect loved ones inadvertently distances the individual affected by cancer and so heightens their isolation (Dewar and Morse 1995). Women may also withhold concerns from health care professionals, fearful that they will take up too much time or appear ungrateful by raising problems (Leigh 1992). This is a salient point for the professional providing breast cancer follow-up because their skills in facilitating the recipient to communicate key issues is likely to impact on their overall wellbeing.

Of note, the experience of surviving breast cancer can also be perceived as a positive occurrence. Many women have the potential to gain valuable strengths from their experiences, finding they are able to make positive life changes as a direct result. Some studies report women stating that subsequent to their diagnosis of breast cancer, they value everyday people and activities much more (Wyatt et al 1993[20], Ferrell et al 1995, Ruff Dirksen 1995). Positive attitudes also derive from an appreciation of being alive, decreased concern for trivial matters and a heightened appreciation of family members and loved ones (Cella 1987, Carter 1993, Ferrans 1994[5]).

Cancer (and breast cancer) has recently been more commonly categorised as chronic disease, because in many ways it has taken on the fundamental characteristics of a chronic illness. These include unpredictable trajectories, long term duration, uncertain remission times, an ever-present possibility of recurrence, the potential to be disabling and stigmatising, and profound, ongoing effects on the sufferer (Chekryn 1984, Faithfull 1994, Leigh 1994, Smyth et al 1995, Department of Health 2001a). Bury (1991) distinguishes between the meaning of illness (and treatment) for the individual in terms of consequences and significance. Consequences encompass the effects of breast cancer such as ongoing symptoms and side effects. Significance relates to personal connotations and imagery and encompasses how an individual regards themselves and how they think others see them. For example a woman with breast cancer care might perceive (real or imagined) that family and friends behave differently towards her as a result of her illness experience or her uncertain future.

Thus chronicity suggests the interplay of individual emotional, physical, social, spiritual and informational needs and these may change over time and will not remain static. There is clearly a need to understand the impact of breast cancer on all aspects of wellbeing and how this may affect longer-term psychosocial adjustment (Irvine et al 1991). Of note, current models of breast cancer follow-up are designed to monitor for recurrent disease, rather than to facilitate individual survivors to live optimally after treatment, that is to manage, mitigate or adapt to chronic illness by addressing their key needs as outlined below.

2.3 Ongoing needs after treatment for breast cancer

Numerous studies exploring the experience of surviving breast cancer and the potential needs that this engenders document similar recurring themes, as reported by the women affected. These can be broadly categorised into emotional, physical, social, spiritual and informational.

One definition of needs is that they represent deficits, which when fulfilled, achieves a goal. Problems may exist for an individual when for some reason, they cannot meet their needs (Clarke 1990a). Thus the emotional, physical, social, spiritual and informational needs of women would need to be met in order to avoid problems developing in these areas of care. Similarly a need can also be defined as a want (Concise Oxford Dictionary 1996), implying that in order to fully meet the needs of women attending follow-up after treatment for breast cancer, it is essential that what they want from it is accurately determined.

Even when deemed in remission, women continue to face problems arising from the chronic nature of breast cancer long after the initial diagnosis and completion of therapy (Northouse 1981[15], Ferrans 1994[5]). Knowledge and awareness of these problems are specifically relevant to provision of care at the time of follow-up because if left unmet, ongoing needs are likely to hinder adequate coping and recovery by women. Coping is defined as constantly changing cognitive and behavioural efforts to manage specific demands that are appraised as exceeding the resources of that person (Lazarus and Folkman 1984 p141). Bury (1991) offers a definition of coping in the context of chronic illness as the 'cognitive processes whereby the individual learns how to tolerate or put up with the effects of that illness' (p460). Hence it follows that failure to address the needs of women with breast cancer will result in their reduced ability to cope with its consequences.

Emotional needs (as explained previously) include fear of recurrence and death and living with uncertainty, feelings of injustice and anger, depression, loss of control over life and increased health worries (real or imagined) (Chekryn 1984, Welch-McCaffrey et al 1989, Dow 1992, Fredette 1995[7]). Survivors may also continue to experience anxiety (specifically related to their cancer) similar to post traumatic stress disorder, and characterised by flashbacks (Cella 1987, Carter 1993, Allen 2002).

Unfortunately evidence from the literature indicates that the emotional needs of women are not being met after completion of treatment for breast cancer. In fact the prevalence of emotional morbidity is estimated to be as high as 20 to 30 percent at two years post diagnosis (Wolberg et al 1989[19], Maguire 1994) and it has been suggested that emotional needs may be associated with long term anxiety or depression (Irvine et al 1991, Palsson and Norberg 1995). Women have admitted to feeling angry and significantly less attractive or feminine (Tilden and Weinert 1987, Irvine et al 1991). They also report experiencing problems with sexual and social relationships, disruption to their quality of life, and loss of role (Morris et al 1977, Northouse and Swain 1987, Kemeny et al 1988[10]). The mere existence of these problems highlights the necessity for remodelling current breast cancer follow-up so that in the future women can be engaged in a system of care that adequately addresses their needs.

It has been proposed that the severity of emotional morbidity sustained may well be affected by the extent of surgery that women undergo. When comparing women who undergo mastectomy with those who have surgery conserving the breast (such as a lumpectomy or wide local excision), the former recount higher levels of anxiety about the disease returning. They feel less attractive, experience difficulties in sexual relations and with clothing and greater loss of body image integrity (Steinberg et al 1985, Kemeny et al 1988[10], Ganz et al 1991[8], Rijken et al 1995[16]). These are the likely ramifications of undergoing mastectomy in a culture that is so image conscious. However, of note, two of these studies (Kemeny et al 1988 and Ganz et al 1991) found no statistically significant differences between quality of life and performance status overall between the two groups studied (women having mastectomy versus breast conservation surgery), implying women will not necessarily experience improved quality of life because they have not suffered the loss of their breast. In addition, improved technical ability and availability of breast reconstruction surgery might have an impact on these findings if similar studies were replicated today.

Breast cancer will inevitably impact on physical well-being and evidence from the literature supports the notion that women also have unresolved physical symptoms, largely arising from treatments rather than from the cancer itself (Hassey-Dow 1995, Ferrell et al 1997[6], Burstein and Winer 2000). Indeed, Bury (1991) makes the point that treatments can equally become part of the problem as well as part of the solution. A significant symptom is pain, secondary to surgery and/or radiotherapy in the breast and axilla, which is frequently neuropathic in nature. Adverse effects of treatments cause approximately 15 to 20% of chronic pain problems experienced after cancer (Ferrans 1994[5]) and breast cancer is no exception. Alarmingly some studies suggest that pain effects as many as 47% of women with breast cancer, to some extent, over time (Miaskowski and Dibble 1995). The failure of doctors to acknowledge, assess or manage pain effectively is highlighted by Ferrans (1994)[5]. Correct assessment and effective management is immensely important, not least because women place great importance on staying active and having a purpose in life (Northouse 1981, Ferrell et al 1995)[15], which, along with functional quality of life, will inevitably be hindered by chronic pain (Caffo et al 2003)[2].

Cancer related fatigue is also widely reported in the literature and women with breast cancer are no exception to this (Blesch et al 1991, Ferrell et al 1997)[6]. A consistent relationship between undergoing breast cancer treatments (surgery, chemotherapy, radiotherapy and hormone therapy) and development of fatigue has been demonstrated (for example Greenberg et al 1992, Stanton and Sneider 1993, Mast 1998, del Mastro et al 2002). Haghighat et al (2003)[9] prospectively investigated factors predicting fatigue in women with breast cancer and discovered 49% of their sample of 112 participants experienced fatigue and the strongest predicting factors were depression, pain, current tamoxifen usage, anxiety and undergoing mastectomy. This suggests that fatigue is multidimensional, with physical and psychological factors influencing onset of cancer related fatigue as much as treatment side effects. Hence interventions are relevant to introduce in follow-up consultations where attention can be placed on, for example, emotional needs and pain relief, as well as on minimising the side effects of treatments.

Women treated for breast cancer are also at risk of developing lymphoedema, either in the limb or the breast or chest wall. Lymphoedema is a chronic, high-protein tissue swelling (Bianchi and Todd 2000) that results from damage to the lymphatic system at the axillary glands caused by surgery, radiotherapy or axillary disease. It results in swelling in the arm and hand that can impair movement and function (Tobin et al 1993) as well as interfering with body image integrity. It is considered a chronic condition that a woman can live with for many years and as such its presence can cause a variety of psychological and psychosocial problems as well as physical and functional difficulties (Woods 2004). Lymphoedema can occur months or years after completion of treatment for breast cancer and is more responsive to treatment if interventions begin at an early stage (Woods 2003) so it is essential that any schedules of follow-up care enable women to recognise early symptoms and facilitate prompt referral for management. The potential for longer term onset of symptoms after treatment for breast cancer become particularly pertinent if the duration of breast cancer follow-up shortens, as the majority of women may not develop the problems until after being discharged from follow-up clinics at two years.

Menopausal symptoms secondary to chemotherapy and endocrine therapy for breast cancer induced ovarian malfunction are widely reported in the literature (Nagamani et al 1987, Love et al 1991[12], Vassilopoulou-Sellin and Zolinski 1992[18], Demark-Wahnefried et al 1993, Carpenter et al 1997, Mortimer et al 1999). The menopause is defined as ovarian failure accompanied by oestrogen deficiency resulting in permanent cessation of monthly menstruation and loss of reproductive function (Utian 1999). It can occur naturally in women between the ages of 45 and 55 years, but can also be induced by chemotherapy. Chemotherapy can stop the follicles within a woman's ovaries growing and maturing, which in turn reduces the amount of the female hormone oestrogen in the body, leading to complete absence of eggs (ova) or smaller numbers of eggs overall. If this dysfunction occurs, the periods may become irregular or may eventually stop (amenorrhea), causing temporary or permanent infertility. Loss of menstruation may happen a few months after treatment is completed. Conversely function may take a few months (even up to two years) to return after treatment. Even when periods recover after completion of the cancer treatment, the menopause may occur at a younger age than usual.

Any woman who is found to have a tumour that contains cells with the ability to bind to oestrogen or progesterone will also be offered endocrine treatment (Fisher et al

2001). Endocrine therapies used in the treatment of breast cancer (such as Tamoxifen and Anastrazole) do not induce menopause in the way that chemotherapy does but as antagonists (acting in opposition) to oestrogen, they can also cause side effects that mimic menopause and oestrogen deprivation (such as hot flushes) irrespective of the age or previous menopausal status of the woman taking them.

The documented menopausal experiences of women undergoing breast cancer treatments include an alarming array of problems such as hot flushes, vaginal dryness, irregular menstruation, weight gain, dry, thinning hair, dyspareunia (difficult or painful sexual intercourse) and decreased libido (Carpenter and Andrykowski 1999[3]). Such effects are commonly worse for women whose menopause is induced by cancer treatments than in those who undergo a naturally occurring menopause (Young-McCaughan 1996[21], Loprinzi et al 2000[11]). However the prevalence of these and the meaning for the women concerned is poorly described. Coinciding with amenorrhoea, women also lose their ability to produce viable ovum (eggs) so inducing menopause also inevitably impacts on fertility and causes reproductive system changes in younger women (Hassey-Dow et al 1994, Ferrell et al 1997[6]). These authors remind us that attention to these key issues should be an integral part of follow-up care and should not be sacrificed by focussing only on the clinical examination of the breast.

Similarly, women may need reminding about the longer-term side effects of chemotherapy, which can be very alarming, especially if some time has elapsed and the patient fails to associate them with her treatment. An example of this includes irregular menstruation. In premenopausal women, the periods may become irregular or stop temporarily or permanently during and after treatment. Initial cessation of function may not necessarily indicate treatment induced menopause because menstruation can return up to two years after completion of treatment. Chemotherapy induced ovarian failure and use of aromatase inhibiting hormone therapies also cause rapid and significant bone loss, especially in the spine, with implications that breast cancer survivors are at higher risk of osteoporosis (Schapiro et al 2001). Thus follow-up could include information about strategies to counter this and assessment of bone density in high-risk individuals. It is important to recognise how the presence of such symptoms may make a woman feel, that is, to consider what the total symptom experience may be and the personal meanings attributed to it rather than merely the nature of the physical symptoms endured. Failure to recognise which issues are most profoundly affecting a woman's life is likely to curtail the potential to provide meaningful and optimally supportive care.

Several studies document the significant impact of breast cancer on social functioning. They report that women may experience ongoing difficulties with family support, concerns for children, financial difficulties, altered insurance risk status and employment problems (Lewis et al 1985, Northouse 1989, McCaffery 1991, Ferrans 1994[5], Hassey-Dow et al 1996, Abbey 1997).

A qualitative descriptive study evaluating multi-dimensional quality of life in 21 people following treatment concluded that breast cancer has a consequential impact on social and role functioning both at home and in the work setting (Ferrell et al 1997[6]). In this study the area of greatest concern related to the impact of breast cancer on the family, including an intense fear of the risk of daughters developing the disease. Luker et al (1995[13]) also reported that the risk of family members getting breast cancer was the second highest concern to women attending breast cancer follow-up clinics. Clearly women need accurate information about hereditary risk of breast cancer development in their family members, which is actually unlikely to be a concern for most women as the majority of cases are sporadic, with only approximately 5-7% of cases attributable to a germline genetic abnormality (Easton and Peto 1990). Studies indicate that even women who have a known family history of breast cancer and have been exposed to information pertaining to this, inaccurately identify risk to themselves and family members (Evans et al 1993). Information can be crucial for correcting misperceptions and for some women the necessity for referral to genetic risk counselling clinics is evident (Hassey-Dow 1995).

Individuals with long-term health concerns are also at high risk for social isolation as relationships may disintegrate under the stress of chronic illness. Isolationism (feelings of isolation) on the part of the survivor can be self-imposed or may occur as a result of rejection by others. People affected may have concerns about how and when to disclose their diagnosis, and the unpredictable course of breast cancer may prevent some individuals from planning to engage in social activities (Tilden and Weinert 1987), in case future illness will later preclude them. Returning to employment can be seen as an integral part of coping by some because it represents regaining of continuity of daily routine and normality (Fredette 1995[7]). Yet employment discrimination, loss of benefits and stigma in the workplace are documented by cancer survivors (Hassey-Dow 1995), as well as breaches of confidentiality about medical information and an absence of work placed support (Carter 1994).

Spiritual needs experienced by breast cancer survivors revolve around attempts to elicit the meaning of illness, changes in religious convictions and re evaluation of the direction of one's life (Ferrell et al 1997[6]). Some women endeavour to make lifestyle changes as a result of having breast cancer because it provides a sense of control, allowing them to do something for themselves, rather than merely waiting for a recurrence to happen to them. These include reducing stress, taking more exercise, and changing their diets, for example to include more phyto-oestrogens (naturally occurring chemicals derived from plants with a similar molecular structure to oestrogen). Whilst such substances have the potential for anticarcinogenic biological activity and alleviation of vasomotor and other menopause related symptoms, clinical data remains inconclusive and women should always seek advice before commencing such therapies (Ginsburg and Prelevic 2000). Women may also seek out fellow breast cancer survivors, for example through support groups, as comparisons with others may be source of comfort. However this can prove unhelpful if contrasting treatment regimens are discovered but not understood or if the other person develops recurrent disease, thus reminding the woman of her unpredictable future with regards to the cancer (Bury 1991).

A hugely significant issue as expressed by women with breast cancer, and integrated in to their emotional, physical, social and spiritual needs, is the need for adequate information. Over twenty five years ago research studies alluded to women receiving inadequate information about a diagnosis of breast cancer and subsequent treatments and made reference to the 'wall of silence' surrounding many aspects of their clinical care (Morris et al 1977). Evidently things have been slow to improve. A large study of informational needs and sources of information of women (n=105) with breast cancer at the time of diagnosis and a mean of twenty-one months from diagnosis demonstrated that 66 percent had unmet informational needs (Luker et al 1995). In addition, the participants hardly ever saw the consultant and felt uncomfortable contacting the breast care nurse in case their questions were perceived to be inappropriate or trivial (Luker et al 1995). Also of particular relevance was that for women receiving follow-up care the use of professional sources of information was lower than when they were initially diagnosed and over time women had replaced them with information from magazines, television and radio. Presumably this was because professionals were less available to them at this time; indeed these women reported feeling uncomfortable accessing health care professionals for their information needs. This suggests that the traditional model of follow-up care in which doctors monitor the progress of women at infrequent and possibly impersonal hospital clinic appointments is, at least to some extent, failing to address the needs of those who attend. The study concluded that information giving should be seen as an ongoing process and that consideration should be given to individual informational needs according to the patient, rather than the professional's agenda (Luker et al 1995[13]).

Receiving adequate (and accurate) information about their disease and its treatment is an integral part of recovering from breast cancer because women cannot implement effective coping strategies if they perceive they have been inadequately informed (Fallowfield et al 1995, Palsson and Norberg 1995, de Bock et al 2004). DiGiacomo (1987) describes her experiences of treatment for Hodgkin's disease and believes that amidst uncertainty and fear, knowledge is the only kind of power, imposing order and meaning and reducing the fear. When there is a continuous need for support, adjustment and coping are more likely with long term arrangements in place for information provision and counselling (Wilson-Barnett 1988).

Many people with cancer are manifestly unhappy with the amount and manner of information given to them by doctors (Fallowfield et al 1995, Bilodeau and Degner 1996), frequently deeming it fragmented, inaccurate, inappropriate or insufficient (Chalmers et al 1996). It would seem that the delivery of cancer treatment, including follow-up, is unsatisfactory from the consumer's perspective, communication is badly handled, sufferers are not sufficiently informed and care is not sufficiently patient focused (Corner 1996). People also complain of excessive waiting times, lack of continuity of care and insufficient access to experts (National Cancer Alliance 1996). With regards to doctor-patient communication, inadequately informed women, who therefore do not demonstrate knowledge, may actually exacerbate a paternalistic approach by doctors and further raise anxiety (Derdiarian 1986, Mackillop et al 1988, Wong and Bramwell 1992, Suominen et al 1994). Of note, sources of dissatisfaction expressed by users specifically about aspects of the patient-physician communication include a difficulty expressing concerns, that the doctor should listen more to what was said, and that they should tell them more about their individual problems or treatments. Specifically related to follow-up, women have described factors most difficult to endure. These include frustration at a lack of technology that ensures early and accurate detection of the disease, unexplained procedures, health care professionals disbelieving symptoms reported, suspected recurrence after assurances of being cured and lack of information, considered fundamental to regaining some control (Dewar and Morse 1995). In addition being forced to rely on others, the loss of former self (being able to achieve goals) and intractable pain are particularly traumatic and frightening (Dewar and Morse 1995). Areas of information pertinent to follow-up and reported as inadequate include ongoing treatment side effects, diet and likelihood of recurrence (Ferrans 1994[5], Luker et al 1995[13], de Bock et al 2004).

Interestingly, the knowledge acquired by doctors is constructed predominantly by biomedical experts and does not rely on women's actual experiences. As a result, it may conflict with the authentic emotional experiences of women (Potts 2000) which would inevitably affect the value of information provision as perceived by those women. Of course, nurses may also fail to adequately perceive individual women's needs. Studies based largely in general hospital and psychiatric care, rather than cancer care, suggest nurses can be inaccurate when assessing worries of those they are caring for, overestimate the number of worries and base their perception of need on preconceived stereotypes (Johnston 1982, Eddington et al 1990, Farrell 1991).

Personal accounts of women may be important in raising the health professional's awareness of the nature and magnitude of the problem and can provide a rich source of evidence from which to develop better assessment, recognition and supportive interventions (Rhodes et al 2000). Doctors may struggle to respond to reported symptoms that are apparently inexplicable or without a recognised cause because they do not arise from a documented, pathological process, that they are traditionally trained to act upon. Malterud (1993) stresses that adequate information provision by doctors (medical clarification) is important because doctors may perceive that women want healing or interventions, when they actually need explanations. For example being told that a swelling in the arm is indicative of lymphoedema and not recurrent breast cancer.

Women with breast cancer are likely to need varying amounts and types of information over time. However the availability of professional support diminishes as the recovery period progresses, despite evidence that information needs continue for months if not years after completion of therapy (Neuling and Winefield 1988, Wong and Bramwell 1992, Smyth et al 1995). Inadequate attempts to address information needs of women might be attributable to various factors, not least a failure on the part of the woman to realise their intention to ask specific questions. A study exploring the information-seeking behaviour of cancer outpatients reported that nearly a quarter of individuals did not receive the information that they desired, such as about diagnostic tests, physical symptoms, treatments and their likely prognosis (Borgers et al 1993). Nevertheless, it is important to note that in this study 25% of participants who were successful in realising their intention to secure information remarked that this was due to the initiation by the specialist health care professional, not themselves. This has obvious implications for professionals in terms of the necessity to possess not only knowledge of the key areas women identify they wish to know about, but also the communication skills to deliver this information in a sensitive and easily understood manner.

Inadequate information may have profound implications because women with breast cancer actively seek knowledge about the disease and treatments in order to alleviate anxiety and make side effects less traumatic (Ferrans 1994[5]). Information gathering has been widely reported as an important strategy to facilitate coping and control (Johnson 1982, Wyatt et al 1993[20], Fredette 1995[7]), not least by validating an individual's feelings, perceptions and experiences (Chalmers et al 1996). Conversely insufficient and inadequate information engenders feelings of uncertainty and insecurity in women with breast cancer (Palsson and Norberg 1995). A survey of 109 women undergoing treatment for breast cancer reported that over half suggested they could have received better support after discharge from hospital and been helped more effectively by being listened to and receiving more positive attitudes but also reported information as the best source of help. Overall the women felt that they did not receive enough support and information about their illness and the needs for information and psychological support seemed to be enormous (Suominen et al 1995[17]). Coping inevitably improves if women know what to expect, why and how long for (Graydon 1994), particularly with regards to treatment side effects as this normalises them (lessening worry that they herald new disease) and provides reassurance (Polinski 1994).

Reassurance is a notoriously difficult entity to measure and describe in definitive terms, and yet it may be important for women to enjoy peace of mind. Inadvertently, women, when describing the crucial importance of their clinical check ups, are probably recognising the value of care that enhances psychological well being (Stierer and Rosen 1989) because, as demonstrated earlier, the threat of recurrent disease is ever present. Women with breast cancer have emphasised the importance of confirming relationships with health care professionals, that is those that include the components of respect, creating and maintaining a free discussion climate and receiving understanding (Palsson and Norberg 1995). Together these can enhance an individual's sense of control and improve their handling of problems. This might explain a woman's motivation to continue seeking follow-up consultations with recognised professionals (Morris et al 1992[14], Adewuyi-Dalton et al 1998[1]). However if women continue to exhibit this dependence on medical input, in that they want to attend for follow-up care and undergo investigations (de Bock et al 2004), it raises the question of how much this continuing dependence is actually fostered by the health care providers themselves. Potential imbalances of power between lay women and doctors (those who traditionally provide breast cancer follow-up) are explored below and are clearly relevant in respect to how these may influence the nature of the follow-up consultation for both users and providers.

2.4 Power issues in the doctor-patient relationship

Interestingly, the word patient[2] derives from the Latin 'patiens', meaning to 'suffer' (Miller and Crabtree 1998 p 310). Suffering is a condition that can be defined as an

---

[2] The term woman has been favoured over patient in this work because labelling people who survive breast cancer as patients in itself can be said to perpetuate the notion of these women continuing to adopt the role of being ill, thus relying on input and 'healing' from doctors.

emotional response to that which is being endured or its ramifications and indicates acknowledgement of what has happened by the individual suffering (Morse 1996). Arguably women attending breast cancer follow-up clinics continue to suffer to some extent (as outlined by their needs above), hence they seek the support and reassurance of doctors. Schafer (1982) suggests people commonly rely heavily on the advice and reassurance of doctors, especially if seriously ill, and he terms this submissive deference (Schafer 1982). People might be regarded as submissive in the cancer care setting, yielding power to more knowledgeable doctors who they need to rely on to treat their disease successfully. Understandably the desire to be rid of the disease and a fear of recurrence or death are sufficient to make people with cancer more submissive (DiGiacomo 1987). When attending for a follow-up consultation the status of the individual becomes ambiguous with regards to labelling because the notion of patient implies ill health, yet one is also not assured of continuing good health, thus rendering survivors as neither ill nor healthy but continuing to be at risk.

Palviainen et al (2003) describe power as a matter of authority and control. In medicine, doctors have traditionally retained power because they decide what treatment individuals receive and what information should be imparted. Indeed the medical profession has been accused of abusing its monopoly of power, which transforms people into technical entities, mystifies them and increases their dependency yet further (Lees et al 1987). Being able to effect changes in clinical practice inevitably relates to questions of power and influence. However nurses are arguably also disempowered by medical paternalism (Breier-Mackie 2001), not least because nursing is an occupation traditionally for women that involves acting as representatives for predominantly male doctors. Nurses have been traditionally trained to carry out doctors' instructions (Holmes 1991), to promote a model in which the needs of women are subjugated to medical demands (McSweeney 1990) and to generally believe that the doctor knows best, the nurse knows second best and the patient knows least (Salvage 1987). Nurses are more commonly recipients of policy implementation rather than policy makers and this is in contrast to doctors who remain powerful in policy making processes (Karim 2001). Nurses may, consciously or otherwise, perpetuate this reliance when claiming to advocate on behalf of those they care for. This in itself only serves to reinforce hospital created dependency because if nurses mediate, it implies their recipients need this role because of the power invested in the doctors in the first place (Lees et al 1987). An interesting conundrum raised here is that if nurses traditionally claim to advocate on behalf of people with the doctors giving the consultation, whom will then be their advocates during nurse-led care? It is debatable if nurses can fulfil both roles of provider and protector within the same interaction.

Power and knowledge are intricately connected and it could be said that knowledge equals power. Indeed the power traditionally accorded to doctors is likely to have stemmed from the belief that they have expert knowledge that lay people do not possess (Kennedy 2003). However, in view of the acknowledgement of the multi-dimensional problems arising from a diagnosis of breast cancer discussed earlier, different types of knowledge need to be distinguished from each other. Whilst doctors may have greater medical knowledge pertaining to the pathophysiology of breast cancer and its clinical management, women are likely to possess greater knowledge of the impact of breast cancer and of the lived experience of the effects of the treatments endured (Canter 2001, Kennedy 2003, Hewitt-Taylor 2004).

In illustrating this Fosket (2000 p21) refers to embodied knowledge, giving the example of when a woman finds a new lump/symptom that is real and meaningful to her but may not be considered a legitimate source of knowledge by doctors, at least until biomedical interventions have confirmed it. In this setting the woman's knowledge is deemed less credible by virtue of the power and position of doctors, rather than on the content of the knowledge itself (Fosket 2000 p23). Their assumed knowledge, expertise and social standing reinforces the status of doctors (Baum 1994). Thus increased biomedical knowledge confers more power, just as lack of it confers vulnerability. But embodied knowledge remains relevant to the woman, especially if she has experienced 'biomedical failure' (such as missed diagnosis) in the past (Fosket 2000 p 25).

'Voice' (that is being able to express thoughts and preferences and being heard) is an essential prerequisite to achieve influence because people who are not heard are not people in power (Malterud 1993). Clearly health care professionals have the power to include or exclude the voice of the woman in history taking and reasoning (for example, deciding whether to respond to symptoms reported by ordering tests) (Malterud 1993). Hewitt-Taylor (2004) refers to such actions as coercive power. If women report dissatisfaction with having their symptoms responded to and taken seriously, this suggests that their voice on this subject is sometimes ignored.

This raises an interesting issue because in the case of recurrence, women do have experiential knowledge, and they have been shown to be the most likely source of detection of recurrence. It could be argued that conferring self-management on the woman in follow-up is a form of empowering them. Yet this in itself is a contradiction in terms because self-management implies self-ownership rather than something that is allowed or given by others. A further contradiction begins to emerge because women are effectively *given* authority back by the doctors hence they remain in charge of the strategy for follow-up care and surveillance. Once deemed capable by doctors, women are then expected to assess their own risk and relevance of any symptoms, after weighing up information that is contradictory or difficult to understand. However, having been given this responsibility of interpreting and reporting new symptoms, more so with the advent of less intensive and shorter duration of follow-up, biomedicine then re asserts itself as the more powerful partner in the relationship with embodied knowledge. It seems paradoxical that if any intervention is required, then a wholly biomedical focus is reverted to once again (Potts 2000).

A key issue with this exchange of responsibility is that biomedical health strategies are not neutral. Within breast cancer follow-up, there is a shifting of responsibility from the doctor back to the patient for self-monitoring, potentially leading to self blame if new disease occurs, but the reality is women cannot be truly responsible because they cannot really control whether or not they get a recurrence. If women choose to make lifestyle changes such as adopting new diets and recurrence still occurs they may consider themselves responsible because their choices failed. Knowledge from those in power may also be contradictory to their own experiences and perceptions, for example they feel pain but doctors cannot detect a cause or provide an explanation for it. Given the established risk factors for breast cancer responsibility cannot really lie in causation so the focus shifts towards detection, yet a paradox emerges as it is acknowledged that investigations are ineffectual in detection during routine follow-up (this is explored in Chapter Three).

Doctors can also retain power by use of medicalised language, that is use of terms that are quite meaningless to the women and therefore preclude them having full input in to their description. Corner (1996) cites an example of this with people with lung cancer, whereby substituting the term breathlessness for the biomedical label of dyspnoea facilitated richer descriptions of this phenomenon because patients could identify with the term when questioned about it by the nurses.

Expert power is often compounded by gender power. As people with breast cancer are in the majority a female client group cared for largely by male doctors, the latter may hold power afforded by their gender as well as by their professional status (Potts 2000). This reasserts the importance of user involvement when planning services, to ensure adequate and appropriate representation of people accessing care. Gender power refers to more than just the differences between men and women and also influences how organisations (such as hospitals) are socially constructed, their roles and functions and their values (Corner 2001). For example nursing is rendered subordinate because of its historical role in assisting doctors, but also its attention to the traditionally feminine functions of caring and domestic labour (Corner 2001).

Schain (1990) contends that in any human transaction there exists the components of power and control, specifically who is to initiate and who is to follow and who will hold the balance of power in decision-making. Control over decision-making can be seen as an intrinsic part of professional dominance, illustrated by acceptance of the importance of giving information, because this implies the information belongs to the professionals in the first instance (Miers 1999). In busy follow-up clinics doctors may have an 'agenda' to work through, that of taking a history and completing an examination according to local protocols. Follow-up outpatient clinics could be accused of employing tacit oppression to get through the ever- increasing workloads. Doctors could arguably be said to have a vested interest in preserving the woman's ignorance because it enhances their own power and their control of the consultation (DiGiacomo 1987). Of course, because someone has sought the opinion of a doctor, they may want him or her to influence their decisions and seek their advice because they are specialists in a particular field. However, this is based on the assumption that the professional is concerned about the well-being of the woman and it is likely that women can and would participate in decision making if they are given adequate information to do so (Curtin 1983, Degner et al 1997).

Degner et al (1997, 2003[4]) explored the information needs and decision-making preferences of 1012 women with breast cancer seen in oncology clinics. They found that less than half achieved their preferred level of control within the outpatient consultation. This may have resulted from inadvertently poor information giving by the doctors, but equally may have arisen from a conscious decision about how much information to impart and how much to involve the women in the process of information exchange.

Concealment of information interferes with trust and undermines the therapeutic relationship as well as exacerbating anxiety, so it is important for health care professionals to use language that dispels ignorance without dispelling hope (Schain 1990). DiGiacomo (1987) describes being bullied into accepting more treatment for Hodgkin's through the strategic manipulation of information. In contrast, when adequate information was provided to her, it helped her to become a collaborator rather than an object of treatment. Doctors may underestimate an individuals desire for information, and their ability to comprehend medical terminology. They also tend to overestimate how much time they have spent with women and report benefits in more detail than risks (Schapiro et al 1992). A perceived lack of reassurance by women correlates with low satisfaction, whilst clear communication of the expected outcomes enhances satisfaction (Ben-Sira 1982, Korsch et al 1982, Waitzkin 1984).

Albeit, not always willingly, doctors can be said to have power where resources are concerned. This includes access to resources, for example which doctor is seen and when, and also the power to decide which treatments to employ and in what order. Discussions with women about their preferences for breast cancer treatment may impact slightly on decisions made but ultimately it is usually the doctor that holds the power in terms of prescribing medicines, ordering investigations and making referrals to other health professionals. However, it is important to remember that limited resources ensure decisions that affect one individual will inevitably have wider implications overall. For example, Hewlitt-Taylor (2004) points out that sometimes an individual may benefit from an intervention that is expensive or not readily available. Empowering that one person to access the intervention will inevitably mean impinging on the resources available for others, thus decisions regarding empowerment of women are often complex and far reaching.

The state of medical knowledge about breast cancer, although progressing, can still be considered incomplete meaning that exact prognosis remains unpredictable for many individuals. The definition of cure is not a definitive term but instead has a relative nature, invariably equated with five year survival or remission. Hence fear of cancer results not just from lay people's ignorance or projections but also reflects the fact that cancer remains problematical for biomedical science (Rosser 1981). It is unsurprising that women may have uncertainty relating to the efficiency of medicine to cure them definitively. The unknown origin of breast cancer, its erratic course and unpredictable outcome all contribute to the plight of both doctor and patient (Schain 1990). It is arguable whether a comprehensive, minimalist, follow-up protocol with no use of routine investigations will be realistically implemented in practice. Doctors traditionally seek the support of information derived from diagnostic tests when uncertain about the health status of a patient, even if they are aware of the limitations of such an approach. Recent studies, several years after the emergence of evidence questioning the clinical efficacy of routine follow-up, continue to demonstrate that UK oncologists discharge only 15% of people with breast cancer after five years, and only 43% after ten years (Maher 1995). This practice may be further compounded if the woman indicates that failure to assess them adequately will result in legal as well as clinical repercussions for the doctor concerned. Interestingly, claims for compensation for a delay in diagnosis of breast cancer are second only to those arising from the birth of neurologically impaired infants in America (Physician Insurers Association of America [PIAA] 1995) and litigation in this field is also noticeably increasing in Great Britain (Rainsbury 1996).

The fact that women continue to experience a multitude of ongoing needs and problems after treatment for breast cancer is indicative that the traditional system of follow-up care has been unsuccessful in understanding, assessing and responding to the experiences of the women who attend (Potts 2000). Paradoxically the duration and severity of morbidity (physical and emotional) that individuals face as a result of cancer treatments varies enormously whilst follow-up schedules do not. Instead they are pre determined and fail to be influenced by the unique progress of each person surviving the disease. This may be because in health care there is commonly a discrepancy as to who decides whether a need exists. If consumers of health care (patients) are unlikely to be able to judge initially what kind of health care intervention is most effective for their needs, then they must inevitably rely on information from health care professionals, and thus allow professionals to determine their needs on their behalf. Yet people with differing values and experiences may recognise divergent needs, meaning that health professionals are in danger of failing to identify the same needs as those of women with breast cancer. For example, women who use the service may perceive that the main purpose of breast cancer follow-up clinics is to obtain reassurance and support, whilst the doctors conducting follow-up consultations are more likely to regard detection of recurrent disease as the priority. In light of this, developing an appreciation of the experiences and an understanding of the ongoing concerns faced by women living after breast cancer would seem crucial to planning a model of care that is truly effective in maximising their recovery (Northouse 1981[15]).

2.6 Summary

This chapter has explored women as the users of breast cancer follow-up, including their ongoing emotional, physical, social, spiritual and informational needs and their perceptions of the current system. This suggests value in continued monitoring and support. However, whilst the potential existence of such needs is widely appreciated within the literature and gaps in the current system are apparent, detailed and meaningful changes are unlikely without first addressing the imbalances of power between women and the health professionals providing follow-up, notably doctors. This may involve challenging the *system* within which breast cancer follow-up operates (because it is likely that this dictates the divisions of power) and ensuring the integration of the views of women is seen as important as those of the health providers are. Whilst knowledge of the potential issues facing women after treatment for breast cancer appears prevalent, suggestions for strategies to help women cope with the problems they face remain elusive.

Furthermore, ongoing needs do not appear to have been acknowledged within recent national guidelines and recommendations that now endorse the practice of stopping follow-up after two to three years (National Institute of Clinical Excellence [NICE]

2002). If wide ranging needs, specifically as a result of treatment, remain prevalent, then at very least it would seem crucial to retain open access to health care professionals for women over time. The above findings and the lack of research in this important area highlights a requirement for further investigation to ensure that the woman's perspective is ascertained and accommodated within the service provided during follow-up care. Acknowledgement that cancer has the capacity to profoundly affect a person's life, even if they remain free of the disease, in itself reminds us that the subjective experiences and personal impacts are no less important to recovery than the clinical outcomes of the treatments.

Chapter 3. CINICAL EFFICACY OF BREAST CANCER FOLLOW-UP

3.1 Introduction

The following chapter details the nature and purpose of breast cancer follow-up, the schedules offered, the procedure and the outcomes. Thus it aims to contextualise the elements of 'what', 'why', 'when', 'how' and 'how good' pertaining to breast cancer follow-up. Detailed arguments for and against the continuance of breast cancer follow-up are presented, as is consideration of what these may represent in terms of biomedical versus woman centred approaches to care.

For this section of the review eighty-nine citations were accessed, of which eighty-one appear in the review. The remaining work was excluded as a result of serious methodological flaws, or because the contents represented repetition of material already retrieved. The literature used dates between 1980 and 2001, with the majority being published in the 1990's. They originate predominantly from the United States of America, Canada, Japan, the United Kingdom and several countries within Europe including Italy, Germany and Sweden. The international context is relevant to breast cancer follow-up because of the approaches of different countries in managing this area of care. Interestingly, papers exploring the needs of women during follow-up derive from various countries, suggesting recognition of the importance of meeting these needs globally. Certainly the demands on capacity and resources exist globally because of world-wide increases in breast cancer incidence rates. However, the focus on the clinical efficacy of breast cancer follow-up is notably absent from the American literature. This might reflect their private medicine system and litigation driven ethos, which tends to promote more intensive surveillance at both screening and follow-up of breast cancer, such that reducing throughput and resource management are not priorities in the same way that they are in Europe. The material reported is derived from systematic reviews, randomised controlled trials, prospective research studies, retrospective audits, meta-anlayses, literature reviews, editorials, commentaries, and unpublished academic work. Of note the lead authors are exclusively medical, and were all working in the field of breast cancer follow-up, as surgeons, oncologists or radiologists.

3.2 Routine Clinics and Investigations

On completion of treatment for primary breast cancer (with the exception of ongoing endocrine therapy such as Tamoxifen or anastrazole, as these are taken for a further five years), women are deemed disease free and commence follow-up, a schedule of monitoring and routine surveillance. This involves clinic visits for a check-up (usually by a doctor) within the hospital outpatient department, which lessen in frequency as time progresses. The consultation consists of a brief history taking, a clinical examination and routine investigations performed at the discretion of individual doctors in response to symptoms noted (see Figure 3.1).

Frequency and Duration:

Follow-up is provided to women after completion of adjuvant treatment for breast cancer 3 monthly for 2 years, then 6 monthly until the end of the 5th year post diagnosis, then 1 yearly until the end of the 10th year post diagnosis.

[N.B. Since undertaking this work, The National Institute of Clinical Excellence (NICE 2002) has produced the updated document on breast cancer service guidance. It suggests that follow-up should continue for only two to three years (except if clinical trial protocols require longer). Therefore women are commonly now seen for a shorter duration]

Investigations:

Mammography is performed at the end of the 1st year post diagnosis for all women.

Women with Ductal Carcinoma in Situ (DCIS) will then receive annual mammograms.

Women with invasive carcinoma will have annual mammograms for 2 years, then one every 2 years thereafter.

Chest x-ray, bone scan and liver ultrasound are performed yearly to detect for metastatic disease

[N.B. Since undertaking this work The National Institute of Clinical Excellence (NICE 2002) updated document on breast cancer service guidance suggests that routine tests to detect metastatic disease are not of any clinical benefit and do not improve survival. Therefore usually no investigations, other than mammograms are now performed routinely on asymptommatic patients]

Clinical Procedure:

At each clinic visit, the following clinical examination is performed:

palpation and examination of breast/chest wall on side affected by cancer
palpation and examination of contralateral breast
palpation and examination of bilateral axillary & supraclavicular nodes
examination of neck and spine for tenderness
palpation of liver

Examples of Indications for Intervention (not inclusive)[needle aspiration, biopsy, diagnostic imaging procedures such as bone scan, liver ultrasound scan, chest X-ray, CT scan, blood chemistry]:

- detection of a new lump on the side of the affected breast or on the contralateral side
- detection of abnormality at 'routine' mammography
- detection of skin changes (other than those post radiotherapy treatment) such as new skin nodules, puckering, peau d'orange.
- detection of palpable axillary or supraclavicular lymph nodes
- reported spinal tenderness
- detection/ reporting of jaundice
- reporting of new bone pain which is persistent, unresolved and worsening
- detection/ reporting of shortness of breath
- reporting of persistent headaches

Figure 3.1: MODEL DEPICTING BREAST CANCER FOLLOW-UP

Recent years have witnessed a gathering momentum to ensure that care is clinically effective (Rycroft-Malone et al 2002). Clinical effectiveness is the extent to which specific interventions do what it is they are intended to do, that is maintain and improve health and secure the greatest possible health gain from available resources (National Health Service Executive 1996a). In order to evaluate whether breast cancer follow-up clinics accomplish their intent, it is crucial to explore what they profess to achieve.

Conceptually, follow-up care can be considered as a screening programme, in that its principle aim is to 'screen' for early detection of local or distant recurrent breast disease (Rojas et al 2001). Local recurrence can exist contralaterally, that is occurring on the other breast, or ipsilaterally, occurring on the same side as the initial cancer, either in the remaining breast tissue or on the chest wall. Metastatic disease is when the cancer cells have migrated from the original local site and have spread to other parts of the body. Other reasons for follow-up care are reported to include improved survival; uniformity in the documentation of treatment failures; monitoring of treatment outcomes and of the rehabilitation progress; evaluation of psychological and emotional needs; and provision of psychological support (Horton 1984, Schapira 1993, Brada 1995, Snee 1996). Evidence can also be gathered concerning the natural history of the disease and evaluation of treatment side effects (Wickerham et al 1984, Stierer and Rosen 1989, Del Turco et al 1994, Dewar 1995). These aims are believed to fulfil the expectations of the doctors and patients alike (Brada 1995). Nevertheless, there is considerable debate in the literature associated with the efficacy and delivery of routine follow-up care in relation to detecting recurrence and positively influencing outcomes for women.

The most common routine diagnostic investigations for women with breast cancer encompass mammogram, bone scan, liver ultrasound, chest x-ray and blood tests. These reflect the most common sites of breast cancer recurrent disease which in order of likelihood, are breast and chest wall, bone, lung, liver and brain. Magnetic Resonance Imaging (MRI) is not used for screening and is widely considered a poor predictor of local breast cancer recurrence (Coulthard et al 1999[3]). A conspicuous concern is the apparent lack of agreement as to the frequency and duration that these investigations should be performed. Several reviews have been carried out to determine the practices of surgeons and oncologists when ordering asymptomatic investigations (such as liver ultrasound scans, chest x-rays and blood chemistries) in the breast cancer follow-up setting. These reveal a noticeable lack of consistent practice and failure to adhere explicitly to existing local guidelines on the indications for their usage (Benard et al 1994, Stark and Crowe 1996, Lash and Silliman 2001). This is despite the fact that data which questions the efficacy of intensive follow-up practices has been available for some years and has been endorsed by several guidelines for practice and consensus conferences around the world (De Lena et al 1995, Rojas et al 2001).

In addition, follow-up clinics usually take place on a routine basis at pre set time intervals, often determined according to the practices of the consultant, rather than by what individuals may require. At the commencement of this research women were commonly seen every three months for the initial two years, then six monthly or yearly thereafter for a further five to ten years. This pattern of more intensive input early on is not necessarily reflective of clinical evidence about relapse times for the majority of women. Retrospective analyses have demonstrated an annual hazard rate of relapse after breast cancer of 5% in the first year, increasing to 10% in year three for women with disease positive lymph nodes, and 1% in year one, increasing to 5% in year three for women with disease negative lymph nodes (Wheeler et al 1999[20]). This suggests early intensive follow-up schedules provide no clear clinical gain since relapse is less likely in the first year. Similarly longer-term follow-up (for example up to ten years) has been deemed clinically less appropriate because up to 80 percent of recurrences occur by the end of the fourth year following treatment (Scanlon et al 1980, Schapira 1993, Katlove et al 1995). It seems prudent, therefore, to focus clinical follow-up at different duration and frequency for those at differing levels of risk of relapse thus addressing the criticism that currently follow-up care is often pursued in an irregular, haphazard and costly manner (Horton 1984, Richert-Boe 1995). However, the most recent Department of Health guidelines on breast cancer follow-up recommend discharging *all* attendees after two to three years and make no mention of individualised clinical or psychological needs (National Institute of Clinical Excellence [NICE] 2002).

In summary, it appears that there is no consensus with regard to how often women should be seen, how long follow-up observation should last, what tests should be performed and the efficacy of routine clinics. However, if follow-up care is to ensure best possible outcomes for all women its delivery may need to be wide-ranging and diverse in order to accommodate individual needs (Horton 1984). It seems unlikely, therefore, that a schedule based on tradition and which recalls women at predetermined intervals - regardless of individual progress - could hope to achieve all of the above outcomes in any meaningful way.

3.3 Value of routine follow-up in detection of recurrent disease

There are two commonly held assumptions concerning follow-up care. Firstly, that most recurrences are detected earlier with routine surveillance and secondly, that subsequent earlier initiation of treatment offers a better chance of cure or longer survival (Schapira 1993). However, neither of these proposals has been supported by research and many studies cast doubt on the clinical effectiveness of routine follow-up and investigations. Appendix B summarizes 21 such studies that include randomised controlled trials, prospective research studies and retrospective audits specific to the clinical efficacy of breast cancer follow-up and includes their country of origin. Descriptive work (such as government reports and papers, editorials and commentaries) have not been included in the table. In addition, studies not specific to breast cancer follow-up and those that were largely repetitions of another paper (the same authors published in another journal) were also omitted to avoid repetitiveness. Papers appearing in appendix B have been allocated a corresponding number within the text to allow the reader to cross-reference accordingly. These studies suggest that routine examination and investigations may identify metastatic disease in only five to twelve percent of asymptomatic women. The evidence supports a need to scrutinise follow-up practices more closely.

The research and audit evidence and two systematic reviews (Smith et al 1999, Cochrane Library 2001) also highlight that the identification of recurrence varies considerably depending on the investigation. A retrospective study of 208 asymptomatic women with lymph nodes which contained cancerous cells demonstrated detection rates of recurrence of five percent for six monthly chest X-rays, eight percent for annual bone scans and 12 percent for blood tests (Pandya et al

1985[13]). Low identification of recurrence has also been established in other studies (Perez et al 1983, Schapira 1991). Two large retrospective analyses of over 1125 and 550 women found investigations including liver ultrasound, blood chemistries and bone scans detected recurrent disease in only 116 women (10.3%) and 21 women (4%) respectively (Imoto and Jitsuiki 1998[9], Pivot et al 2000[14]). Another audit of 442 asymptomatic women indicated that chest x-rays detected 2.7 percent, bone scans 3.4 percent and liver chemistry tests only 1.3 percent of recurrent disease (Schapira 1993). While a review of nearly 8000 bone scans highlighted that only 52 (0.06 percent) detected occult (hidden) bone metastases in asymptomatic women (Wickerham 1984[21]). Also of concern in the latter study was the estimated false positive rate of 22 percent leading to unnecessary plain X-rays and increased anxiety for the women concerned.

The lack of efficacy of these methods of disease surveillance has also been demonstrated in randomised trials. A large prospective study randomised women to receive either intensive surveillance (assessment by physician, bone scan, liver ultrasound, chest x-ray and blood tests) or physician assessment alone (at the same frequency but with investigations only if indicated) (Gruppos Interdisciplinaire Volutazione Oncologier [GIVIO] 1994[7]). At a median follow-up of 71 months no significant differences in overall survival or time to detection of recurrence between the two groups was demonstrated. A total of 132 deaths, representing 20% were recorded on the intensive follow-up group (n=655) and 122 deaths, representing 18% were recorded in the minimal follow-up group (n=665). The mean time to detection of distant metastases was 53.39 months in the intensive follow-up group compared to 54.07 months in the other, thus yielding an advantage of the intensive protocol of just 1 month (GIVIO 1994[7]). When considering the efficacy of investigations, it should be noted that physical examination is not necessarily more successful in detecting recurrence, with identification rates of only approximately 15 to 20 percent being reported with this approach (Schapira 1993, Katlove et al 1995, Loong et al 1998[12]).

Whilst the benefits of earlier detection of distant metastases have never been established, an exception to the lack of efficacy of investigations in detecting recurrence is the mammogram. Mammography has been consistently proven to successfully screen for new and potentially curable local lesions, especially contralateral cancers (Mellink et al 1991, Pace and Tinker 1994, Kollias et al 2000[11]). Mammography is also likely to identify or confirm the presence of local recurrence in two thirds of women investigated (Ashkanini et al 2001[1]). Detection of local disease is especially applicable because an initial diagnosis of breast cancer in itself confers a higher future risk of contralateral (on the other side) breast disease (three to five times higher than the general population who have never had breast cancer). There is also an ongoing, increased risk of ipsilateral (same-sided) disease of 1 to 2.5% per year. However, it is recognised that surgical scar tissue and radiotherapy induced changes to the breast tissue that can lead to difficulties interpreting mammograms in individual who have undergone these treatments (Holli et al 1998).

In addition to the questionable efficacy of routine follow-up in detecting recurrence, the literature also raises the issue of how potential symptoms of new disease become apparent in terms of the timing and frequency of scheduled follow-up appointments (Perrone et al 2004). In contrast to investigations, signs and symptoms noted by women are the first indication of recurrence in over 70% of patients (Scanlon et al 1980[15], Mansi et al 1988, Muss et al 1988, Loomer et al 1991, Schapira 1993, Moore et al 1999, Hiramenek 2004). Between 75 and 95 percent of women who develop signs and symptoms do so between routine follow-up visits (Dewar and Kerr 1985 [5], Schapira 1993, Grunfeld et al 1996, Gulliford et al 1997[8], Joseph et al 1998[10]) and hence attend early for an interval consultation.

A retrospective review of the presentation patterns of women with breast cancer recurrence (n=108) (Donnelly et al 2001[6]) demonstrated that the practice of three or six monthly visits is unlikely to capture the majority of recurrences. In this study 74% of women presented at earlier (interval) clinic appointments, only 17% drew attention to symptoms themselves at routine visits, 2% were found by annual screening imaging (local recurrence only) and 7% were detected unexpectedly during the doctor's clinical examination (again, all local recurrences). The median time to presentation was 19 months. The conclusion from this study was that most recurrences are discovered at unscheduled interval appointments, whilst routine screening and clinical examination detect only local (potentially curable) recurrence but not systemic metastases. Those women presenting with distant recurrence at routine visits were already symptomatic, reaffirming that long term, intensive follow-up surveillance is inefficient and unnecessary (Donnelly et al 2001[6]).

Another study reported higher levels of recurrence detected at the routine follow-up appointment (23% overall). But it was also noted that the mean number of relapses detected at routine visits dropped as time progressed from 26% during the first 36 months, down to just 16% between 36 and 60 months (Pivot et al 2000[14]). This again supports the notion of a more individualised approach rather than uniformly following everyone up for several years. Of note symptoms that prompt women to initiate an interval appointment vary according to the site of metastatic spread. Examples include skin involvement, masses, palpable lymph nodes, localised progressive bone pain (such as persistent backache with increasing intensity), shortness of breath, chest pain, weight loss, right upper quadrant [liver] pain, jaundice, nausea, mental status changes and persistent headaches (Stierer and Rosen 1989[18], Loomer et al 1991).

In summary, laboratory and imaging procedures (with the exception of mammography) detect only a minority of recurrences and are not reliable in routine, pre scheduled follow-up settings where women are asymptomatic (Pandya et al 1985[13], Boccardo et al 1995). In addition women are reported to be the most reliable source for detecting recurrence (reporting symptoms in between scheduled visits) (Schapira 1993, Pivot et al 2000[14]). Therefore, there is little clinical evidence to support continuance of the traditional approach of periodic clinical follow-up of women with breast cancer.

3.4 Value of routine follow-up in improving survival

There is a belief among patients and physicians that if the recurrence is detected early, there is a higher likelihood of disease control, complete remission, or at least extended survival (Schapira 1991). However, while local recurrence and contralateral breast cancer are detectable and potentially curable (Dewar 1995), metastatic breast cancer is essentially incurable and early detection of recurrence may have only a minimal influence on ultimate survival (Schapira 1993, Grunfeld et al 1995a). In addition, most studies (for example Morris et al 1992, Del Turco et al 1994[4], GIVIO 1994[7], Brada 1995 and Snee 1994[17]) show no difference in survival times between women with recurrence detected symptomatically or asymptomatically. The findings of the few studies (such as Ciatto et al 1989[2]), that have reported longer duration of survival in cases where relapse is detected by routine follow-up may be largely explained by lead-time bias (when early detection merely increases the period during which disease progression is observed). Length time bias may also feature (when cases with a long pre-clinical phase, and therefore presumably less aggressive disease, are more likely to be detected by surveillance programmes) (Rojas et al 2001). To obtain meaningful results which exclude the possibility of diagnostic anticipation, survival should be measured from the time primary treatment commences, rather than from the date of detection of metastases.

A prospective randomized trial was carried out to evaluate the effectiveness of earlier (asymptomatic) detection of lung and bone metastases in reducing mortality from breast cancer (Del Turco et al 1994[4]). Women in whom distant metastases had previously been excluded were randomized to intensive follow-up (physical examination, chest x-ray and bone scan performed at regular pre set intervals) or clinical follow-up (physical examination only). Whilst earlier and increased detection of chest and bone metastases was evident in the intensive follow-up group compared with the clinical follow-up group (112 versus 71 cases), no differences were demonstrated in the overall five year mortality between the two groups. This led the authors to conclude that periodic chest x-ray and bone scan may facilitate earlier detection of distant metastases but this anticipated diagnosis is the only effect, with no impact on *prognosis* evident after five years.

These studies and others (such as Wagman et al 1991[19]) have highlighted doubts concerning the value of early detection in improving survival and have potential implications for women who may live longer asymptomatically with the knowledge they will die of their disease. In consideration of these issues some researchers (Schapira 1993, Pivot et al 2000[14]) have suggested that, on ethical grounds, routine surveillance should be minimised until successful therapies are available to significantly prolong survival or cure women whose conditions recur. Although this remains debatable and some women may prefer to have full knowledge of their diagnosis and likely prognosis as soon as possible.

In summary, follow-up programmes based on physical examination and yearly screening mammography alone are as effective as traditional, intensive approaches using multiple asymptomatic investigations, in terms of time to detection of recurrence, efficiency in detecting recurrence and overall survival from breast cancer (Pace and Tinker 1994, Cochrane Library 2001). Of note, the literature presented thus far focuses on the value of breast cancer follow-up from an explicitly biomedical perspective, that is the clinical, technical value of surveillance in terms of detecting disease recurrence and overall survival. This is epitomised by the primary outcomes measures cited in the systematic review conducted by the Cochrane Review group (Cochrane Library 2001), which are disease free survival, overall survival and occurrence of metastases detected asmptomatically. Also, clinicians refer to cure in relation to the objective parameter of remaining five years disease free, even though both physical and psychological morbidity and indeed recurrence can occur long after this time (Faithfull 1994). This emphasis on a disease-cure model implies clinical efficiency is the priority, with the person being regarded as the passive recipient of care, instead of adoption of a more humanistic approach, in which the experiences of the woman are considered within a individualised framework (Playle 1995). It indicates that follow-up itself has arisen (and continued) for biomedical purposes, rather than for the purpose of improving the quality of life for women after treatment for breast cancer. This seems in contrast to the literature presented in chapter one (that highlights women have profound needs existing over time), failing to take into account women's perceptions of breast cancer follow-up and calls in to question the motives for continuance of this area of clinical practice.

3.5 Women's Perceptions of Breast Cancer Follow-up

The predominant focus of research on the medical value of follow-up detailed above has resulted in a paucity of data examining users' perceptions of the current system and its impact on psychological well being and quality of life. However, the absence of improved quality of life resulting from traditional intensive follow-up is demonstrated in two randomized prospective studies. In one of these Brown et al (2001) conducted a randomised controlled trial to compare standard clinic follow-up (n=31) with follow-up initiated by the women (n=30), in terms of breast cancer specific quality of life, psychological morbidity and satisfaction. In the self-initiated group, women did not attend any routine appointments, but were given written information of signs and symptoms of recurrence and advised to contact the breast care nurse if they experienced any problems. The results demonstrated no major differences in quality of life or psychological morbidity between the two groups at 6 months and one year. However more women in the standard follow-up group cited reassurance and being checked out as advantages, whereas more women in the self-initiated follow-up group reported convenience as a main advantage. Of note, these results may have been influenced by a self-selection bias on the part of the participants. A feasibility study undertaken by the same authors found only 8 out of 100 women approached would accept self-initiated follow-up, suggesting that those agreeing to take part in the randomised study differed in terms of their attitudes towards breast cancer and the lesser emotional importance they placed on clinic appointments.

The second study compared outcomes of examination with bone scan, liver scan, chest x-ray and blood tests, with a minimalist protocol where diagnostic tests were only performed when indicated by symptoms (GIVIO 1994). The results suggest that the type of follow-up does not affect dimensions of health-related quality of life, including health and quality of life perceptions, emotional well being, body image, social functioning, and satisfaction with care. This study refutes the argument that intensive follow-up protocols reassure women, but nor does it support an alternative hypothesis that more frequent investigations increase stress and anxiety (GIVIO 1994, Snee 1994).

Whilst health-related quality of life was unaffected by the type of follow-up care received in the study cited above, more than 70% of the participants still expressed a preference for more intensive surveillance (to see a doctor and undergo investigations). This is perhaps because these visits provide reassurance and there is a desire on the part of patients to continue to participate in the system of health care that alleges to care for their ongoing well being. In support of this theory, Morris et al (1992) studied the attitudes of 223 women to their follow-up after treatment for breast cancer. They concluded that the majority preferred regular visits to attendance only when symptomatic (85%), breast clinic visits to General Practitioner (GP) follow-up (76%), and reported feeling less anxious and more reassured having attended clinic (81%).

Interestingly the desire, on the part of people with cancer, to continue follow-up (Renton et al 2002) is not necessarily based on its efficacy in meeting their multi-dimensional needs, because numerous studies reflect its failure in this respect (Collins et al 2004). Moore et al (1999, 2002) describe an assessment of needs of people on follow-up for lung cancer that found that these consultations usually focussed on physical problems, with little discussion about other (psychosocial) concerns such as coping with the diagnosis. This has also been found in studies on other oncology outpatient consultations (Rogers and Todd 2002). Doctors in Moore et al's study tended to emphasise physical problems in the medical records and rarely documented psychological or social problems in the notes. A subsequent nurse-led model of follow-up was implemented and the authors remark that whilst the holistic approach was appreciated by many participants, it was challenging for those that relied on the perceived safety of the medical model, that is having regular examinations and investigations by doctors. "Patients' previous experience of healthcare was steeped in medical culture and although often not leading to direct therapeutic benefit, investigations such as chest x-rays had become powerful symbols of how their disease should be managed" (Moore et al 1999 p 440). The authors conclude that such symbols need to be recognised when planning care that is truly responsive to individual needs. This raises a dilemma, in that investigations of proven clinical inefficacy, and some considerable expense, remain largely crucial to vulnerable patients in desperate need of reassurance that they remain free of cancer recurrence.

In a study of doctor-patient communication within outpatient clinics between ten oncologists and 240 people receiving palliative care, the oncologists were found to devote 64% of their conversation to medical or technical issues and only 23% to health related quality of life concerns (Detmar et al 2001). The people attending, however, divided their communication more equally between medical/technical issues (41%) and quality of life issues (48%). This is an important finding that may help to explain why people are generally more reluctant to report non-physical issues, because it is not encouraged and because of the notion that the doctor's scant attention negates its worth and relevance to the consultation in hand. It also compounds the theory that some interruption to emotional and physical quality of life is an inevitable consequence of treatment for breast cancer and so should be tolerated and accepted in return for being 'cured' of one's breast cancer (Dow 1992, Fosket 2000)

In contrast Epstein (1995) and Gulliford et al (1997) describing a study of women with breast cancer, report that participants were highly supportive of pursuing less frequent follow-up and seemed willing to take responsibility for seeking medical attention as and when needed in the presence of new symptoms. However, these findings represent a minority overall, and Rainsbury (1996) makes the important point that participation in a trial that involves careful scrutiny of outcomes in both arms could bias women's views and represents quite different conditions than being literally discharged from care with no input from the researching team.

Women certainly in the main seem firmly committed to a system of regular clinical examination and this has subsequently been rated as one of the most important components of follow-up by patients (Mosconi et al 1995). Such that attempts to discharge long term cancer patients in remission proves difficult, with as many as a fifth insisting on attendance even after 10 years (Chait et al 1998). There is clearly merit in finding ways to equip such anxious people with survivorship skills that would render them less dependent on hospital follow-up.

Thus the majority of women with breast cancer express a preference to be seen in a hospital breast clinic and to continue to have frequent diagnostic investigations (Morris et al 1992, GIVIO 1994, de Bock et al 2004). This affirms that an important function of the follow-up clinic is reassurance. The paradox is that as randomised trials to do not show improved quality of life in women who do have intensive (asymptomatic) surveillance (GIVIO 1994), the reality is that actually no extra reassurance is gained from doing these (Brada 1995). This draws attention to the issue of cost in that, ineffective, expensive models of care cannot be continued merely because the users desire them. Perhaps a more relevant and constructive consideration is what motivates the continued practice of follow-up and what model might replace the existing one so that the needs of the users and the providers are catered for successfully.

3.6 Motivations for continuing breast cancer follow-up

Consideration of why and how breast cancer follow-up has arisen and crucially whose purposes it may serve, might help to illustrate what a woman-centred approach to follow-up might look like and how it could be informed. It is difficult to explain the dominance of an almost exclusively utilitarian, resource driven approach to follow-up at a time when the National Health Service (NHS) policy claims to place significant emphasis on care explicitly tailored to individual people's needs and designed with user involvement and opinion at its core. Taking in to account service users views, increasing their empowerment and encouraging their input in decision making are themes that are central to government health policy with their recent documents consistently alleging support for these concepts. The National Health Service policy framework for commissioning cancer services (Calman-Hine 1995) states a prime objective of re-organised cancer services is the provision of patient-centred care and the green paper 'Our Healthier Nation' (National Health Service 1999) also highlights this focus as a priority. In 1996, the NHS Executive's Patient Partnership Strategy was launched with the stated intent of making the commitment to user involvement in health care a reality in everyday practice (NHS Executive 1996b). Ensuring needs of users are met necessitates involving them in policy and practice development. The NHS Expert Patient Taskforce (Department of Health 1999a) seeks to empower patients to be active partners and collaborators in many areas of clinical care. More recently the Cancer Plan (Department of Health 2000a) stresses the importance of empowering people to improve services and facilitate choice and control over what happens in all aspects and stages of their care. Similarly the document 'Your Guide to the NHS' (Department of Health 2001b) declares its intended commitment to user involvement and to providing a high quality health service shaped specifically around the needs and preferences of those who access it. Such work rests on the fundamental view that people's perceptions, however uninformed they may be, are real and inevitably inform their actions (Briscoe 1985).

It is plausible that the government is making public its intention to include the opinions of users in the development of services because of a growing appreciation of the relevance of evidence deriving from personal experiences when responding to the needs of people with cancer. This involves making a distinction between 'illness-as-diagnosed' and 'illness-as-experienced' (Briscoe 1985 p98). There is increasing emphasis on the role of users in *evaluating* the effectiveness of services and in enabling them to be active participants in health care research, rather than just subjects (Maslin-Prothero 2003). Carter (1989) stresses the importance of research studies that successfully describe the individual experience of cancer and their interpretations of the meaning of illness, and these are of particular relevance to the long-term adjustment of cancer survivors. Consequently, some authors radically suggest abandoning wholly biomedical models of care, which view health and illness as purely mechanical and physical (Corri 2003). This is because they reduce disease down to descriptive labels (such as morbidity figures), not constitutive of the illness itself and ultimately saying nothing about the identity and needs of those affected (Williams 1999). In terms of service planning, Maher et al (1995) remind us that women with breast cancer, with their wealth of experiential knowledge, can suggest solutions that clinicians may fail to see.

Perhaps the most frequently measured variable, when describing individual's perceptions of how their care was provided, is satisfaction (Koch 1992). The World Health Organisation (WHO) suggests that a key component of quality assurance, in general, is individual satisfaction with the services provided (WHO working group 1989). Broadly, qualitative data pertaining to individual satisfaction is derived from three main sources, experience (observation), enquiry (interviews, surveys, questionnaires) and examination of documentation/material already produced by others (such as records of complaints and compliments received) (Froggatt 2001). However, researchers remain divided as to whether this is a crucial and pivotal outcome measure or a largely meaningless and somewhat crude evaluative mechanism (McGee 1998). Mimnagh (2002) asserts that user satisfaction is a notoriously unreliable assessment of the standard of care provided, and urges caution about the commonly held fallacy of assuming care is good if people like it and bad if they do not. User satisfaction is gratifying but not necessarily a useful outcome measure of significant health benefit (Nesbitt 2002) and this may be so because satisfaction with a service may not indicate the actual quality of what is provided. Clearly quality in the context of health care is more than the consequence of consumer satisfaction since the expectations of consumers may be low and their knowledge limited (Redfern and Norman 1990).

A key question here relates to whether the recipients can actually effectively judge the technical competence of their doctors, or whether they merely base their confidence in them on interpersonal skills and caring. In the context of breast cancer follow-up, it is debatable as to what extent people can evaluate the effectiveness of the clinical examination or investigations that they undergo. Research supports the notion that women may be more likely to express dissatisfaction and indeed look elsewhere, if they dislike the doctor, are not given enough time or feel that the doctor was not interested in them as a person (Korsch et al 1982, Schain 1990, Del Giudice et al 1997). They are less likely to be dissatisfied as a result of genuine concerns about their knowledge and competence. According to these previous studies, the characteristics of doctors rated as most helpful are warmth, sensitivity, taking the time to explain and answer questions, and encouraging participation, rather than their clinical examination skills. Interestingly, studies that have required nurses (including cancer nurses) to rank their perceptions of the most important caring behaviours reveal an insight into what individuals also consider important. These include listening to them, touch and comforting, allowing them to express feelings, getting to know them as an individual, being perceptive regarding their needs and calling them by name, thus individualising care (Larson 1986, Komorita et al 1991, Beck 1993).

Another potential flaw with using satisfaction as a measurable outcome of care is that a perceived need for care depends on the beliefs and knowledge of the person affected, and hence on value judgements (Bowling 1992, Bowling 2005), and the recipient may have limited experience on which to base their judgements. Thus they will inevitably be making comparisons to previous episodes of care, which may have been particularly poor, such that even a small improvement will be welcomed. Interestingly, research studies involving measurements of user satisfaction almost unanimously fail to define what is meant by satisfaction for the respondents who are attempting to rate it (Bowling 1992).

Controversially Dingwall and Allen (2001), with regards to eliciting user satisfaction, question the appropriateness of hospitals attempting to cater for patients' every wish and impulse. They suggest that hospitals are not places where people go to have a nice time, but where people go to have things done to them, albeit with their active co-operation. Their view is that users have been wrongly encouraged to expect that the experience of health care will be comparable to that of any other consumer service, that is available on demand and in exactly the manner that they desire, and that this is inevitably an unrealistic expectation. Therefore, whilst it remains of certain importance to the individual to be satisfied, this alone may not ensure an impact on their outcome, in that satisfaction reflects patient perceptions of their care rather than a guarantee of a definitive improvement in health. There are also real methodological difficulties with capturing patient experiences and perceptions in a comprehensive way. Low response rates and responder self selection biases cast doubt on the representativeness or otherwise of the views collected (Day and Klein 2001).

In opposition to these viewpoints, Scotland (2002) contends that the debate concerning the relationship between user satisfaction and standards of care provided is, perhaps, the greatest difference in the paradigmatic thinking between nursing and medicine. Increasingly nursing researchers are convinced that consumer response may be equally as important as the operational performance (Koch 1992) if not more so. Feedback from people informs us about what the actual consumers think of nursing and medical care and ensuring their needs are met necessitates attention to their preferences. Clearly a system which relies on clinical experts only deciding on what constitutes quality without the users themselves entering this negotiation process is on some level flawed (Koch 1992). Thus a counter argument is to accept that the preferences of women do have an impact on their outcomes, if only by influencing compliance with care, and so there seems an obvious need to take this into consideration when designing evaluative studies (Sowden et al 1995).

Inexplicably there is a disparity between the stated intentions of government policy and the realities with regards to user involvement in breast cancer follow-up. Recent years have witnessed a proliferation of national guidelines and protocols, yet with them comes the emergence of an apparently resource-driven approach with an emphasis on effectiveness and efficiency, such as speed of patient throughput, rather than considering the effects on women and their experiences (Bond and Thomas 1991). Inevitably value for money will always, by necessity, be a major motivating force in the NHS, however if personal experience, arguably as important an outcome as economic efficiency or clinical effectiveness, is negated, one has to question for whom effectiveness is intended, the women or the health care professionals?

In fairness, there is limited value in taking the time to assess women's viewpoints if one is unable to act upon the findings and it cannot be assumed that activities promoting user participation will inevitably result in beneficial effects (Maslin-Prothero 2003). In the absence of infinite resources, health care professionals have been largely socialised in to roles that value adherence to a system that is rationed by time and money, over the needs of the individual (Corner 2001). In breast cancer follow-up clinics, with an ever increasing demand for throughput and finishing later and later at night, it may be easier to foster relationships around compliance, rather than therapeutic alliance. Thus perpetuating the practices of care that result in the women remaining submissive and not argumentative in the presence of doctors (DiGiacomo 1987).

Overall there appears to be a lack of investment in research from a woman- centred perspective. As a result some authors contend that breast cancer follow-up is an example of service provision that has traditionally been service led rather than needs led, granted at the convenience of providers rather than women. Indeed, there does seem to be little evidence of involvement of women in its planning and delivery despite the government alleging this as a priority. The literature presented above pertaining to the now questionable clinical value of breast cancer follow-up has led to recent calls to cease, or at least reduce, this practice, but without any demonstrable evidence that women themselves have contributed to this suggestion. The National Institute of Clinical Effectiveness (NICE 2002), in order to make recommendations about how health services should be delivered, has produced an updated document on breast cancer service guidance. This states the purpose of follow-up is to assess and manage treatment effects and to identify early signs of disease recurrence, thus perpetuating the emphasis on biomedical outcomes and viewing disease in terms of its likely clinical outcomes rather than its impact on quality of life. It reiterates that long-term follow-up has not been shown to offer any benefit to women, yet no statement is made that alludes to how 'benefit' is defined (clinical or psychological), or whether this viewpoint arises from the women themselves.

A more humanistic approach would involve a shift away from professional domination and power towards more open forms of communication that focus on subjective experience as vital and integral to planning and organising care (Corri 2003). With regards to breast cancer follow-up, surveillance of disease and detection of recurrence are important factors, but are not enough on their own to evaluate outcomes of care. An increased woman- centred focus would ideally place less emphasis on routine clinical examinations and investigations and concentrate more on the women's subjective experience of illness and symptoms and their subsequent impact on quality of life. It would also seek to address psychological and social needs to enable women to cope more successfully with their cancer (Moore et al 2002). In consideration of this, literature pertaining to ideas for alternative models of cancer follow-up is presented next.

3.7 Alternative Models of Follow-up Surveillance

One alternative to conventional medical follow-up in an outpatient clinic setting is the adoption of a minimalist approach, with only examination and mammography rather than intensive diagnostic approaches. These have been appraised earlier in the review, however two other alternatives have also been considered. Firstly, centralised compared to decentralised follow-up, that is surveillance offered by a specialist compared to that delivered in primary care by the General Practitioner (GP). Secondly, regular contact by telephone (instead of face-to-face consultation).

For this section of the review 21 citations were accessed, of which 18 appear in the review, originating almost exclusively from the United Kingdom. The remaining work was excluded because the content were deemed irrelevant to the focus of the review or because they represented repetition of material already retrieved. Ten research studies, including randomised controlled trials, prospective research studies and retrospective audits are presented in appendix C. The remaining material (7 citations) are excluded from the table either because they are government reports/papers and commentaries that make them unsuitable for the subheadings on the evidence table (that is they do not include samples or lack specific outcome measures) or because they represent earlier repetitions of the same work (the same authors published in another journal). Papers appearing in appendix C have been allocated a corresponding number within the text to allow the reader to cross-reference accordingly. Of interest a few of the papers cite doctors as the lead authors, although writing about the outcomes of extended *nursing* practice. The smaller number of relevant papers accessed reflects the fact that alternatives to follow-up have been considered only recently and these continue to represent new concepts, rather than widely accepted and evaluated ideas.

Follow-up in Primary Care

Previous studies have explored the possibility of follow-up being carried out by the General Practitioner (GP) in the community (Dewar 1995, Maher et al 1995, Adewuyi-Dalton et al 1998[1], Chait et al 1998[2]). Whilst this model has demonstrated safety and efficacy and GP's appeared willing (Grunfeld et al 1995a[3], Grunfeld et al 1995b, Worster et al 1996), women expressed some anger and distress about being discharged to the GP and losing the support and specialist services of the hospital. In spite of the women's adverse feelings, actually no significant differences were found in their rating of health related quality of life or in the time taken to detect recurrence (Grunfeld et al 1996[2]). This implies that GP follow-up did not actually harm quality of life but the women's *perceptions* were that it did because of their desire to be seen by more specialised personnel and thus remain in safer hands. The significant flaws in the clinical value of follow-up render it quite inefficacious at detecting recurrent disease, suggesting women are actually at no more risk with their GP's providing follow-up and hence bona fide quality of life was unaffected. In one randomised study, a third of women approached refused to participate because they did not wish to accept randomisation to follow-up in a primary care setting (Grunfield et al 1995b). This is because, whilst continuity of care is rated highly by women, suggesting GP follow-up might confer advantages, access to the expertise of specialist hospital based services is valued more, particularly in the early stages of follow-up (Adewuyi-Dalton et al 1998[1]).

In another study by Maher et al (1995) women even viewed the hospital as their best defence against recurrence. Here focus groups were held with women on follow-up to elicit their views of alternatives to the current system. These views challenged the utilitarian approach of clinicians, with women suggesting that if a community approach were adopted it should be staffed by someone with specialist knowledge, such as a specialist breast care nurse, rather than by a generalist. The advantages and disadvantages to both women and health care professionals, of replacing specialists by generalists in this setting merit further exploration.

Rainsbury (1996) interestingly rejects GP follow-up on the grounds that it encourages care by non-specialists, who individually see less than one breast cancer recurrence every six years. This is in contrast to national guidelines that recommend breast specialists see between 50 and 150 cases per year to retain expertise and effectiveness (The British Association of Surgical Oncology [BASO] 1998, 2005). The crucial importance of adequate GP training prior to changing follow-up practices is noted by other authors as well (Chait et al 1998). Thus Rainsbury (1996) advises caution with the encouragement of non specialist input at a time when, as stated earlier, litigation in the field of breast cancer, in particular delayed diagnosis, are increasing in the UK each year. These sentiments are echoed by Rodger (1997) who comments on the absence of any studies that address the doctor's views of follow-up and their need to learn about the behaviour of the disease and any associated morbidity arising from the cancer or treatments.

Telephone follow-up

Telephone care has been explored as a possible substitute for routine outpatient clinic follow-up, notably for people with chronic medical conditions. The hypothesis is that telephone calls initiated by the hospital could provide an opportunity to increase the frequency of contact and improve satisfaction whilst also saving time for both those being called and health care professionals.

Wasson et al (1992[9]) reported a study that involved substituting clinician initiated telephone calls for some clinic visits over a period of two years, in 434 men with general medical conditions such as hypertension, angina, diabetes, respiratory disease and arthritis. This demonstrated that telephone care significantly reduced the numbers of clinic visits, use of medications, use of blood tests and duration of hospital visits. Telephone care was also less expensive and resulted in the same patient perceptions of satisfaction, access and quality of care when compared with traditional clinic visits in a control group of men.

A similar approach has been adopted in the specialty of rheumatology. In one study described by Pal (1998[7]), following a detailed clinical assessment, 170 people with a range of conditions, such as arthritis and soft tissue rheumatism, were followed up by telephone at a pre arranged date and time. The format of the call was to discuss their condition and any changes, and to give relevant test results. A summary of the content of the call was sent to the participant as well as to the GP. Evaluation revealed people were generally highly satisfied with the new approach, and agreed that it could save time and money, might prove more relaxed long-term and obviated problems with transport and waiting to be seen. Concerns expressed were the impersonal nature of the model and the fear that misunderstandings might occur, although no one felt these were insurmountable.

Successful use of telephone follow-up has also been reported in the areas of clinical genetics (Richard 1992), day surgery (Burden 1992), neonates (Siegel 1992) and community dentistry (Oda et al 1986). However it is questionable whether telephone care would significantly reduce utilisation of medical care without adversely affecting self reported health and satisfaction in women with breast cancer as compared to elderly people with chronic medical conditions. Further research is needed to test generalizability in the breast cancer setting, but clearly the potential (demonstrated in these non breast cancer trials) for increasing contact with health care professionals whilst decreasing travelling time, waiting times and costs, is worthy of greater exploration.

Within cancer care there are some examples of telephone care, notably on client groups with the potential for far greater disease related morbidity and worse prognosis than is generally expected in breast cancer care. This is likely to impact on satisfaction with telephone interventions because people who are experiencing greater functional difficulties and who feel more unwell, may derive greater benefit from not having to travel to the hospital on a regular basis.

Moore et al (1999, 2002[6]) describe a study which involved developing an alternative model of follow-up for people with lung cancer, led by a specially trained clinical nurse specialist, that aimed to improve service provision and achieve flexibility and accessibility. Included in this model, participants were assessed monthly by protocol over the telephone. The results indicated that acceptability of the nurse-led telephone care was high. Participants specifically valued feeling cared for, the ease of access to talk to a professional, the unobtrusiveness of being advised whilst at home and the flexibility of the telephone system. The advantages of not attending the hospital included saved time and a reduction in 'wasted' visits in which no actual clinical care was provided. However in this study telephone follow-up was not exclusive, but part of a bigger package of care that also included face-to-face contact in a clinic and open access to appointments five days a week. Supporting telephone follow-up with open access may prove more problematical for women with breast cancer because of the sheer numbers involved and the logistics of ensuring open access to an unpredictable workload. Interestingly a large randomised trial is currently investigating this model of care. Traditional hospital based follow-up is being compared to telephone follow-up administered by specialist breast care nurses and the telephone intervention is primarily focused on providing information and meeting psycho-social concerns (cited in National Cancer Research Institute list of 'Current National Trials 2004'). It is anticipated that this trial will be completed towards the end of 2006.

Nurse-led telephone care has also been explored for people with high-grade glioma (a type of brain tumour) (James et al 1994[5], Sardell et al 2000[8]). In the most recent study, following a period of training, telephone follow-up was provided to participants at regular, pre-set, mutually agreed intervals. Assessment was by open discussion and a semi-structured questionnaire. Forty-five participants, followed up by telephone for a median of six months, received 254 calls, of which all but twenty were routine (pre planned). As well as proving satisfactory for the people being called, this model also successfully reduced medical outpatient workload and was deemed to be an effective form of surveillance from the point of view of clinical efficacy and safety (Sardell et al 2000[8]). Nevertheless, once again the telephone care was not offered in isolation, but was combined with formal medical assessment at a hospital clinic at four monthly intervals (or earlier if indicated). Women with breast cancer would also need some hospital attendance for routine mammographic surveillance, although a model combining some visits with telephone assessment at intervals would be worthy of further investigation.

Wilson and Williams (2000[10]) refer to the possible obstacle of both staff and patients accepting the practice of telephone clinics, that of visualism. This is defined as a prejudice in favour of the seen. They report a study in which the concerns of community nurses in assessing health problems over the telephone were explored. These nurses expressed worries about making the right decisions in terms of health problems that could be safely managed over the phone and those that needed face–to-face assessment and intervention. Telephone care may have the potential to reduce frequency of hospital attendance and therefore leave more time available for those that need to be seen. More work is needed to demonstrate its suitability and acceptability to women with breast cancer, given their apparent desire to maintain hospital follow-up and undergo regular clinical examination and investigations. Interestingly, improved technology raises the possibility of alternatives to traditional approaches to telephone-based care, including consultations by email, and group follow-up by means of Internet chat rooms and teleconferencing calls.

3.8 Summary

To date proposals regarding alternative models of breast cancer follow-up concentrate largely on the service based elements in that they evaluate alternative ways to deliver what is effectively the same clinical service. This results only in moving the burden somewhere else in the system rather than considering what the practice of cancer follow-up actually achieves and for whom. A third alternative to traditional follow-up care is surveillance by an advanced practice nurse such as a clinical nurse specialist (CNS) or a nurse practitioner (NP). The next chapter explores the evolving roles of nurses and their potential and success in delivering nurse-led care. This is relevant in light of the increasing recognition that nurses may be in a position to improve the quality of breast cancer follow-up care by addressing the key issues as identified by women. Managing the clinical examination and ensuring best practice with regards to detection of new disease remains an integral part of the follow-up consultation. Yet the question remains as to whether placing these elements within a larger framework of supportive care, rather than having them as the predominate focus, will result in a more optimum model of care because it is led by the needs of those using it.

Chapter 4. ADVANCED NURSING PRACTICE

4.1 Introduction

The following chapter explores advanced practice roles in nursing, tracing the origins of their evolution within a policy context and their subsequent input into activities traditionally associated with medicine. Specifically nurse-led clinics are appraised because of the potential for wide spread use of such clinics in breast cancer follow-up.

For this section of the review 64 citations were accessed, of which all appear in the review. The literature used dated between 1975 and 2002 and originates from the United States of America, the United Kingdom and Europe. Twenty one research studies, including randomised controlled trials, prospective research studies and retrospective audits, and their country of origin, are presented in appendix D. The remaining material (43 citations) are excluded from the table largely because they are government reports/papers and commentaries that make them unsuitable for the subheadings on the evidence table (that is they do not include samples or lack specific outcome measures) or because they represent earlier repetitions of the same work (the same authors published in another journal). Papers appearing in appendix D have been allocated a corresponding number within the text to allow the reader to cross-reference accordingly. The majority of the authors are nurses writing about nursing and include clinically based nurses and academics.

4.2 Evolution of Advanced Nursing Practice Roles

It has been proposed that "advanced nursing practice is concerned with adjusting the boundaries for the development of future practice, pioneering and developing new roles responsive to changing needs and with advanced clinical practice, research and education to enrich professional practice as a whole" (UKCC 1994 p2). The term Advanced Nurse Practitioner (ANP) is now widely accepted as an umbrella title that encompasses within it both the roles of Clinical Nurse Specialists (CNS), Nurse Practitioners (NP) and more recently, Nurse Consultants (NC).

Clinical Nurse Specialists

In the United Kingdom (UK), between the 1940's and 1970's, it became increasingly noticeable that qualified nurses with ambition commonly moved towards education or management because of the lack of career opportunities and remuneration available in clinical care. Subsequent endorsement of Clinical Nurse Specialist (CNS) roles (a title adopted by the Royal College of Nursing in 1975) served as an attempt to retain and promote the value of clinical experts within practice whilst also raising the profile of nursing as a whole. Clinical nurse specialists are experienced nurses, commonly holding a rank senior to that of a ward sister, who have developed specialist knowledge within a chosen clinical area, such as infection control, palliative care or stoma care (McGee et al 1996[15]).

Thus the evolution of CNS roles aimed at keeping successful and ambitious nurses in clinical care whilst also improving standards of specialist nursing input. Ensuing employment opportunities increased in a widening variety of settings and CNS's have existed in numerous clinical areas (including breast cancer care) since the late 1970's, with their numbers proliferating throughout the 1980's and 1990's.

Initially application in the area of breast care was somewhat narrow in its focus, demonstrated by early references to post holders as merely 'mastectomy nurses'. However, the last ten years or so have witnessed an explosion, both in the numbers of CNS's in breast care and in their profile as a professional group. In a survey of specialist and advanced practice conducted in England during the mid 1990's, breast care was found to be the 6th most common clinical area for CNS's out of nineteen fields of practice cited (McGee et al 1996[15]). Broadly, traditional CNS's in breast care support people with benign breast disease, and those who are at high risk of, or already have breast cancer and their carers. They provide information and practical advice, monitor physical and psychological progress (Burnet et al 2004), provide emotional support and counselling and have been shown to reduce psychological morbidity, as measured by self-rating scales in women undergoing breast cancer surgery (McArdle et al 1996). In this study 277 women undergoing surgery for breast cancer were randomised to receive current routine care, routine care plus support from a voluntary counselling organisation, routine care plus input from a specialist nurse or all three. The researchers found that support from the specialist nurses alone was of more benefit in reducing psychological distress than any other combination of services and similar findings are reported by Ritz et al (2000[18]). Specialist nurses also give practical advice at all points in the disease trajectory about all aspects of the diagnosis, management and impact of breast cancer (Royal College of Nursing 1999), thus facilitating continuity and co-ordination (Armstrong et al 2002[1]). Indeed the importance of having a specialist nurse to provide all of the above is now widely accepted (Expert Advisory Group on Cancer 1994, Richards et al 1994, Jary and Franklin 1996).

The National Health Service policy framework for commissioning cancer services (Calman-Hine 1995) lends further support by emphasising the importance of nursing input for people with cancer, and crucially access to specialist nurses with expertise in specific cancers, such as breast cancer or lung cancer, commonly referred to as site specific. Central to the development of CNS roles was the notion that they would encompass more than just clinical work and their multi-faceted nature has been repeatedly described in the literature, with core components including clinical practice expertise, education/teaching, management/consultation and research (RCN 1988, McCreaddie 2001[14]). In recognition of this, the RCN Breast Care Nurses Forum propose definitions of advanced nursing practice roles and minimum educational and practice requirements for those aspiring to them (RCN 2002). Of course, some diversity in role function will always be apparent because of several influencing factors. The type of setting worked in will determine overall numbers of referrals and treatment modalities offered, for example, not all centres offer specialist services such as cancer genetics or breast reconstruction. Some CNS's will not be involved with chemotherapy or radiotherapy on site and some have no input in to palliative care. Also there is diversity in nursing practice according to the availability and extent of the local multi-disciplinary team. For example, some CNS's will be actively involved in lymphoedema management and prosthesis fitting, whilst others will have access to input from physiotherapists, lymphoedema nurse specialists and appliance officers whom undertake the majority of such tasks. Finally, different practice settings will require the CNS to have different levels of input in outpatients versus inpatients, private versus NHS patients and on site versus home visits.

Nurse Practitioners

The UK in the 1970's and 1980's also witnessed an increasing number of nurse practitioner (NP) roles which focused on expansion of nursing tasks especially related to domains traditionally regarded as medical, and traditional nursing roles began to extend and expand. Earlier examples of expanded roles included administering intravenous drugs, cannulation and giving chemotherapy. Even today there is still no universally accepted definition of a NP, although the Royal College of Nursing have detailed general principles [see Table 4.1] (RCN 1997). Essentially NP's should retain the capacity for advanced level practice, but whilst CNS's are more traditionally placed within a nursing model of care, NP's commonly undertake tasks more akin with medicine. Most NP models encompass assessment (see the patient and elicit data); treatment (making decisions without a doctor); carrying one's own caseload and receiving direct referrals.

Table 4.1: What do Nurse Practitioners do? (RCN 1997)

- make professionally autonomous decisions, for which they have sole, responsibility
- receive patients with undifferentiated and undiagnosed problems. An assessment of health care needs is made based on highly developed nursing knowledge and skills, including specials skills not usually exercised by nurses (such as physical examination)
- screen patients for disease risk factors and early signs of illness
- develop with the patient a nursing care plan for health with an emphasis on preventative measures
- provide counselling and health education
- has the authority to admit or discharge patients from their caseload and refer to other health care providers as appropriate

The publication of the UKCC document 'The Scope of Professional Practice' (1992) lent support to autonomous and flexible nursing practice by providing a framework for nurses wishing to undertake additional tasks, specifically those more traditionally performed by doctors and allowing them responsibility for their own competence. However it also fuelled tensions between those that recognised and welcomed opportunities for practice and professional development and those who were concerned about the medicalisation of nursing and therefore the loss of its intrinsic value (Finlay 2000). As NP roles become more visible, concerns have continued as to whether these roles maintain the essence of nursing and always incorporate nursing care within them or merely represent substitutes for doctors and result in fragmentation and devaluing of nursing (Edwards 1995). The motives for adopting such roles have also been questioned, in terms of them representing legitimate areas for the advancement of nursing versus nurses being seen as the cheaper alternatives. Hence the use of NP's can be regarded as merely a cost saving exercise aimed at ameliorating service deficiencies (Weston 1975, Edwards 1995, Castledine 1996).

The literature reveals supporters of both views, those that recognise the potential for NP's to pioneer new aspects of nursing versus those that suspect that anyone can be trained to perform mechanical tasks with a view to replacing the necessity for doctors to do them. In contrast, supporters of NP's recognise that the potential weaknesses may lie, not in the philosophy behind the role, but in poor individual interpretation and execution. Salvage and Smith (2000) wisely advise letting go of resentments and boundary disputes and instead directing efforts towards capitalising on the wealth of skills that all professionals can bring to bear on solving health problems and improving services for patients. It would seem prudent in an ideal implementation for post holders to be aware that they need authority and competence in both the medical management of breast cancer *and* specialist nursing care issues. If a nurse performs only the medical and perhaps mechanical tasks without integrating the substance and core of nursing care, there would be no difference between NP's and doctors and no apparent qualitative improvement to the service offered to women with breast cancer. In fact, evidence suggests that such differences do exist and that the skills of the NP enable them to add strength and diversity to nursing care (Lawson and Emmerson 1995), whilst providing a safe and effective service that is highly valued by the recipients.

Elder and Bullough (1990[6]) undertook a comparison of CNS and NP roles, which included questioning post holders about their role activities, percentage of time spent on direct and indirect care, supervision and job satisfaction. They found that significant differences between the two groups emerged in only 8 out of 25 activities specified. Predictably, NPs were more likely than CNSs were to conduct physical examinations, order laboratory tests, prescribe medication and treatments and make referrals as part of their every day work role. CNSs on the other hand, were more likely to teach staff, and conduct support groups. However, *both* groups were involved in teaching people and their families, counselling and psychosocial assessments. CNSs spent more time in indirect care than NPs and more commonly had nurses as their supervisors, whilst NPs had doctors. The authors concluded that the professional views of CNSs and NPs are strikingly similar and that there was little difference in many clinical areas commonly described as components of the CNS role, with large areas of overlapping functions.

A recently published meta-analysis reveals patients are more satisfied if NP's provide care, rather than doctors, partly because NPs offer longer consultations, compile more complete records and are associated with offering more detailed and helpful advice to patients (Horrocks et al 2002). Such themes have also been demonstrated in studies on NPs specifically in breast cancer care. NPs working in breast clinics commonly take histories, examine, request imaging, perform fine needle aspiration cytology and give out test results. This has been demonstrated to be safe, acceptable to women and is associated with better satisfaction, less anxiety, more information provision, equal decision making skills and a lower percentage of inadequate cytology specimens when compared with doctors in a breast clinic (Hammond et al 1995[9], Garvican et al 1998[8]).

Nurse Consultants

The Nurse Consultant (NC) is a newer advanced nursing practice role that was introduced because of ongoing perceived limitations with the existing clinical career structure in nursing which had resulted in expert nurses leaving due to the lack of practice based promotional posts and to improve their earnings. Nurse consultant roles are deemed central to the Department of Health's nursing strategy outlined in their paper 'Making a Difference' (Department of Health 1999b) and are integral in facilitating enhanced evidence-based practice and clinical effectiveness in nursing.

Sub elements of the nurse consultant role are expert practice; professional leadership and consultancy; education, training and development; and practice and service development. Post holders should ideally possess skills and competencies similar to that of CNS's but with greater breadth and complexity (NHS Executive 1999). Contentions have arisen as to whether such posts should be less specific in their focus (existing, for example, in general oncology), or whether they may be suited to site specific cancers such as breast cancer. Whilst some authors have advocated a move away from site specific approaches on the grounds of their narrow focus, this approach is interestingly contradictory to government papers recommending access to specialist nurses possessing knowledge specific to that illness (Department of Health 2000a, Clinical Outcomes Group 1996). In the absence of formal evaluations of the role, the success, impact and proliferation of such posts remains to be appraised in the future.

4.3 Describing Advanced Nursing Practice

The characteristics that make up advanced nursing practice (ANP) have received much attention in the literature in recent years but a lack of consensus continues to exist with regards to inequity and inconsistencies among post holders. Most attempts to define advanced nursing practice relate to the role of clinical nurse specialists as these posts have existed the longest and are probably the most numerous of all ANP roles. Characteristics that are fundamental to specialist nursing practice include clinical expertise (demonstrable by advanced clinical judgement), involvement in education and research and sound leadership (Hamric and Spross 1989, McSharry 1995, Wilson-Barnett 1995). Other authors have contributed additional and interrelated sub roles such as change agent and consultant (Fenton 1985, Autar 1996, Bousfield 1997). Benner's seminal work on expert practice (Benner 1984) echoes the above characteristics and refers to expert practitioners as having in-depth knowledge of a particular client group and highly developed clinical judgement.

Manley (1997[12]) proposes a more detailed conceptual framework for advanced practice that results from analysis of the results from an action research project in which the author performed in a nurse consultant role within a critical care unit. The conceptual framework identifies four integrated sub roles performed by the advanced practitioner and an accompanying set of skills and processes essential to these sub roles (see figure 4.1).

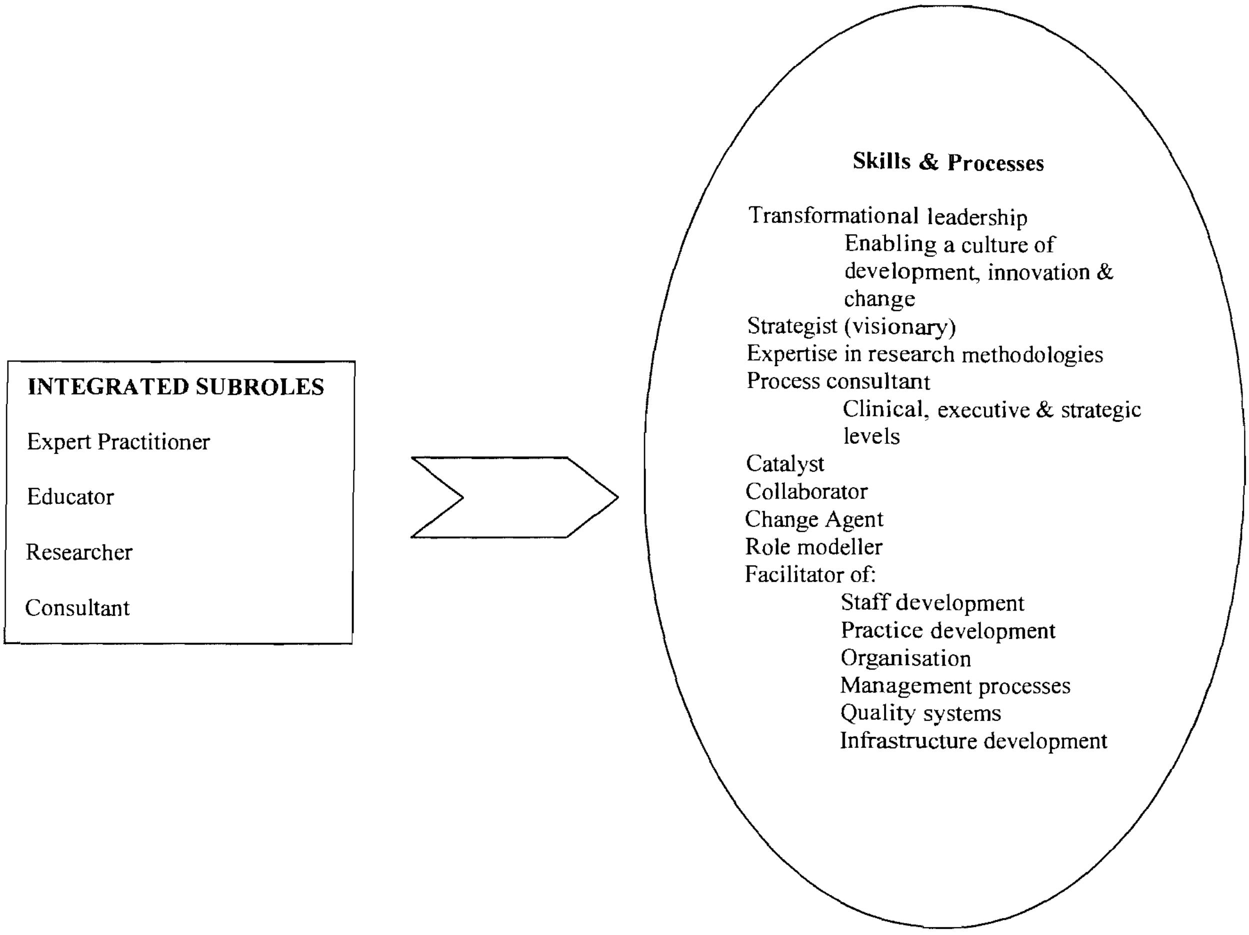


Figure 4.1: Sub roles and skills associated with a Nurse Consultant Advanced Practitioner Role (sourced from Manley 1997[12], Manley 2000a)

This conceptualisation of advanced nursing practice looks beyond the traditional clinical nurse specialist and nurse practitioner roles, implying that they are not necessarily interchangeable with the role of nurse consultant (Manley 1997[12]). It is arguable that this may be as much as a result of the weaknesses and limitations of individual post holders in CNS and NP roles, rather than in a failure of the roles to successfully encapsulate the elements of advanced nursing practice. Inevitably advanced nurse practitioners (clinical nurse specialists, nurse practitioners and nurse consultants) do not all practice at the same level and confusion specifically continues to predominate with regards to role titles, functions and preparation/qualifications (Ball 1997, Bousfield 1997[3]) as well as pay scales and remuneration (RCN 2002). Throughout the 1990's the profession has certainly continued to struggle to differentiate between varying titles and levels of practice and had also encountered difficulties with recruiting suitable staff, especially at nurse consultant level. This has resulted in part from a failure by governing bodies to produce workable definitions of advanced, specialist and expert practice and to provide direction at a time when advanced practice developments are prolific and nurses in many specialties are struggling with role ambiguity (Flanagan 1998).

It is probable that a key characteristic of all advanced nurse practitioners (irrespective of their role title) is expertise in clinical practice. Hardy et al (2002) attempted to explore expertise using discourse analysis to construct meaning and understanding of expertise in nursing practice. They articulate 4 key features of clinical expertise from four extracts written by nurses working in different clinical areas. The first of these is demonstrating saliency, that is making important and recognising the wider context of care for individuals, such as their social and psychological needs and their responses to a diagnosis, rather than just performing the nursing interventions required for their condition. Saliency also pertains to the ability to recognise significant and relevant information, however small that might otherwise have been overlooked (Perry 2000). The second element of clinical expertise identified by Hardy et al (2002) is observation. This includes an ability to pay attention to non-verbal aspects of communication but crucially involves utilising as well as recognising signs that may alter the proposed course of treatment. Thus nurses with clinical expertise demonstrate an ability to be 'sensitive to changing situations and can respond rapidly in a number of creative ways to ensure an interaction ends with a move towards improved outcomes' (Hardy et al 2002 p199).

The third feature of clinical expertise is described as informed risk-taking, including a willingness to try less conventional approaches to care and using clinical reasoning to take clinical risks. Decisions resulting from these risks commonly include the recipient of the care and can occur because of the rapport developed between them and the expert nurse. The final characteristic of clinical expertise involves acting as catalysts, that is generating and speeding up a process of change for those that they care for. Expertise allows the nurse to alter care and treatment paths, potentially challenging the opinions of doctors to achieve this.

Whilst clinical expertise may be shared by all advanced nursing practice post holders, it may be the sub-roles of researcher, educator and transformational leadership that are more exclusively contextualised within a nurse consultant role. Manley (2000b), in considering the impact and influence of a nurse consultant post holder on cultural change within an intensive care unit, suggests the role enabled other nursing staff to achieve their full potential and inspired confidence and enthusiasm. Crucially the post holder enabled nursing colleagues to practice differently, utilise and understand research findings and develop their evidence base. The nurses described how the nurse consultant influenced them to develop their visions of nursing and to participate in new aspects of care and increased their motivation, autonomy and job satisfaction. It is perhaps this ability to develop others that denotes the most obvious distinction between advanced nursing practice within CNS and NP roles versus the nurse consultant role. However, arguably some senior, highly experienced and effective clinical nurse specialists may also succeed in achieving these outcomes.

Manley and Garbett (2000) and Manley (1997, 2000b) remind us that outcomes are a crucial element of advanced practice roles and that in nursing the ultimate purpose is to improve the quality of care experienced by patients and their families. This is probably only sustainable if post holders conform to a level of competence that is formally assessed. With similar characteristics and sub roles applicable to all of them, it would seem the terms advanced, specialist and expert nursing practice are virtually interchangeable and this in itself further complicates the confusion over the titles that post holders possess. Clearly core competencies detailing the essence of the multiple elements of advanced nursing practice would advance the profession as a whole and help to untangle the 'maze of semantic confusion' that exists currently (Marshall and Luffingham 1998, p662).

Assessment of individual competence within these components has traditionally been poor or absent altogether. There are several reasons why assessment of competence is worthwhile, including accreditation (thus protecting the public), bench marking best practice, directing progression along a clinical career pathway (for example to nurse consultant roles) and achieving a greater understanding of the preparation for and nature of expertise (Manley and Garbett 2000). To address this and to recognise and accredit advanced practice, nursing bodies within the United Kingdom have developed training programmes and initiatives that denote those elements that must be attained to successfully accomplish the associated award. The first of these was the Royal College of Nursing Expert Practice Award introduced with the intention of recognising and valuing expert nursing practice and developing an explicit process for this recognition via successful completion of practice based assessments (RCN 1998). It was hoped that the project would enable greater understanding of the concept of expertise in different nursing specialties and exploration of the links between different levels of expertise and patient outcomes. Yet the programme has not progressed beyond a pilot phase and in-depth evaluation of its feasibility and success remains elusive.

The second practice based programme was the Higher Level Practice (HLP) descriptors produced by the professional nursing governing body the Nursing and Midwifery Council, formerly known as the United Kingdom Central Council (UKCC)[3]. This programme was designed to serve as a guarantee of competence within advanced nursing roles via a robust assessment process that focuses on a *level* of practice, rather than a clinical area, and claims to professionally recognise developed and empowered advanced nurses (UKCC 1999). Assessment is based on demonstration of competence in seven areas known as Descriptors of HLP (UKCC 1999) (see figure 4.2).

- Providing effective health care
- Improving quality and health outcomes
- Evaluation and research
- Leading and developing practice
- Innovation and changing practice
- Developing self and others
- Working across professional and organisational boundaries

Figure 4.2: UKCC Descriptors of UKCC Higher Level Practice (1999)

As an extension of the concept of Higher Level Practice, the recently formed Nursing and Midwifery Council (NMC) has declared its intention to develop competencies for practitioner/specialist consultant roles. A nursing task group has been set up to address the increasing need for monitoring nurses skills as they take on more complex and demanding work and to provide clarity and conformity about currently haphazard career pathways and confusion surrounding the expertise implied by different titles held by post holders. The vision is to create a new category of advanced nurse practitioners, recorded as an annotation in the NMC professional register, holders of which would have to demonstrate proficiency in the national competencies in order to be able to adopt titles such as nurse consultant, clinical nurse specialist, or advanced nurse practitioner. Competencies and regulations governing advanced nursing practice have already been introduced in countries such as Australia and the United States of America, with verification required every 3 years to remain registered. Preliminary information revealed by the NMC suggests a minimum of master's degree or doctorate qualification is likely to be a prerequisite to advanced nursing practice registration within the United Kingdom.

The final programme is the only academic (rather than practice based) award that earns the successful candidate the title of Specialist Practitioner (holder of the Specialist Practice Award conferred by the former English National Board (ENB)) and endorsed by the former UKCC. This involves a programme of study that is integrated in to a degree programme and necessitates demonstration of competence and understanding in various areas that are grouped under the four domains of Specialist Clinical Practice; Care and Programme Management; Clinical Practice Leadership and Clinical Practice Development (see appendix E). Again, the demise of the English National Board has resulted in existing students continuing to complete and attain the award, but no new programme entrants will commence in the future. Arguably such academic awards might also be at masters level, rather than at first degree level. Characteristics attributed to master's level nurses are in keeping with the role elements described earlier and include cognitive competencies (critical analysis, synthesis, problem solving), practice-related competencies (analysis, problem solving, autonomous decision making), research orientation and personal dynamism (personal change, confidence, assertiveness) (Ashworth et al 2001^2).

Although the intentions of these projects were admirable, they have received criticism because they were developed independently of each other, resulting in overlap and uncertainty among applicants as to which one to attain. There are also unresolved difficulties associated with them such as who should be responsible for assessing candidates and how will appropriate practice outcomes be identified and, more importantly, measured. It is now generally accepted that education and practice are mutually important to advanced nursing practice posts and that those aspiring to such

---

[3] The Nursing & Midwifery Council (NMC) took over the UKCC regulatory role in April 2002

roles must demonstrate proficiency in both. However, this is inevitably an evolutionary process with individual development depending on their needs and those of the practice, the organisation and the service that they work in (Manley 1997).

A more recent Department of Health paper entitled 'The Nursing Contribution to Cancer Care' (Department of Health 2000b) offers an alternative approach to role definition by outlining and defining four levels of practice within cancer care [see figure 4.3]. Work is now underway to complete a Core Competency Framework for Cancer Nursing that has been designed to reflect the clinical skills/competencies required by *all* nurses involved in the provision of care to cancer patients and their families, irrespective of the care setting at each of these levels (Wetherall 2003). Thus guidance will be available with specific regards to the education and practice attainment necessary for advanced nurse practitioner posts holders (categories 3 & 4 in the descriptions below). Currently this work has reached a fourth draft and plans to pilot it for feasibility and applicability are being developed.

1. **Health Support Worker**
Staff identified working at this level will provide basic and routine care to cancer patients and their families, irrespective of whether they are working in a generic or specialist care setting, with supervision from a registered nurse. Staff working in specialist areas may undertake a limited range of routine clinical interventions subject to attainment of recognised vocational qualifications

2. **Registered Practitioners**
This group includes nurses working in generic areas, caring for cancer patients but with limited experience of cancer and those just entering the specialty, as well as those who routinely use specialist cancer knowledge, skills and experience within their practice and have achieved a cancer specialist qualification

3. **Senior registered practitioner**
This group includes experienced nurses working in a designated cancer specialty/area, such as Sister/Charge Nurse, Community Nurse Specialists, Clinical Nurse Specialists, Lecturers, Nurse Practitioners, Trust Lead Nurses and Research and Clinical Trials Nurses. They will have a sufficient level of experience and competence to be recognised as functioning at an advanced level

4. **Consultant practitioner**
This group includes nurses with considerable specialist experience and advanced qualifications who hold posts that combine expert cancer nursing with significant professional leadership, consultancy, educational, research and service development functions

Figure 4.3: Levels of Practice within cancer care (Department of Health 2000b)

4.4 Evolving Nursing Roles: Policy Context

Of note, skills and competencies required by health care professionals are receiving attention on a much broader scale nationally. The government strategy 'Skills for Health' was launched in 2002 following decisions by the four health departments, the independent health sector, the voluntary sector and staff organisations to create a new independent organisation to develop the skills of the workforce of the health sector. The work of Skills for Health is central to the strategic development of the health sector workforce and a work programme exceeding £2 million across some of the most critical and high profile areas of the health workforce has been launched. This will involve a strategic scoping exercise to elicit the workforce development needs of small and medium sized enterprises in the health sector and will link with all other major health workforce initiatives such as Workforce Development Confederations. These were established in 2001 (Department of Health 2001c) to plan and develop the whole healthcare workforce, both within and outside the NHS and to ensure that healthcare needs are appropriately met. They take the lead on developing an integrated approach to workforce planning as well as managing education and training providers and clinical placements and ensuring a visionary approach to future workforce needs.

Inevitably the evolution of clinical nurse specialist, nurse practitioner and nurse consultant roles have been influenced by government policy pertaining to the development and modernisation of the workforce within the National Health Service. There has been a noticeable trend towards less obvious boundaries between different professional groups and extending traditional nursing practice, particularly towards activity that has previously existed in the medical domain. For example, a key consultation document, 'A Health Service of all the talents: developing the NHS workforce' (Department of Health 2000c) details the governments intentions to promote team working across professional boundaries and flexible working to make best use of individual knowledge and skills. It also asserts the necessity to consider the opportunities and barriers to effective and efficient workforce planning, to remove the restrictions arising from traditional role demarcations and to maximise the contribution of all staff to care, rather than allowing only particular staff to provide particular types of duties.

Further promotion of these ideals is seen in 'Investment and Reform for NHS Staff – taking forward the NHS plan' (Department of Health 2001d) which details plans for increased numbers of staff and investment in training, changing the way staff work (such as nurses undertaking prescribing), development of new jobs and new responsibilities and increased working across traditional boundaries. An example is given of the Cancer Services Collaborative, an initiative that brings together clinical and management teams and aims to re design systems to improve the experience and outcome for people with cancer.

Similarly the publication 'Shifting the Balance of Power in the NHS' (Department of Health 2001e) details new ways of working, intentions to enhance staff empowerment and methods for developing and utilising skills held by different health professional groups. Of note, user and public involvement is considered integral to these new ways of working and a model of partnership and increased patient choice is described that includes placing a Patient Advisory (formerly advocacy) and Liaison Service (PALS) in every hospital trust and Patient Forums in every Primary Care Trust (PCT). The government states that inter-professional collaborative team working across organisational boundaries is in the best interests of patients (Department of Health 1997).

At the same time changes in medical manpower and working hours (NHSME 1991) have also resulted in the gradual process of nurses adopting more clinical responsibility. The European Working Time Directive (European Council 1993) calling for reduced working hours and mandatory rest periods has inevitably necessitated consideration of staff, particularly nurses, undertaking activity traditionally performed by others.

4.5 Evaluating Nurse-led Care

Thus recent government documents clearly signal a move to dismantle the traditional lines of demarcation between health care professionals (Department of Health 2000c) and lend support to the widely advocated notion of extending nurses' roles and responsibilities to take on some functions traditionally performed only by doctors (Corner 2003). However these moves are disputably less about extension of nursing licence, and more about assisting with shortages of medical staff, reducing the working hours of junior doctors (NHSME 1991) and reducing costs (Doyal and Cameron 2000, Corner 2003). Extended nursing roles arguably represent mere reinterpretations of functions because whilst extended roles may require new skills, the new work is still primarily that of a subordinate profession set within a restricted delegation model (Dingwall and Allen 2001, Corner 2003). Achieving higher professional status is an indisputable priority but nursing continues to struggle to assert its autonomy and still has a subservient rather than a collegial relationship to medicine (Bond and Thomas 1991, Castledine 1999). Paradoxically, the more nursing continues to provide the support necessary for medicine to function and maintain its dominance, the more it perpetuates its subordination to medicine (Rafferty 1996[17]).

In spite of this, nurses have increasingly taken on broader roles and increased responsibility and there has been a noticeable shift in the traditional professional boundaries between doctors and nurses, particularly visible in nurse-led clinics. The rise in the numbers and diversity of nurse-led services available makes it imperative that their benefit to patients and to the delivery and outcomes of care is clearly established (Armstrong et al 2002[1]). A justifiable concern commonly associated with nurse-led care in various practice areas is the *lack* of comprehensive evidence that demonstrates if they actually work, that is do they facilitate meaningful improvement in service delivery and qualitatively enhance care?

Evidently, nurses continue to experience difficulties with ensuring that the care they provide is evaluated effectively (Salvage 1998, McSherry and Haddock 1999). Several reasons probably account for why this rigorous evaluation has not always accompanied nurse-led clinics. First and foremost, nurses have not traditionally been skilled in research methodology (conducting or evaluating research) and have been relatively slow as a professional group in embracing the necessity for devising an evidence base of their own. However since the Briggs Report published over thirty years ago (Briggs 1972), which called for nursing to be a research based profession, there have been gradual changes in nurse education and a resultant expansion in uptake of all aspects of research culture within nursing (Blomfield and Hardy 2000 p114, Cranston 2002). Slowly, the profession is moving from a reliance on tasks and procedures to interventions that are based on rigorous appraisal of evidence (Crinson 1999).

Secondly, even with this new knowledge, nurses are not always accorded the time or resources to conduct evaluation activity. A study funded by the Department of Health conducted an exploration of new roles in clinical practice with the broad aim of establishing whether there is a relationship between innovative staff roles and individual or organisational effectiveness. Mapping exercises and in-depth case studies specifically on nursing roles found that their effectiveness was not always formally evaluated and was inhibited by lack of resources (specifically funding, secretarial support, computers and space), volume of work (leading to time constraints) and opposition from key players (Read et al 1999). More recently, another analysis of case studies of post-holders whom undertook nurse-led services within innovative roles worryingly found that none had carried out definitive evaluation of these roles. Hence, the authors remind us of the necessity to seek methodology that will facilitate objective evaluation and measurement of outcomes as well as quantitative data (Armstrong et al 2002[1]).

Thirdly successful evaluation of nurse-led care is reliant on the need for more careful attention 'to be given to the concept of quality of *care* because it is elusive and rarely well conceptualised in the literature' (Girouard 1996 p589). It is notoriously difficult to articulate the art of caring, in other words to explicitly (and scientifically) describe and demonstrate how nurses actually make a qualitative difference to care. Nursing work may be undervalued because of the lack of knowledge (specifically among doctors) about the scope and nature of nursing and because of the recognised difficulties of describing the caring aspects of nursing work in ways that will not be dismissed as trivial (Dowling et al 1995). Finlay (2000) contends that it is essential that nurses in specialist roles who may be conducting nurse-led clinics relate their work to outcomes for patients explicitly, if they are ever to be valued by their colleagues, employers and the public.

Lastly, and perhaps most controversial, is that the motivations behind the establishment of nurse-led care, specifically clinics, have sometimes been questioned, in terms of them representing legitimate areas for the advancement of nursing, versus nurses being utilised as the cheaper alternative. This in itself may have hindered the progress or, more importantly, the focus of evaluation as stakeholders with competing agendas perceive opposing reasons for promoting and setting up nurse-led clinics up in the first instance. The impetus for change has commonly arisen from altered working practices in medicine rather than in nursing per se. Therefore tensions have arisen between those that recognise and welcome opportunities for practice and professional development and those who are concerned about the medicalisation of nursing and therefore the loss of its intrinsic value (Finlay 2000). Arguably, the desire by one professional group to transfer to another, tasks that they find onerous, especially if such a change will prove cost effective and resourceful, may not have individual care and quality assurance at its core. It seems that nurses must continue to be flexible and responsive to change if they are to retain control of advanced nursing practice roles, thus ensuring that they are truly *nurse*-led, rather than arising from pressurised, hurried or badly thought out implementation (Marsden 1995).

Evidence-based practice (EBP) is defined as an approach to decision-making in which the clinician employs explicit and judicious use of current best evidence available to decide upon the option which best suits the patient (Gray 1997). It remains not only a means of empowering professionals, but also as a mechanism to deliver the safest and most effective interventions (Blomfield and Hardy 2000, Trinder 2000). The key components of evidence-based practice require one to develop the culture, develop the skills, apply the skills and then evaluate the skills in practice (Cranston 2002). All professionals, therefore, should measure in some way the impact of their knowledge and skills in relation to the needs of those for whom they provide a service (Humphris 1999) and nurses conducting their own clinics are no exception to this. The emergence of Government initiatives that emphasise the necessity of measuring effectiveness, for example 'The New NHS: Modern, dependable' (Department of Health 1997) and 'A First Class Service' (Department of Health 1998), reiterate that consumers, managers and clinicians need relevant evidence to be both visible and accessible. Without this they cannot be expected to make judgements about the continuing value of nurse-led care and specialist nurses as a whole (Humphris 1999).

Evaluation in the context of the health service can be defined as the objective critical assessment of the degree to which services fulfil stated goals (St Leger et al 1993). Thus the purpose of most formal evaluation is to produce evidence that will enable the extent to which the intervention (in this case nurse-led care) positively or negatively influences the standard of care overall. It would seem imperative that nurse-led clinics for example provide a quality of care that is at very least comparable to what already exists, and therefore, by implication pre-existing outcomes need to be compared to those arising from the initiation of the nurse-led service. In other words, evaluation of nurse-led care requires attention to comparisons, because if the nurse-led service is considered better, this must be qualified in relation to some baseline measure, something which is all too often lacking (Read et al 1999). Comparison in this context maybe with the pre existing service, which offered a different model of care or to a similar service (the clinic) but offered by a different health care professional (often a doctor). Yet when comparing two professional groups (for example in a randomised controlled trial) it must be remembered that both professionals do not necessarily work under similar circumstances and therefore the same work pressures. It is therefore necessary to determine if differences in patient satisfaction between the two would remain if identical circumstances were in place (Horrocks et al 2002).

Therefore evaluation of the *process* as well as the outcome of nurse-led care is essential to verify and justify its continued development, so that attention is given not only to what promotes the best quality of care but also *why and how.* Process refers to the actions and behaviours of nursing staff whilst giving care and encompasses the interaction between the patient and the nurse, in that the process relates to the manner in which care is delivered rather than to what it results in. For example, a study ascertaining the differences between care from nurse practitioners and general practitioners in primary care clinics revealed the outcome in terms of resolution of symptoms was the same. But the *process* in terms of information provision and duration of consultation differed, with greater preference for nurses in most instances (Kinnersley et al 2000).

Outcome relates to what is actually achieved by the care in measurable terms, such as an improvement in health or well being (Koch 1992). The outcome measures chosen need to be specific to the nurse-led service under evaluation and the needs of those people it serves at that time. St Leger et al (1993) remind us of the necessity to make clear the criteria for evaluation and its relevance to the chosen setting. To illustrate this further they cite an example that evaluation of a new cancer therapy would not be sufficient if it only demonstrated disease regression or survival, without attention to quality of life, patient tolerability, absolute cost and cost compared to best available alternatives. Commonly outcome relates to the recipients of care (the patients), but in the context of extended nurse roles, it may also be prudent to consider the outcomes for the nurses conducting their own clinics.

Commonly cited outcomes such as improved patient care or patient satisfaction are notoriously vague and nebulous and may therefore become meaningless if they are not accompanied by measurable and specific objectives. Without these, a link may be made between an intervention and an outcome inappropriately. For example, if satisfaction is greater with a nurse-led clinic, this may be due to shorter waiting times or more time spent in the consultation rather than being attributable just to the nurse per se. Of greater value is to elicit what it is that nurse does differently to the existing service and thus what it is specifically about ***nursing*** that enhanced the care in that setting. Therefore, if people are more satisfied with nurse-led care, then the precise factors which lead to this should be elucidated (Horrocks et al 2002). This ensures exploration of not only *what*, but also *how* and *why* nurse-led clinics may facilitate an improvement in patient care. If one can demonstrate that nursing care absolutely has beneficial effects for the recipients, then it will strengthen nursing professionalism as a whole as well as providing sound verification for the continual emergence of nurse-led care in many areas of practice. However if the nurse-led clinic service results in an identical outcome but users report greater satisfaction with the process that took them there, then the decision to continue the nurse-led intervention might rest on cost comparisons alone.

Analysis of available evidence suggests nurse-led clinics can be highly successful in improving patient care (for example McCorkle et al 1989[13], Weintrob et al 1990[21], Hammond et al 1995[9], Garvican et al 1998[8], Sakr et al 1999, Kinnersley et al 2000[11], Mundinger et al 2000, Shum et al 2000[19], Venning et al 2000[20], Baildam et al 2002, Cox and Wilson 2003). An extensive review of nurse-led services provided by nurse practitioners in America suggested that they provided improved quality of care when compared directly to physicians. Evaluation in this study included adequacy of physical assessment, resolution of health problems, assessment of patient satisfaction with, for example, information received, and rarity of malpractice claims (US Office of Technology 1986). In primary care nurses have been demonstrated to provide longer consultations, arrange more investigations and follow-up, provide more information and elicit greater satisfaction than general practitioners (Horrocks et al 2002) . They are not necessarily cheaper but are as safe in managing certain illnesses (Iliffe 2000).

A proposed source of reluctance to the instigation of nurse-led clinics is that people may have been reluctant to accept consultations from nurses, preferring, perhaps, to see a doctor for safety or efficiency or because they possess greater knowledge. Nevertheless, Read et al (1999) found patients were universally supportive of nurse-led services, and appeared to have little concern for the professional origin of the practitioner so long as they valued the care that they provided them with. Other difficulties are more practical in nature, such as determining minimum standards of training and supervision for nurses taking on considerable responsibility and aspects of delegated medical practice and the resultant burdens for the nurse that this evokes (Moore et al 2002[16], Corner 2003).

4.6 Advanced Nursing Practice in Breast Cancer Care

The UKCC (1994) states that advanced nursing practice is concerned with adjusting the boundaries for the development of future practice and pioneering and developing new roles responsive to changing needs. In line with this, overlap of CNS and NP roles is already apparent within breast cancer care and considerable ambiguity regarding them remains, as it is sometimes difficult to precisely clarify the differences between CNS's and NP's within the specialty. This is not least because as well as discrete NP post holders, many traditional CNS roles have developed to include NP functions (such as nurse-led follow-up) thus further blurring role boundaries and resulting in blended CNS and NP roles. A comprehensive list of clinical fields of practice associated with the traditional CNS role in breast cancer care is presented in Table 4.2, whilst Table 4.3 details examples of extended role tasks specific to breast cancer care. It may be supposed that an essential difference between CNS's and NP's is the prolonged patient contact enjoyed by CNS's, throughout the *whole* disease process. They may therefore offer improved continuity, whilst lack of continuity is a noticeable criticism of the medical model of rotating junior doctors (Pennery and Mallett 2000).

Table 4.2: Fields of Clinical Practice associated with the role of traditional CNS in Breast Care (source Pennery 2003 p340)

Information, support and advocacy pertaining to:

- Family history and genetics (includes prevention and prophylactic mastectomy)
- Benign breast disease
- National Health Service Breast Screening
- Patients newly diagnosed with breast cancer
- Patients undergoing chemotherapy (and related side effects)
- Patients undergoing radiotherapy (and related side effects)
- Patients on endocrine therapy (and related side effects)
- Breast surgery
- Breast reconstruction
- Prosthesis fitting
- Management of menopausal symptoms
- Management of lymphoedema
- Management of fungating wounds
- Treatment induced fertility issues
- Metastatic disease
- Social issues and finance
- Recovery, rehabilitation and follow-up (including lifestyle changes)

Table: 4.3: Extended nursing role tasks in breast cancer care (source Pennery 2003 p341)

- Family history screening and surveillance
- Accepting direct referrals (for example for breast pain)
- Diagnostics (palpation, fine needle aspiration cytology, ultrasound)
- Seroma drainage
- Implant inflation/ deflation post breast reconstruction
- Prescribing radiological investigations or medication
- Nipple tattooing post surgical reconstruction
- Follow-up consultations and examinations

Research has illustrated the unique contribution advanced practice nurses make with regards to enhancement of quality of life for people with breast cancer. In a randomised study evaluating quality of life in 104 women seen by advanced nurse practitioners in addition to medical care, compared to medical care alone, at six months following a breast cancer diagnosis, specialist nursing interventions were found to contribute significantly to reducing anxiety. The strongest effects were recorded in the sub scales of inconsistency and unpredictability, with nurses significantly reducing the effects of these and improving mood states and well-being (Ritz et al 2000[18]).

The breast care nurse specialist is the only health care professional to have prolonged contact with the woman throughout the whole disease trajectory and thus has significant potential for role development whilst maintaining continuity of care (Poole 1996). Nurses are more likely than their medical colleagues to offer psychosocial support (Del Guidice et al 1997) and commonly claim this area as their jurisdiction that differentiates them from other health care professionals. It has been argued nursing work is patient centred and involves a close therapeutic relationship between nurse and patient (May 1992, Dingwall and Allen 2001). In addition nurses are prepared to recognise the interplay between the multidimensional aspects of cancer, thus it can be reasonably inferred that they are in an ideal position to make a valuable contribution to follow-up care.

4.7 Nurse-led follow-up

Government publications delivering guidance on improving outcomes in breast cancer (Clinical Outcomes Group 1996) state nurse specialists are ideally place to undertake follow-up up of breast cancer patients, providing they have documentary evidence of adequate training. Devolving follow-up care specifically to nurse specialists is not a new concept (Brada 1995) and examples of where nurse-led follow-up has proved successful are emerging within the oncology setting (Baildam et al 2002, Koinberg et al 2004).

James et al (1994[10]) reported on a study that aimed to evaluate the feasibility and impact of an outpatient follow-up up system involving consultations led by an experienced clinical nurse specialist. This achieved patient satisfaction and support and effective surveillance in the defined clinical setting of patients with central nervous system tumours during and after radiotherapy. The authors noted the benefits of nurses providing holistic supportive care to both recipients and their families and the effectiveness of nurses in correctly identifying clinical problems, thus decreasing medical outpatient workload by 30%. Similarly, Faithfull et al (2001[7]) randomised men being treated with radical pelvic radiotherapy for bladder and prostate cancer, to nurse-led follow-up that commenced at the start of treatment and continued for twelve weeks. Nurse-led care was acceptable to the men in 95% of those approached, and satisfaction was again reported as higher in those who received it. Nurse-led clinics in radiotherapy have also demonstrated a marked improvement in continuity of care, increased number of interventions for management of treatment side effects, a rise in the amount of information and advice given and a reduction in waiting times (Campbell et al 1997[4], Faithfull 1999).

Moore et al (1999[16]) describe a study which involved developing an alternative model of follow-up for people with lung cancer, led by a specially trained clinical nurse specialist, that aimed to improve service provision and achieve flexibility and accessibility. Under the new model of care, emphasis shifted from the traditional medical model of examination and disease surveillance to one that focused on the individual's experience of having lung cancer and its impact on their life and general coping, with investigations only when an identifiable need warranted them. The results indicated that acceptability of the nurse-led care was high. The nurses proved as effective (possibly superior) as doctors in detecting recurrent or progressive disease and hence there were no differences in survival between the two groups. Interestingly, whilst patients reported greater satisfaction with nurse-led care, quality of life outcomes remained similar to those with doctors. Of note, the clinical specialties of the chosen patient groups cited in this study and the one by James et al (1994[10]) resulted in significant numbers of participants with disability, poor prognosis and complex treatment and rehabilitation needs, arising from brain tumours and lung cancer respectively. Generalizability with women with breast cancer (who achieve higher performance status and more favourable prognosis) is difficult.

Earnshaw and Stephenson (1997[5]) describe a study in which a specially trained nurse performed follow-up of women with benign and malignant breast disease over a period of two years. This model successfully achieved continuity and facilitated the participants to discuss a broader range of issues, but the absence of randomisation make comparison with the traditional medical input to follow-up difficult.

Hammond et al (1995[9]) describe an evaluation of the effectiveness of nurse-led clinics for people with breast disease in the hospital outpatient setting. NP's working in breast clinics commonly take histories, examine, request imaging, perform fine needle aspiration cytology and give people their test results. As in the first example, nurse practitioners were compared to doctors (in this case senior house officers) although participants were not randomised to either. Patient satisfaction and anxiety levels were two endpoints and were measured using pre validated scales. Again, the results demonstrated that satisfaction was higher and, for those women in whom a cancer was suspected, anxiety was reported as less among those seen by a nurse for their consultation compared with a doctor.

To elicit possible reasons for these differences, (establishing the *why*), communication styles between the two health care professionals was also elicited by tape recording the consultations and applying a pre validated model for conversation and interaction analysis. Among other things, this explores the focus of the conversation (such as if it is patient-centred or not). Interestingly the nurses were found to give more information and more frequently checked the persons' understanding. Some attempt was made to elicit clinical skills by examining the clinical notes and the letters dictated to the GP following the consultation. In both groups no major deviations from the Unit's diagnosis and treatment protocols were found. A final outcome related to the acceptability of the nurse-led clinic by asking participants their preference for seeing a consultant, a house officer or a nurse practitioner for a variety of different clinical problems. Whilst the consultant was favoured for some situations, patients who had previously been exposed to the NP more frequently selected them, demonstrating a change in attitude and acceptability once they had experienced nurse-led care. This study represents another illustration of evaluative work that seeks to measure numerous end points which, once again pertain to both the process and the outcomes of care. Clearly it only relates to one nurse in one clinic and may not, therefore, be generalizable, but is successful for demonstrating the safety, acceptability and improved service to patients of this particular model of care.

Finally, a randomised study exploring nurse-led follow-up available on demand versus physician follow-up in 264 women with primary breast cancer found no significant differences in emotional well being, satisfaction and accessibility between the groups, and concluded that nurse-led follow-up is safe and satisfying for women with early stage breast cancer (Koinberg et al 2004).

4.8 Summary of Literature Review

Chapter Two explored women as the users of breast cancer follow-up, including their ongoing multi-dimensional needs and their perceptions of the current system. This was to set the background against which women may experience life after completion of breast cancer treatments, which in turn will influence their perception of follow-up care. Acknowledgement that cancer has the capacity to profoundly affect a person's life, even if they remain free of the disease, reminds us that subjective experiences are no less important to recovery than the clinical outcomes of the treatments. Chapter Three presented the current level of knowledge regarding the practice of clinical follow-up after breast cancer, including a detailed review of surveillance methods to detect new disease. It highlights that the value of routinised follow-up care for people with breast cancer may be questionable both in terms of detection of recurrence and improved survival. In addition, very little research has been conducted on users' perceptions of follow-up care. This focus renders the woman the missing ingredient (Maher et al 1995) and suggests that a new model of follow-up care is indicated which better meets peoples' needs. Chapter Four described the evolving role of advanced nurse practitioners and begins to make the case that they may be in an ideal position to ensure optimum care of people attending for breast cancer follow-up.

Thus breast cancer follow-up warrants further attention, both in terms of exploring the subjective experiences of women and health professionals and also of rethinking the model of service delivery. In order to implement person-focused care it is essential to gain knowledge of individual perceptions and preferences. Women attending are, after all, an essential source of data about how services function and have a right to have their views considered when planning and evaluating services (Avis et al 1995). The first two studies were therefore initiated to find out more about what women and doctors think about the practice of breast cancer follow-up and to explore their experiences thoroughly so that better information is available to help women and health professionals optimise this episode of care. The third study was a randomised controlled trial comparing the practice of breast cancer follow-up by doctors and a specialist nurse. Together the three studies serve to address unanswered questions arising from the literature review and to add to existing knowledge about optimum breast cancer follow-up strategies.

Chapter 5. OVERVIEW OF RESEARCH DESIGN

5.1 Overall project purpose

The review of the literature demonstrates flaws in the medical model of follow-up for women who have completed adjuvant therapy for breast cancer and indicates the potential for nurses to undertake activity traditionally associated with doctors. Thus the overall aim of this research was to develop and evaluate a nurse-led model of follow-up for women with breast cancer, informed by an exploration of current practice.

5.2 Overall project design

The overall project consists of three phases, encompassing three studies and developmental work (see Figure 5.1).

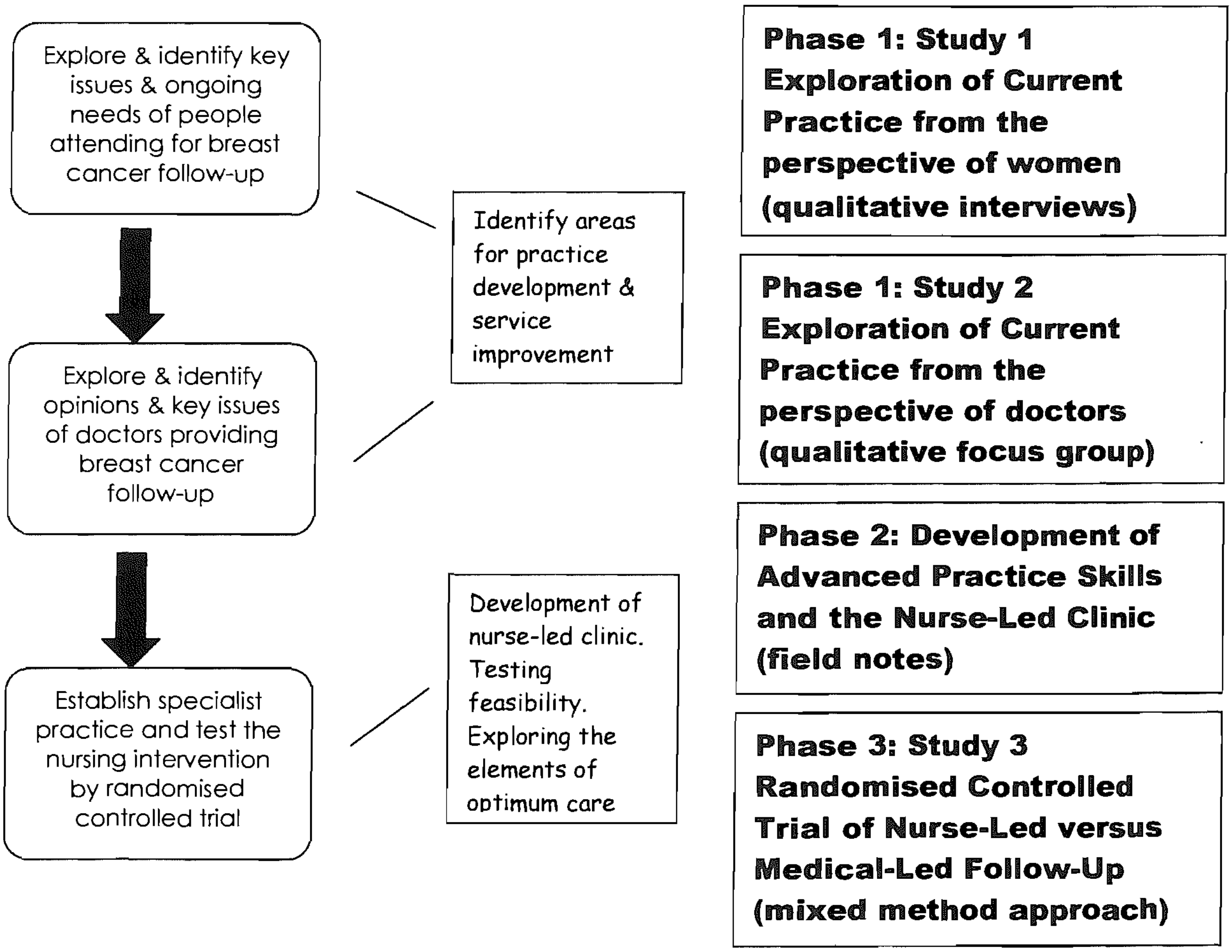


Figure 5.1: Schematic Representation of the links between the research studies

Phase One included two studies.

The first study aimed to explore current practices of breast cancer follow-up from the perspective of women who attend. It investigated what happens to women in the follow-up outpatient setting, their potential needs and the impact of their concerns at different time points after completion of breast cancer treatment. Qualitative interviews were undertaken with the intention of offering insight into how individual women perceive quality of life after breast cancer treatment and their experiences of attending for follow-up. This was to ensure that the development of a nurse-led model of follow-up was informed by the needs of individual's attending, a crucial element of achieving appropriate and effective care.

The second study aimed to explore current practices of breast cancer follow-up from the perspective of doctors who conduct the consultations. A qualitative focus group was undertaken to ensure that the development of a nurse-led model of follow-up was informed by the opinions of health professionals experienced in follow-up provision. Doctors were considered ideally placed to offer an insight in to the similarities and differences between the views of providers and users and to contribute to the identification of strengths and weaknesses of the current system.

The objectives of Phase One were:

i) to describe the emotional and physical impact of undergoing treatment for breast cancer (study 1)

ii) to identify subsequent care needs after treatment is over for those that remain free of further disease (study 1)

iii) to describe the strengths and weaknesses and function of the current system as perceived by the doctors providing it (study 2)

iv) to verify or refute areas of need identified from the literature review (studies 1 & 2)

v) to identify discrepancies and similarities in the perceptions of users and providers of breast cancer follow-up regarding its strengths and weaknesses (studies 1 & 2)

vi) to identify ways in which organisation and delivery of breast cancer follow-up care could be changed for the better for women and health professionals (studies 1 & 2)

Phase Two included the developmental work.

This involved undergoing a process of preparation prior to undertaking a new, extended role and to commencing the nurse-led follow-up clinic. A period of observation in outpatients was useful to explore the organisational practicalities of outpatient care. Field notes were used to record my experiences of developing a protocol for the nurse-led intervention (including defining practice boundaries and development of advanced nursing practice skills), training and learning the skills and establishing the practicalities of the nurse-led clinic.

The objectives of Phase Two were:

i) to prepare and train myself for the extended role activity of conducting follow-up consultations

ii) to develop the nursing intervention for provision of follow-up care

Phase Three included the randomised study.

This final study aimed to evaluate a nurse-led model of breast cancer follow-up. A randomised controlled clinical trial was undertaken to identify differences in provision of follow-up by doctors and nurses in terms of quality of life and satisfaction as reported by the women.

The objectives of Phase Three were:

i) to compare the outcomes of provision of breast cancer follow-up by doctors and a specialist nurse, evaluating women's satisfaction with care

ii) to further identify subsequent care needs after treatment is over for those that remain free of further disease

iii) to identify alternative models of breast cancer follow-up care

5.3 Applications of Qualitative research

Qualitative research seeks to explore social processes and values and to capture individual perspectives, experiences and inferred meanings (Froggatt 2001) without resorting to mechanistic methods and aims to consider individual views and behaviours in detail, adding depth to data gathered. In this way *all* data may be given attention so that minority or unexpected data is not neglected. Proponents of qualitative methodology refute that quantification is the only way to achieve objectivity, arguing that statistical methods may measure variables that are most easily quantifiable, rather than most theoretically relevant (Cook and Fonow 1990). Qualitative research has many diverse applications, in that it crosses the humanities, social sciences and physical sciences, is multi-paradigmatic and sensitive to the merits of a multi-method approach (Denzin and Lincoln 1998).

Qualitative research has been charged with the accusation of being less scientific than quantitative approaches on the grounds that the latter conventionally values nature over culture, objectivity over subjectivity and because the lack of statistical analysis (numerical precision) renders the data as 'soft', rather than deriving hard facts, descriptive rather than explanatory and less concerned with establishing causality (Hunt 1991, Henwood 1996). However the validity of this argument relies on a preset definition of science, rather than challenging prevailing conceptions of what science actually constitutes (Woolgar 1996).

Science has been described as a way of generating and testing the truth about events in the world of human experience (Wallace 2004). The defining characteristics of science have been and continue to be the focus of considerable debate, but one idea central to popular conceptions of science is the notion of discovery (Woolgar 1996). Thus it follows that to discover something meaningful, in this case potentially leading to improvements in care, is a contribution to knowledge and understanding and hence also to science. Quantitative research is just one approach to science and qualitative research can gain its acceptance by arguing for the importance of inquiry that leads to an understanding of the meaning of the experience as interpreted through the eyes of the participants (interpretative) and a sensitivity to the contexts where behaviour and meaning naturally occur (naturalistic) (Henwood 1996).

Of course, it should be recognised that the researcher's attempts to place significant emphasis on individual meanings can result in value-laden, rather than fact based data. Subjectivity may render data biased but whilst the potential for different researchers to reach differing outcomes from the same data is acknowledged, it is hoped that these differences arise more from individual emphasis and orientation rather than in the nature and meaning of the story being told (Ball 1990). It is, however, essential that the researcher demonstrates that they have captured the range of possible interpretations, rather than merely 'finding' in the data what they were expecting to see (Ingleton and Seymour 2001).

Hence it follows that a potential problem with qualitative research is how to simultaneously ensure reliability and validity without one counterbalancing the other. The in-depth, nature of analytic approaches to qualitative data more commonly results in smaller and arguably more selective sample sizes, such that the statistical probability of generalisation (analogous to transferability) becomes weak. In addition qualitative research designs may lack rigour and reproducibility, as replication to other contexts is clearly more difficult with specific situational accounts. Also different accounts may be obtained from different people in the same situation because different samples may have competing perceptions of reality (Froggatt 2001). Ingleton and Seymour (2001) suggest nine methods of enhancing rigour in qualitative inquiry including contextualisation of enquiry, respondent validation, theoretical sampling, triangulation, audit trails and reflexivity.

5.4 Applications of Quantitative research

Quantitative research methods are suited to proponents of value free and objective approaches to data analysis, which enables numerical measurement and statistical inference. Widely considered a formal, objective and systematic approach to research, it establishes information about relationships between variables and produces evidence pertaining to causal relationships. This may be especially relevant, given the current ideology of the National Health Service, which inevitably demands evidence supported by facts and figures and emphasis placed on cost-effectiveness, accountability and performance indicators (Playle 1995). Quantitative studies generate empirical knowledge, which is verifiable, quantifiable and 'synonymous' with science (Carter 1991 p140). Such studies commonly achieve generalizability, in that findings can be applied to similar populations elsewhere. They have the capacity to test hypothesis and compare interventions. The researcher aims for objectivity, distancing themselves from the subjects and remaining detached as far as possible and this in turn serves to minimise bias. The quantifiable nature of quantitative work ensures the data gathered is amenable to complex statistical measures, such as estimation of confidence levels, which lends further credence to the reality of relationships between measures or variables.

Quantitative research designs are criticised for failing to capture individual experiences and perceptions and therefore neutralising the nature of human behaviour. Whilst the detached nature of the researcher may limit bias, it also renders the influence and relevance of the relationship between the researcher and the researched as less recognisable or significant. An attempt at minimal interaction between researcher and subject to gain objectivity serves to 'render the participants as objects' (Hunt 1991 p125). It is plausible that meaningful and relevant data arising from quantitative research is likely to be neglected and omitted if it does not display statistical significance in formal analysis.

Quantitative research might also be criticised for failing to retain a natural setting and instead creating an artificial environment. However it is possible to carry out experimental research in natural settings and as directive interviewing, adopted by some qualitative researchers, can be accused of creating relatively artificial ways of eliciting data, the dichotomy between artificial and natural becomes much less simple (Hammersley 1996). Similarly it is presumptive to suggest that experimental findings can not be generalised to the real world because the participants are too influenced by the experimental situation. This is often dependant on how the study is designed and inevitably the presence of a qualitative field researcher in the natural world will also influence people's behaviour around them (Hammersely 1996).

5.5 Rationale for mixed method research approach

Within this thesis I have employed a research design that combines a range of methods, sources of data and underlying theory in order to explore breast cancer follow-up from the varying perspectives of those most closely involved (women and health professionals).

Triangulation, undertaken for the purposes of completeness, involves using multiple strategies in an attempt to reveal the varied dimensions of a domain of interest (Norman et al 1992). Multiple sources of data may not always confirm each other, but should contribute additional understanding. Thus triangulation enables the researcher to converge on a single version of reality by gathering more than one perspective about that reality (Seale 1999) and exploring the links between one data source and another.

The various and diverse aims of this research endorsed the adoption of methodological, data source and theory triangulation. All methods have their weaknesses, but used together they can add strength to the overall research design. The multiple methods used include interviews, a focus group, a randomised controlled trial and two different postal questionnaires. The three data sources used were women attending follow-up and doctors and a clinical nurse specialist providing follow-up. Two different philosophical foundations (feminist and post positivist) underpinned the work throughout and both quantitative and qualitative theoretical approaches were also adopted.

Meaningful exploration of the reasons for women's preferences for different professionals and their needs on follow-up was suited to thematic analysis of their anecdotal accounts/words from semi-structured interviews and questionnaires. Similarly the accounts of the doctors views of follow-up derived from analysis of the focus group transcripts provided a different form of qualitative data about breast cancer follow-up. The two approaches can together provide different sorts of data and information that complement each other. The qualitative data in this case informs on the perspectives of women attending for follow-up and doctors providing it whilst the quantitative data from the randomised controlled trial identifies causal patterns in the interactions and processes. A comparison of two different health care professionals was scientifically approached with the adoption of a randomised, controlled trial, amenable to quantitative, statistical analysis. Counting the frequency of the phenomena (statistical analysis) allowed exploration of the data to look for patterns (statistical inference) and identification of relationships and issues of interest. This then directed further qualitative analysis of data associated with the variables of statistical interest that enhanced the trial by enabling descriptions and explanations of variances within the results.

Quantitative methods rely on acquiring data that is numerical and can be analysed with the use of statistics. Qualitative methods are more focused on understanding the nature of the phenomena under study in natural (rather than experimental) settings. In light of these differences, debate ensued as to the appropriateness of quantitative techniques for resolving nursing research questions. Nurses generally have inclined more towards a sociological basis to studies, more commonly choosing to neglect experimental designs (Bond and Thomas 1991). However, nursing research can never be exclusively about philosophical issues and will inevitably need to also address practical and political issues such as cost effectiveness and provision of evidence for policy makers planning care delivery.

Both quantitative and qualitative research methodologies can be applied to a variety of types of health services research, each bringing a different approach in their own right and different endpoints, but it is contested as to whether this means they represent fundamentally different and thus not commensurate paradigms. Whilst in the past researchers have been affiliated to one or the other, there is now an increasing realisation of the importance and contribution of both approaches to knowledge, not least because research in to complex human behaviour does not fall neatly into either category (Hammersley 1996). As such the qualitative-quantitative divide might be increasingly regarded as artificial and rhetoric (Seale 1999) and the two approaches not as diverse or mutually incompatible as historically conveyed (Clark 1998).

The reliance of qualitative data on words, rather than numbers might lead to questions about the precision of the data analysis. However, in reality many researchers use both words and numbers (Corner 1991), for example combining tables and statistics with quotations. In addition qualitative researchers may use words to denote quantitative descriptions, for example 'frequently' and 'more' (Hammersley 1996). Adequate precision may not warrant the use of numbers only and the presence or absence of something can be described precisely in words (Hammersley 1996). Leininger (1985) in a more sophisticated comparison of the two approaches than merely the notion of hard and soft data (Burns and Grove 1987) reminds us that in order to explore the nature of being human, methods other than those that reduce people to measurable objects are required.

In other words the two approaches can explain not only *what* is happening, but also *why* it happens. Broadly quantitative research applies a deductive approach to theory development. Qualitative research adopts an inductive approach to testing and generating theory, although, one must be careful of over simplification, as not all quantitative research involves hypothesis testing, and some qualitative research is explicitly aimed at theory generation (Hammersley 1996). On some level, all research involves both deduction and induction (in the broad sense of the terms) because in all research we move from ideas to data and from data to ideas (Hammersley 1996).

Reichardt and Cook (1979) wisely advise researchers stop building walls between methods and start building bridges and triangulation might be one way to achieve this. By using a technique in which qualitative and quantitative methodology are commonly employed sequentially or simultaneously, the researcher can maximise the strengths and minimise the weaknesses of each approach used. Utilisation of a range of methodology and theoretical perspectives enriches and validates the findings of each.

A criticism of triangulation is that it assumes that the various data sources will lead to one complete picture of reality. Data from different sources is used in an attempt to confirm the truth. However if competing versions are provided the researcher is faced with adjudicating as to which is the most relevant and 'true' account to report (Hunt 1991 p126). If triangulation produces inconsistent, conflicting or contradictory findings, this will only add to the researcher's confusion, making theory generation almost impossible (Cutcliffe and McKenna 1999). Similarly, all of the sources may provide inaccurate accounts/ results, in which case triangulation will only serve to confirm and support what is essentially inaccurate theory. A challenge for researchers adopting triangulation is combining numerical and textual data in a meaningful way, interpreting divergent results and deciding whether, and how, to weight different data sources in terms of importance or significance (Mitchell 1986, Corner 1991). In addition, debate about philosophical stances must not negate the necessity to address the practical and political problems of undertaking nursing research and there will always be a need to provide strong evidence for policy makers in health care.

5.6 The Research Setting

The NHS Trust in which the studies took place is situated on two sites, in West London and Surrey. The health care professionals at both sites care for women who have been diagnosed and treated for breast cancer although some difference exists in the clinics at either site. When a woman has completed all active treatment for breast cancer (for example surgery, chemotherapy and radiotherapy) they are entered in to a schedule of care known as *routine follow-up*. Longer-term endocrine therapies (such as Tamoxifen) may be ongoing, but the woman is deemed disease free and needing only routine care. Follow-up care is provided in the Outpatient Department, most commonly by the Consultant team who initially saw the woman on presentation. Generally, women receiving follow-up care are seen by the Registrars or House Officers since the Consultant will be assessing new people.

The frequency and nature of follow-up care varies between different doctors and women and is also determined by participation in clinical trials. However, at the time of conducting the research it was most common for women to be seen three or four monthly for the first two years, then six monthly for up to five years, then annually for up to ten years. The numbers of doctors and women in these clinics differ but they are usually considered busy and oversubscribed. In addition, the numbers of women seen by the clinical teams is increasing, reflecting the increased incidence of breast cancer and improved survival after treatment.

5.7 Summary

This chapter has presented an overview of the whole project design, which includes three studies and developmental work incorporated in to three phases. The first phase consisted of exploring current follow-up practices from the perspectives of women attending and doctors. The second phase described the preparation I needed to undertake to be proficient in running a nurse-led follow-up clinic. These phases shaped the development of the nurse-led follow-up clinic and the third phase consisted of its evaluation, when compared to doctors providing this aspect of care. The three phases and the data arising from them are presented in the succeeding chapters.

Chapter 6. PHASE ONE: EXPLORATION OF FOLLOW-UP PRACTICE RESEARCH DESIGN

6.1 Introduction

The literature review demonstrated flaws in the traditional medical model of follow-up for women who have completed adjuvant therapy for breast cancer. I felt, in light of this, that adoption of an explicit woman-focused approach that recognises the importance of the needs of individual's attending breast cancer follow-up is crucial to identifying appropriate and effective strategies of care. Therefore the first of two qualitative studies in phase one used interviews to examine the practices of breast cancer follow-up from the perspectives of women at different time points during their recovery. The informants all had personal experience of attending for follow-up consultations for differing amounts of time. However, the nature of follow-up necessitates that women work in partnership with the health professionals conducting the consultations, so the second study in phase one used a focus group to examine the practices of breast cancer follow-up from the perspectives of doctors who regularly provide consultations to offer insight in to similarities and differences between the views of providers and users.

6.2 Aims and Objectives of Study One: Interview study of women

The aim of the first study was:

i) To ascertain women's perceptions of routine follow-up care after completion of adjuvant treatment for breast cancer

The objectives of the first study were

i) to describe the emotional and physical impact of undergoing treatment for breast cancer

ii) to identify subsequent care needs after treatment is over for those that remain free of further disease

iii) to verify or refute areas of need identified from the literature review

iv) to identify ways in which organisation and delivery of breast cancer follow-up care could be changed for the better for women

6.3 Aims and Objectives of Study Two: Focus Group with doctors

The aim of the second study was:

i) To explore and describe the views of doctors about their experiences of conducting routine follow-up consultations after treatment for breast cancer

The objectives of the second study were

i) to describe the strengths and weaknesses and function of the current system as perceived by the doctors providing it

ii) to verify or refute areas of need identified from the literature review

iii) to identify discrepancies and similarities in the perceptions of users and providers of breast cancer follow-up regarding its strengths and weaknesses

iv) to identify ways in which organisation and delivery of breast cancer follow-up care could be changed for the better for health professionals

6.4 Paradigmatic Approach

A paradigm, in the context of research, relates to the set of philosophical assumptions that guide the researcher's approach to inquiry. Increasingly researchers are compelled to pay adequate attention to the rationale and appropriateness for the choice of methodology employed, not just in terms of the practical application of these methods to what is being studied but also the fundamental philosophy that underpins them. Philosophical approaches in the context of research method focus on assumptions relating to general features of the world, encompassing aspects such as mind, matter, reason and evidence (proof) for knowledge because different research methods may share or differ in their philosophical conceptualisations of truth (Clark 1998).

It is conceivable that methods cannot stand as atheoretical tools because data are not detachable from theory (Neilsen 1990) and research rigour 'involves being clear about one's theoretical assumptions' (Maynard 1994 p25). In choosing a research paradigm, theory is used to focus the inquiry and to facilitate the development of outcomes. Thus I wanted my work to be guided and informed by a paradigmatic approach that I could learn from and become more knowledgeable about. However it is a recognised difficulty that researchers are not always able to place a whole research study in the context of just one paradigm, preferring instead to adopt related philosophical standpoints to underpin diverse methodology and key issues of interest under investigation. This is epitomised within this work because it comprises of two qualitative studies succeeded by a quantitative study (described in the next chapter) and involves three different methods. I have, therefore, chosen selected paradigmatic theory to act as a conceptual template, rather than being used as pre set categories into which to force the analysis (Morse 1998). Seale (1999) supports this approach and encourages the constructive use of methodological debate to enrich research practice, without necessarily feeling compelled to 'solve paradigmatic disputes', that is rather than adopting only one paradigm, learning valuable lessons from several to place the research in a sound philosophical context.

In exploring different theoretical approaches to underpin my qualitative research I was cognisant of the importance of ensuring the chosen theory would be complementary to the quantitative study that was to follow and also suited to different methods of inquiry. I found during my reading a natural affiliation to feminist methodology.

Feminist research has largely been located in qualitative methodologies and has been described as 'inclusive, involved and socially relevant' (Nielsen 1990 p6) and, of relevance to women with breast cancer, is exclusively directed at the needs, interests and experiences of women (Webb 1993). Essentially, this philosophy challenges the view of the way knowledge is produced and whose view of the world it seeks to represent (Robson 2001). This struck a chord with me, as I wanted to challenge the reasons for and model of delivery of breast cancer follow-up and had inferred from the literature review that the traditional approach might be more representative of the views of doctors than of the women attending.

Feminist researchers have had long-standing concerns about the treatment of women in health care systems (Olesen 2000) and their perspectives are closely linked with issues of power and dominance. A key element of this philosophy is that an indicator of the quality of the research is the study's capacity to empower a group of people because if the people being researched endorse the study, they then give it greater value (Seale 1999). Feminist research aims not only to explain the consequences of dependence (or oppression), but also what the causes and motivations for dependence may be in given settings and these were all themes prevalent in my literature review. If, for example, women attending for breast cancer follow-up express the need for reassurance, use of feminist theory can explore the ramifications of this with regards to the potential powerlessness and vulnerability of being a 'patient', reliant on the doctor's chosen response to any needs that you might have.

Feminist approaches to research endorse the idea of bringing about change, in that the research findings are used by the subjects as well as by the researchers. A key objective of a feminist approach is for the research to succeed in being instrumental at improving women's lives at least to some extent (Webb 1993). This might be important if, as some authors suggest, common patterns of medical interaction suppress the voices of women and generally the medical establishment are sceptical that methods other than scientific experiments can produce legitimate knowledge about the voices of female patients in clinical practice (Malterud 1993). Of course in feminist research the analysis focuses on the distinct experiences of women and can be about women as well as for women. This is of particular relevance in a study where all of the participants (women with breast cancer) and the researcher (myself) were female, whilst most of the doctors conducting follow-up were male and I would be extending role into the domain of a male dominated medical profession. Feminist research facilitates development of knowledge about issues such as the gendered nature of language, and approaches to health care delivery. This seemed relevant in that there are different approaches to follow-up provision between cancers affecting men versus women.

Reflexivity is a core tenet of feminist methodology. Reflexivity has been described as the turning back of the experience of the individual upon themselves (Mead 1934) and reflects the philosophy that the self (in this case the researcher) cannot be viewed as static. Focusing on acknowledging and reacting to the researchers feelings are a feature of feminist research and this belief is also linked with issues of power because models in which researchers and subjects are separated will inevitably be less likely to ensure power imbalances existing between them are broken down. Arguably, such imbalances do exist because researchers have a different status from their subjects and exploit them, at least to some extent, by objectifying their words in transcripts and analyses (Webb 1993). Therefore it could be said that neither researcher integration nor separation are wholly achievable. However attempting to redress power inequalities between the researcher and the researched facilitates construction of the meaning of the research encounter, so reflexivity is a way of achieving an expansion of understanding and is central to the production of knowledge (Gergen and Gergen 1991, King 1996). Robson (2001) asserts that researcher detachment in feminist studies is neither feasible nor desirable, especially in cases where there is a commitment to bring about changes in practice. This is not least because the researcher and the researched share similar experiences, hence proponents of feminist theory reject the assumption that maintaining a strict separation between the subject(s) and the researcher produces a more valid, objective account (Cook and Fonow 1990).

Triangulation is seen as conducive to a feminist methodology strategy, as reliance on only quantitative approaches may prevent certain types of experiential information being elicited (Cook and Fonnow 1990).

6.5 Study Designs

Feminist research might be considered to be more about the approach than the method of data collection although there is no distinct method of feminist inquiry. The approach should maximise the ability to explore experience, thus feminist researchers emphasise the importance of listening to, recording and understanding women's own descriptions and accounts (Maynard 1994) and formulating questions that arise from the position and perspective of women (Harding 2004). I wanted this approach to guide my study and thus to use methods (techniques for gathering evidence/data) that enabled me to listen carefully to how women attending for breast cancer follow-up describe this time in their lives.

In order to meet the objectives of each study two approaches to data collection were used. Firstly, to explore in depth and gain insights into the experiences of women attending breast cancer follow-up semi-structured interviews were used. The purpose was to elicit information about current practice, including the gaps and strengths of medical follow-up and the pros and cons as perceived by those receiving the care. In designing this study it was important to me to retain my nursing values and this meant ensuring that the voices of women with breast cancer were heard. This is in line with my chosen feminist approach to the research because it legitimates women as having knowledge and recognises that they have something meaningful to say (Harding 2004). I wanted to discover first hand from women the emotional and physical impact of undergoing treatment for breast cancer and to identify areas of care regarded as important after treatment is over for those that remain free of further disease.

Yet it seemed incomplete to merely focus on women's experiences without taking into account how that experience emerged, that is what the characteristics and circumstances guiding that experience were (Scott 1991). It therefore seemed prudent to also understand the experience of providing breast cancer follow-up. Thus a focus group was held in order to gain insights into the experiences of doctors who frequently conduct breast cancer follow-up consultations. In order to bring more completeness to my understanding of women's experiences of breast cancer follow-up and in line with the feminist approach to exploring sources of social power, it made sense to seek the input of those that potentially held power in this context, that is the doctors who provide follow-up.

Whilst a feminist standpoint might be to claim that exploring women's experiences of oppression produces more complete and less distorted knowledge than visible from the position of the 'ruling' gender (Maynard 1994) and women are, to an extent, vulnerable and subjugated to rules enforced by doctors in the follow-up setting, I was aware that not all of the doctors were male and I wanted to see if there were differences between the two viewpoints of providers and users of this service. The design of phase One is illustrated below in figure 6.1.

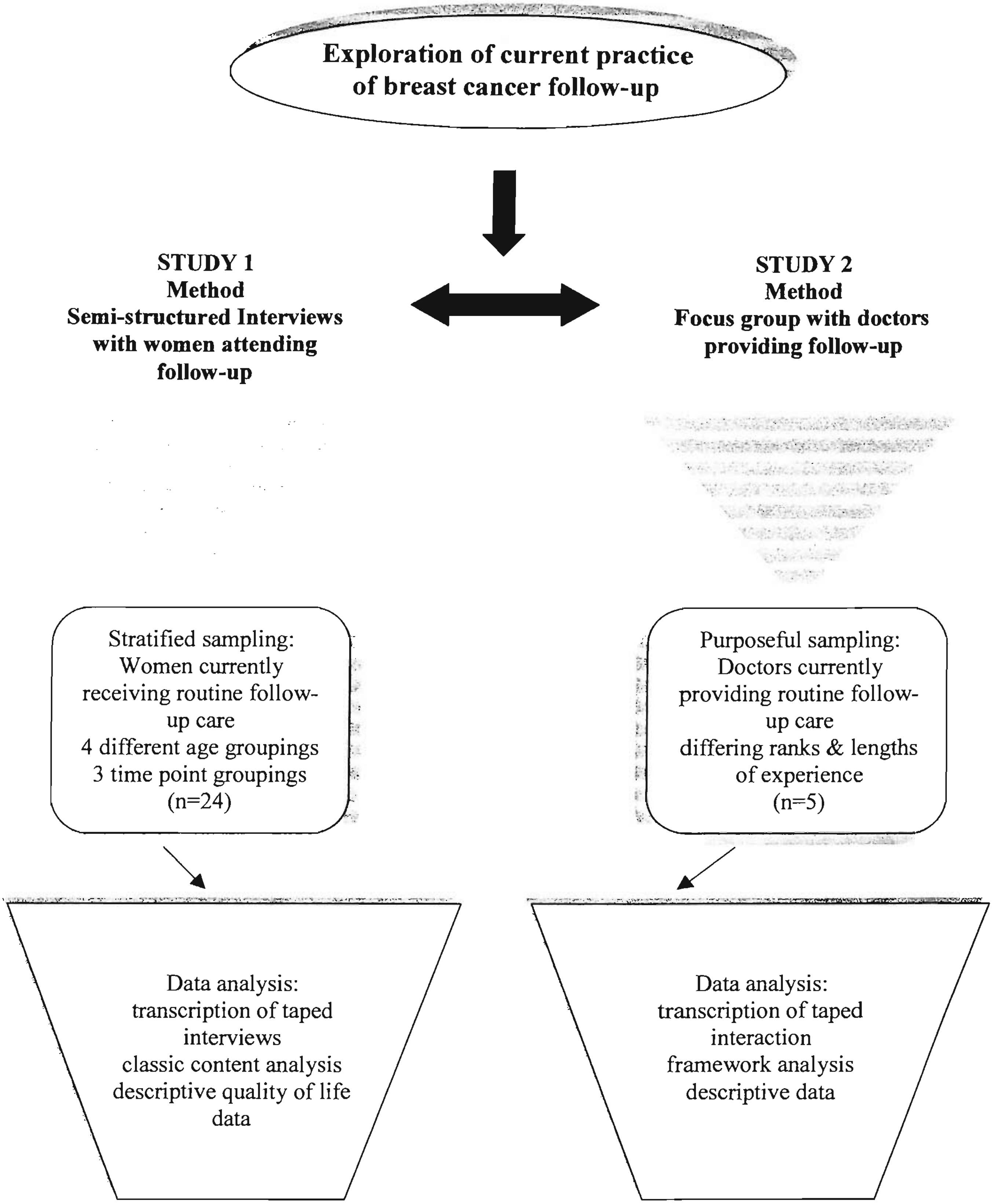


Figure 6.1 Illustration of research design of Phase One

6.6 Study One: Interviews with women

6.6.1 Introduction

This first qualitative study explored the needs of women attending for routine breast cancer follow-up, in light of the impact of the disease and its treatments, at different time points during their recovery. The informants all had personal experience of attending for follow-up consultations for differing amounts of time. The intention was to describe the emotional and physical impact of undergoing treatment for breast cancer and the subsequent care needs after treatment is over for those that remain free of further disease. Data were collected using semi-structured taped interviews, a choice of method commonly associated with a feminine stance because it enables studying of women from the perspective of their own experiences (Harding 2004). The results from this qualitative work offered insight into how individuals perceive life after breast cancer, thus informing the nurse-led intervention and identifying how care could be changed for the better.

6.6.2 Population and Sampling

Participants in this study were recruited from surgical and medical clinics at both the sites of the NHS Trust involved in the study (see appendix F for explanatory invitation letter and consent form). The clinics of six consultants were accessed in total. This included two surgical and one joint medical and surgical clinic from each site. Women were considered eligible for the study according to pre-set inclusion criteria as follows:

- they had received all treatment for breast cancer at the NHS Trust hosting the study and were currently receiving routine follow-up care;

- they were asymptommatic (to ensure their follow-up is routine and not influenced by any present symptoms);

- they were able to understand and speak English (in order to be able to complete the interview successfully).

Men with breast cancer were not excluded but none appeared in the sample.

Participants were selected via the clinic lists using systematic, stratified sampling. Systematic sampling involves the selection of every *k*th case from the clinic list, for example, every tenth person on a patient list (Feher Waltz et al 1991). Whilst this may be considered at odds with qualitative method, qualitative researchers can supplement their inquiry with quantification techniques when aspiring to certitude as achieved partly by an adherence to appropriate techniques (Smith and Heshusius 1986) and this type of sampling is often used when eliciting a range of perceptions from a specific population. The sample is not truly random in that not every person has an equal chance of being selected. However, systematic sampling designs can be applied in such a way that an essentially random and representative sample is drawn (Polit et al 2003). This can be achieved by shifting the random start partway through the list (Feher Waltz et al 1991), as would happen each time that a new clinic list was accessed.

Stratification was employed in order to encompass women with a wealth of different experiences, over different time frames and at different ages and to ensure the sample reflected the variety of women in the follow-up population. Stratification is the process of dividing the population to be sampled in to distinct groups (or strata) (Hedges 2004). This was considered appropriate as it was anticipated that this approach would enable the capture of the widest range of views by assuring that most groups were represented (Feher Waltz et al 1991). The strata were the age of women and time interval since completion of treatment. Four age group bands and three time intervals were selected (see Table 6.1). This created twelve groups into which two women were recruited, resulting in a disproportionate sample (Feher Waltz et al 1991) of 24 women in total.

Table 6.1: Stratification bands (phase one) [indicating patients in each band as denoted by letters of the alphabet]

	No. of months individual has been attending follow-up			
		6 – 11 months	12 – 23 months	> 24 months
Age	< 40 yrs	A L	F O	B S
	41–50 yrs	K U	E N	J V
	51-60 yrs	Q X	D R	M T
	> 61 yrs	H W	C I	G P

6.6.3 Data Collection

Data pertaining to women's perceptions of routine follow-up care after completion of treatment for breast cancer were collected using a semi-structured interview, the content of which was compiled after an extensive review of the literature and represented a summary of known recommendations and areas of concern (see Appendix G for interview schedule). The semi-structured interview technique enables the researcher to guide the respondent through a set of broad questions using a topic guide, so that conversation is encouraged and relevant data is collected to encompass the 'hows' and 'whats' of that aspect of the respondents lives (Silverman 1993, Fontana and Frey 2000). It was important to me to ensure that the women had a chance to voice their opinions on breast cancer follow-up without having my views imposed on them. With feminist philosophy underpinning my research, I was keen to advocate openness and egalitarianism in the interviews. Therefore the interview schedule represented a framework, with the exact order of questions posed varying according to the flow and direction of the conversation. The semi-structured format chosen allowed a process of exploration, superficial and in-depth coverage of certain areas and gave the participants more freedom to respond in their own words and to express their own opinions as opposed to a structured and rigid approach that does not enable flexibility with questioning or responding (Fontana and Frey 2000). In this way I attempted to give the women greater visibility and to allow them to recount their experiences of follow-up in their own words so that the data gathered represented the perspectives of the women taking part (Hakim 1987). The interviews, therefore, served to develop ideas and themes and were concerned with understanding how people think and feel about the topic in question.

To facilitate data collection the interviews took place either in the hospital setting or at the woman's home, according to individual preference. The average duration of each interview was 58 minutes.

Interviewing can lead to vulnerability for the participant. Whilst the researcher may be experienced at interviewing, the interviewees are likely to be unfamiliar with the process of telling their story and focusing exclusively on themselves (King 1996) and this might hinder disclosure. Oakley (1981), an influential feminist researcher advocates openness and engagement on the part of the interviewer to help to address this imbalance. With feminist philosophy guiding my work, engagement and openness were essential to enabling me to move away from the 'masculine' paradigm of objectivity and detachment in which the research interview is a mechanical instrument of data collection where one person asks the questions and the other gives the answers and the interviewees remain entirely passive throughout (Oakley 1981). I gave consideration as to deciding how to present myself to the women, that is as a senior, clinical nurse specialist or as a researcher. I decided to explain both of my roles and that the research was being conducted as part of doctoral studies. I wanted to gain their trust. Self-disclosure (as proposed by Oakley 1981) was difficult at times because my personal ethos as a nurse is to be there for the other person but I did talk about my work and my aspirations in terms of achieving a doctorate qualification. King (1996) suggests that defining boundaries within the interview process requires a strong sense of self. I struggled at times with ensuring I displayed warmth, empathy and genuineness versus maintaining a social and intellectual distance as I did in my professional role. However I was keen to establish a non-hierarchical relationship and this was only possible by being prepared to invest my own identity in the interaction (Oakley 1981). Proponents of feminist approaches tend to argue against research hierarchy because of the ethical requirement that women researchers treat other women as equals not subordinates (Hammersley 1991). Feminist research particularly emphasises affectivity and encourages researchers to be aware of their feelings and biases, as this is insightful for learning. Affectivity was also achieved through non verbal communication, including being conscious of my physical position and posture, making eye contact, nodding to demonstrate listening and understanding (King 1996) and using counselling skills of paraphrasing, reflecting and open and closed questioning.

I started the interview by asking the women to tell me about their experiences of being diagnosed with breast cancer and the path that led them to the current stage of attending for follow-up care. I guided the conversation to elicit information about the experience of follow-up, the good and the bad aspects of it and probed where appropriate to obtain more detailed descriptions and to clarify their responses. I was aware of my intrusion into their personal lives and thoughts and was keen to ensure that I adequately managed their emotional needs (some of the women cried during the interview). In line with feminist research philosophy of giving the woman control, and not controlling the interview myself, when participants became upset I checked if they wanted to move on or to stop and take a break. I did not make that decision for them.

An interesting issue raised for me during the interviews was whether to give advice during the interaction. Many of the women asked questions and this highlighted a slight conflict in roles, not because I had any difficulties answering their questions but because I was conscious of the tape running and of getting through the schedule in a reasonable amount of time. I decided that I would answer questions raised during the interview as fully and accurately as possible because by doing this I was empowering the women through knowledge and this is very much in line with a feminist approach. It also contributed to an engaging approach and served to meet the needs of the women at that time rather than merely exploiting them for data provision. I think answering questions came naturally to me as a nurse as well as a researcher guided by feminist approaches. Nursing engenders the instinct to help people and to problem solve.

If I was ever unable to answer a specific question I pointed the women where to seek that information. In this way a greater rapport was established and, once again, allowed me to be seen as more than just a data collector. Oakley (1981) refers to the principle of no intimacy without reciprocity. I reciprocated intimacy with self-disclosure and answering questions. This resulted in a successful relationship that appeared to promote open discussion. I offered a debrief, once the taping had finished, to discuss how they had reacted or to answer any further questions that arose and several women commented after the interview that they had found it cathartic and appreciated being able to comment freely on aspects of breast cancer follow-up that they found negative, as well as having a voice to suggest ideas for improvement.

The interviews were taped in order to improve conceptualisation of the research problem (Oppenheim 1992). In addition, taping reduces loss of information, ensures accuracy of verbatim data, avoids excessive reliance on memory recall and negates the need to make written notes throughout, which in turn could distract the flow of communication. The tapes were transcribed verbatim. Again to demonstrate my lack of exploitative intentions and in line with a feminist approach of protecting privacy (Olesen 2000), I explained that no one else would listen to the tapes and that their names and personal details would be changed so that they could not be identified. Advantages of interviews as a method of data collection is that they ensure face to face contact, thus they allowed me to check out ambiguity there and then, minimising misperceptions or misinterpretation on my part or that of the respondent. However face-to-face contact deprives the subject of anonymity and confidentiality, in that the researcher knows who has said what and this may inhibit participants from making critical or negative comments, hence my assurances regarding anonymity and confidentiality. I also offered the women a copy of the transcript and to send them any publications/results arising from the study if they wished. This is a further example of the reciprocal approach, that is the emergence of an exchange relationship that gives value to the participants' co-operation and involvement (Patton 1990).

A potential weaknesses of interviews as a method of data collection is that the researcher may exhibit bias in the direction their questioning takes, or in the analysis/ interpretation of the data, but the concept of bias is generally associated with quantitative research. Qualitative interviewing can never really be impersonal because an interview is a complex and shifting process occurring between two individual human beings (Jones 2004). Thus instead of attempting to remain unbiased by removing the natural effects of interpersonal interaction, I tried to enable the women to trust me and to believe that I would not use the data against them or regard their opinions as foolish and that they need not say things merely because they are trying to say what they think I want to hear (Jones 2004). In addition, as transcribing is a lengthy and laborious process, it was crucial that the transcripts were checked for accuracy as 'misquotes' could alter the meaning of what has been said.

6.6.4 Data Analysis

The descriptive nature of qualitative data can expose the researcher to a charge of placing emphasis on meanings and truths of their choice during analysis, rendering the results value-laden and subjective. To counter this, it is essential for the researcher to be explicit in the process of data analysis and the steps taken to reach their conclusions (Froggatt 2001) and is a critical part of demonstrating rigour. In this study the interview data was analysed using classical content analysis (Ryan and Bernard 2000) to clarify the way text is processed from interviews. Content analysis enables valid inferences to be drawn from the text (Weber 2004) by developing the data beyond a merely descriptive approach and is important to investigation of both latent and manifest meanings (Henwood 1996). Thus the interview tapes were transcribed and the texts produced were examined in order to analyse the words used and capture the experience of attending for breast cancer follow-up. An inductive, thematic, content analysis was carried out in order to identify predominant themes. This comprises reducing the text (the verbal data) of the transcripts to a series of codes. Coding is a fundamental process in qualitative data analysis and is the basis for making reliable and valid inferences about the area of interest (Henwood 1996). It involves interpreting of the data and assigning labels to bits of data so that all text under that label can be retrieved and brought together (Ryan and Bernard 2000, Froggatt 2001); thus many words from the text are classified into much fewer content categories (Weber 2004) according to the perceptions expressed by the participants.

A category is a sub unit of a theme and categories can be grouped together as links and relationships in the data become apparent and this, in turn, enables recognition of the emerging themes (Ingleton and Seymour 2001). A category is thus a way of conceptualising the data by grouping together concepts. As well as enabling the researcher to identify categories relevant to the research question, coding also highlights other issues, perhaps not previously considered. Some sections of the transcripts will be given more than one code whilst others will have none.

Initially the categories were deliberately broad and captured areas of interest deriving from first reading through the transcripts. After repetitive comparing of units of data with others in the same category, the categories were gradually refined and revised as the whole body of data was worked through (Polit et al 2003) and it was clear that no new themes were evident.

In practice the process was achieved by listening to the taped interviews repeatedly to ensure familiarity. The tapes were then transcribed verbatim onto computer and stored as both written text and computer files by myself and by a medical secretary working in a clinical trials team who had extensive previous experience of transcribing research interviews and medical consultations. The texts were checked for accuracy against the tapes. I then read through hard copies of each transcript and attributed a code to lines, sentences or paragraphs that represented a theme or idea (Hewitt-Taylor 2001). For example, the code 'time given during consultation' was attributed to data referring to the length of the follow-up consultation and the opinions relating to whether this was considered too long or too short and the reasons why. Any text that was not directly related to the subject in question was excluded from coding. Examples included descriptions of breast cancer treatment and discussion around medical problems during follow-up that were unrelated to breast cancer.

I made a decision not to use a computer package to analyse the data (such as NUDIST). This was because, as a novice to this process, I wanted to develop first hand experience of content analysis and was interested in the detailed and repeated reading of small pieces of text. In the future I would gain experience with computer based analysis programmes but I found it useful to gain traditional experience initially.

The use of an inductive approach on data enables the themes to be drawn from the participants' perspectives, rather than emphasising the researcher's preconceived ideas. After coding, each hard copy of the transcripts was photocopied and cut into segments so that all data pertaining to the same category within the same code could be placed together. Passages of texts with similar labels were grouped into broad themes and sub-themes were then identified which encompassed several categories.

As data analysis forms part of the research methods used in an enquiry, it is important that it is consistent with the overall philosophical underpinning of the research (Hewitt-Taylor 2001). Decisions about the levels of precision, structure and context of data analysis applied should be dependant on the nature of what is being described and the purpose of describing it, as well as on the resources available and does not need to be committed to only one paradigm (Hammersely 1996). As a qualitative study, exploring perceptions of follow-up in the eyes of the women who attend it, it was deemed important that the analysis predominantly involved words in preference to numbers. However, whilst largely focussing on subjectivity and meaning I thought it would be useful to provide some descriptive statistics of the themes generated and quantify the numbers of responses in some categories. Counting how often codes occur is helpful in clarifying whether the reality is in accordance with the overall impressions that the researcher gains during the analysis (Hewitt-Taylor 2001, Polit et al 2003). I realised that counting may be contrary to other positions in qualitative research because an issue that occurs only once might still be considered sufficient for inclusion as a category or theme. Therefore exclusive counting of frequency was omitted to avoid diminishing the precise and in-depth meanings within the data (Morgan 1993) and to maintain a feminist philosophical research stance in which the analysis focuses on the needs, interests and distinct experiences of women. In line with this, direct quotations are provided within the results to capture individual viewpoints and subtle nuances of meaning, regardless of whether or not they represent a majority.

In light of the importance of reflexivity as a core tenet of feminist methodology, I needed to retain an awareness of my own contribution to the interview and how that might have influenced the narrative I was analysing. Scheper-Hughes (1983) reminds of the importance of acknowledging the multiple identities that shape us as a researcher and how they influence the interaction with the participants. Inevitably I bought my own frame of reference to understanding and interpreting the data (Koch 1995). I have therefore sought to validate my work by owning my own background and by using the first person in order to own my presence in the work and acknowledge the dependency of the data on my presence (Ball 1990). I have spent over ten years working as a clinical nurse specialist in breast cancer. More specifically with my role at the hospital in which the research took place, some of the women in the study already knew me in this role and had had contact with me whilst undergoing treatment for breast cancer. It seemed important to consider my own preconceived ideas about what themes I thought would emerge from the interviews. I felt that follow-up clinics were predominantly impersonal and involved large numbers of attendees that were seen for very short periods of time. I assumed the women would report feeling hurried but also that they would feel reassured as a result of having attended. Considering my own views and practice is crucial to qualitative data analysis because writing is more than just transcribing and represents a process of discovery (Richardson 2000).

In accordance with the feminist research perspectives being closely linked with challenging or resolving issues of power and dominance, I wanted the data analysis to be truly representative of what the women participating told me, that is to be a voice for their concerns. Even with being cognisant of reflexivity, a researcher could be said to remain in the more powerful position by virtue of the mere fact that they write up the account (Olesen 2000). I attempted to balance this with trying to empower the participants rather than take power away, hence I offered the women a copy of the transcript of their interview in an attempt to try to avoid stealing their words (Opie 1992). In fact all of the women declined this offer.

6.7 Study Two: Focus group with doctors

6.7.1 Introduction

The second qualitative study explored the opinions of doctors who regularly provide breast cancer follow-up. Thus the participants all had extensive personal experience of conducting follow-up consultations and examining women in this clinical setting. The intention was to describe the strengths and weaknesses and function of the current system as perceived by the providers. Data were collected using a focus group and the results from this qualitative work offered insight into similarities and differences between the views of providers and users of breast cancer follow-up, thus beginning to identify how care could be changed for the better for both parties.

6.7.2 Population and Sampling

For the purpose of this study, one focus group was held with doctors who regularly conducted breast cancer follow-up consultations in outpatient clinics and who would provide consultations to women in the medical arm of the randomised controlled trial. It is generally recommended to conduct more than one group in order to increase the reliability of the data and enable the researcher to determine the point at which consensus on the key issues has been reached (Sim 1998). However in this case the medical clinic that would run alongside the nurse-led clinic during the study contained a maximum of 5 doctors providing follow-up at any one time before they rotate to a different team. Numbers were therefore deemed too small to run two groups, as ideally 4 to 8 members should constitute one focus group (Macleod-Clark et al 1996, Cote-Arsenault and Morrison-Beedy 1999).

The participants were selected using purposeful sampling. This involves subjects being chosen according to the needs of the study and is often used when the researcher requires a sample of experts in small fact finding studies (Polit et al 2003). Informants who will most facilitate the development of emerging theory are chosen because of their specific knowledge in the subject area and their ability to enhance the researcher's understanding of the key issues (Field and Morse 1992, Hedges 2004). Yet generalisability with this form of sampling is weakened. In this case only doctors who would be conducting breast cancer follow-up in the medical clinic that ran alongside the nurse-led clinic were included. All doctors meeting this criteria were approached because of small numbers overall.

6.7.3 Data Collection

A focus group was used to elicit the opinions of doctors about breast cancer follow-up consultations, which they regularly conduct in the hospital outpatients department (see appendix H for focus group guide). The purpose of this group was to elicit the opinions of doctors about the current system thus allowing comparison with the perceptions and needs of the women whom they care for. Although the participating doctors were not all female, the focus group approach was deemed to be in line with feminist research philosophy because it enabled me to explore sources of power within health care and specifically the breast cancer follow-up setting because it could be said that the doctors who provide follow-up potentially hold power over the frequency and content of the consultation. Madriz (2000) argues that, when used on women, focus group epitomise the feminist collective approach to women's lives by enabling collective rather than individual acquisition of data.

Focus groups are a method of qualitative research during which the researcher uses group interaction to produce data about a specific set of issues. As well as a primary means of collecting quantitative data, they can also be used to supplement other methods, adding more to the researchers understanding of the phenomenon under study (Morgan 1997). Focus group methodology was initially predominantly the domain of social scientists and is a popular approach to market research. Such groups have more recently been used in health care to elicit the views of patients and service providers (Murray et al 1994, Owen 2001) and hence are also considered an effective technique for exploring the needs and attitudes of staff (Kitzinger1996).

Rationale for choosing a focus group include that they ensure data is derived from a large amount of interaction from several people in a relatively small amount of time. They also accord some degree of control to the researcher in that significant issues can be explored and ambiguity clarified as they arise. It could be presumed that focus groups capitalise on nursing skills and abilities such as gathering potentially sensitive information and therapeutic communication (Morrison-Beedy et al 2001). Potentially more stimulating than self- administered surveys (Bristol and Fern 1996) and distinguishable from broader group interviews by the explicit use of group interaction as research data (Kitzinger 1996), the group was more likely to induce participation and enabled the doctors to relate their experiences with their own peers, thus sharing a common frame of reference. In this study, participants commented on each other's point of view, a fundamental process to the nature and content of responses elicited from the group, in that the researcher could observe strength of opinion, contradiction and debate which further serves to identify shared concerns (Clarke 1999). Thus this appeared an acceptable approach to yield in-depth and insightful data about breast cancer follow-up as perceived by doctors.

Advantages of a group approach include that it provides evidence about similarities and differences in the opinions and perceptions of the participants without resorting to analysis of each subject's statements individually. Group interaction can serve to enhance the depth of conversation because of stimulation of thoughts arising from what others have said. Stewart and Shamdasani (1990) suggest that comments from one participant may trigger a chain of responses from others, thus providing a stimulus for elaboration and analysis. Group support may also actively facilitate discussion of difficult (not politically correct) topics and may more easily generate critical or negative comments which individuals may be reluctant to disclose (Kitzinger 1996). Group dynamics encourage participants to explore the issues of importance to them, in their own vocabulary, and pursue their own priorities (Pope and Mays 1996).

Possible disadvantages of focus groups as a methodology are that they are unnatural social settings, potentially affecting the data revealed. Similarly, the presence of the researcher may affect the nature of the interaction either by inhibiting participants from making critical comments or by biasing the direction that the conversation takes. Care must be taken not to narrow the focus of the discussion by assuming in advance what the important issues are. The presence of the researcher and the other participants also compromises confidentiality and anonymity for all the other group members (Kitzinger 1996). The group composition can also affect the interaction in that some participants may dominate and prevent everyone having equal time to talk. In this situation the researcher may be confronted with the dilemma of giving control to the group, at the risk of digressing or hearing less of the topic in question, versus taking control of the discussion, but then losing the free flowing, spontaneous comments (Morgan 1997). Conversely some group members may not be vocal causing conversation to flow poorly or may want to appear to conform with the majority views causing them to abstain from expressing a view that they may have revealed in private with the researcher. Clearly the researcher needs to be skilled in managing group dynamics and leading/ influencing discussion in a research environment notably less naturalistic than an observation study would be. Ensuring no one in the group is marginalised was important to me as a researcher adopting the philosophical underpinnings of a feminist approach. Finally, some researchers have questioned the validity of focus group methodology in that the obvious influence of group composition at the time might mean that another group held in the same place on the same subject but with different participants may well fail to produce the same responses and outcomes.

Clearly small numbers inhibit generalisability, but in this case the researcher sought further understanding of breast cancer follow-up from the perspective of another professional group to supplement information derived in the main randomised study. The focus group consisted of five participants. Six in total were invited, of which the remaining one was a consultant surgeon. He had actually agreed to participate, but did not take part on the day due to his clinic running over time and because he was attending another commitment later that evening. Therefore, no doctor approached declined to take part. It is acknowledged that the absence of the consultant might have affected the dynamics and the discussion within the focus group. In terms of dynamics, it is possible that the doctors felt more able to voice their negative or critical views of the current system in which they provided follow-up because their senior colleague was absent. However, the content raised would inevitably have been influenced by the consultant's presence, not least because of his vast experience. He would not have shared the learning needs of the junior doctors and spends less clinical time providing follow-up, more commonly seeing complex cases and those women at high or suspected risk of recurrence. Reflecting the predominance of men in the specialism of surgery, only one of the participating doctors was female.

The focus group was held in the Outpatients Department at the end of a breast cancer follow-up clinic. This afforded the advantage of the doctors already being at the location, thus negating the need for travel or finding a spare room. As two of the participants were on call that evening, there were no concerns about staying late after clinic had finished. As the clinic had finished and other staff had departed there was minimal chance of being interrupted, however a note was placed on the door of the room used asking people not to enter and explaining that tape recording was in progress. The information room in the department ensured a relaxed, familiar comfortable setting, with seating (armchairs) appropriately arranged in a circle. The tape recorder was placed on a low coffee table in the centre of the circle. Refreshments and snacks were provided.

Macleod-Clark et al (1996) emphasise the importance of opening instructions by the facilitator. Initially I established the ground rules that stated only one person should speak at a time, everyone should have a chance to participate, no one individual should dominate the conversation and the views expressed would remain confidential within the group. A guide was used to direct the discussion. This detailed the ground rules as above and the key areas of interest to be covered. I also endeavoured to remain flexible and to encourage diversity and expansion of comments and opinions. Open-ended questions were employed to enable the participants to respond in their own words. In addition, and in line with my chosen feminist approach as a researcher (even though the participants were almost exclusively male), I was careful to pay attention to minority opinions and explored exactly how the opinions expressed were constructed (Kitzinger 1996). I wanted to identify why doctors perceive that gaps in follow-up care may occur.

As mentioned when describing the interviews I recognised the necessity for reflexivity and for owning my identity and recognising its potential influence on the group processes and outcomes. I have extensive experience of facilitating groups with lay people and staff and was knowledgeable about the subject of follow-up as a result of over ten years clinical nurse specialism in breast cancer. I am aware that my close professional working relationship (and friendship) with the doctors may have influenced the interaction. I attempted to minimise this by stressing that there were no right or wrong answers and that all comments, positive and negative, were important. A central theme to a feminist approach to conducting research is trying to ensure the true voice of the participants is reflected, but the authenticity of the social interaction within groups could be questioned because the necessary presence of a facilitator influences that interaction (Madriz 2000). The group lasted 65 minutes.

6.7.4 Data Analysis

As discussed in the previous section on interviews, it was essential for me to establish a decision trail so that the process of data analysis and the steps taken are made explicit. In this study the focus group data was analysed using framework analysis, a method developed by the Qualitative Research Unit at the UK National Centre for Qualitative Research to clarify the way text is processed from interviews (Ritchie and Spencer 1994). The stages reflect the process of shifting, charting and sorting the data according to key themes and issues. I chose this technique for analysis to broaden my research knowledge and to gain experience of another method of qualitative data analysis.

The focus group was audio-tape recorded and transcribed verbatim by myself. Familiarisation with the data involved repeated listening to the tape and reading the transcripts. Voice identification was achievable because I knew all of the participants. This enabled me to identify predominant themes and sub themes, which were then numbered and indexed, thereby creating a thematic framework within which the data was sifted and sorted. The index was applied to the written transcript and the categories within were refined and gradually modified as the whole body of data is worked through (Ritchie and Spencer 1994). Any references to the index discovered in the text were recorded in the margin of the transcript by a numerical scheme that linked backed to the index. The end result was a set of data structured within an analytical framework that was grounded in the participants' own perspectives and accounts, rather than emphasising my own preconceived ideas.

As stated previously, data analysis forms part of the research methods used in an enquiry, and it is important that the approach is consistent with the overall philosophical underpinning of the research (Hewitt-Taylor 2001). As a qualitative study, exploring perceptions of follow-up in the eyes of the doctors who provide it and using only small numbers of participants, it was deemed important that the analysis involved words in preference to numbers. Counting of frequency was omitted because of the small sample size and to avoid diminishing the precise and in-depth meanings within the data (Morgan 1993). Direct quotations are provided within the results to capture individual viewpoints and subtle nuances of meaning, regardless of whether or not they represent a majority. Descriptive data is presented on the characteristics of the group members, then the themes are explored in turn and salient quotations are used to illustrate each theme further.

6.8 Ethical Considerations

Approval for both qualitative studies was obtained from the Committee for Clinical Research (CCR) and the Local Research Ethics Committee (LREC) within the Trust. Agreement was also sought from each Consultant and from the Clinical Head of the relevant client groups. Women were informed of the interview study in writing via an explanatory letter and a consent form (Appendix F). In addition, the name and telephone number of a breast care nurse (not myself) were provided and women were given the opportunity to ask questions and to seek further information, thus enabling their consent to be fully informed.

Potential participants for the interviews were notified that their decision to refuse or to terminate participation would not affect the attitudes of any of their carers. Confidentiality was also assured thus guaranteeing that any information provided by the subject would not be made accessible to parties other than those involved in the research. The women are referred to by letters of the alphabet, rather than by name in the results to protect their identity.

All of the interview transcripts and the focus group transcript and tapes were securely stored and will be destroyed on successful completion of this thesis. Privacy was maintained by conducting the interviews in secluded rooms or at home and the focus group in a secluded room.

I was aware of the need to ensure the data analysis was reliable and valid. Reliability, although a quantitative concept, can be considered important because accuracy can be compromised in qualitative work due to problems arising from ambiguous word meanings or category definitions or as a result of inaccurate data entry. I transcribed all of the interview tapes myself but had 25% duplicated by a medical secretary with experience in transcribing so that these could be checked against mine for accuracy. Two main types of reliability are relevant to content analysis, reproducibility and stability (Weber 2004). Reproducibility refers to the extent to which content analysis produces the same results when the same text is coded by more than one coder. As I was the only person performing the coding and analysis in both studies, this reduces problems with two people assigning different codes to similar text content, although not as much as if a computer coding package had been used (Weber 2004). However, a potential issue of rigour relates to the fact that only I performed the coding during the content analysis. This introduces the potential risk that the categories I identified during coding were influenced by my preconceived expectations or pre-existing prejudices relating to breast cancer follow-up. It is feasible that my subjectivity may have biased the analysis and it was essential that I attempted to capture the full range of possible interpretations and not just what I expected to find.

Stability refers to the extent to which the results of the content analysis (classification) are invariant over time and is determined by the same content being coded by the same coder without inconsistencies being produced. To check this I repeated the analysis on 10% of the interview transcripts and 2 pages of the focus group transcript one month after the initial analysis to check for any inconsistencies. None were found.

Validity, within a quantitative research paradigm, refers not so much to objectivity but authenticity (Lincoln and Guba 2000). Lincoln and Guba, albeit commonly in the context of grounded theory as a qualitative research method, have written extensively about validity in qualitative studies. To be valid, the data should be trustworthy, reflecting how things really are and this can be achieved through attention to method (rigor in the application) and interpretation (defensible reasoning). Some methods are more suited to qualitative research that focuses on human experiences (Lincoln and Guba 1985) so I tried to achieve validity by careful selection of methods, properly applied to enhance objectivity. Validity in interpretation involves presenting descriptions that can be agreed with. I tried to ascribe salience to my interpretation of the data (Lincoln and Guba 2000) by attempting to present ample raw data (direct quotations and passages of text) to allow the reader to interrogate my interpretations to enhance validity (Smith 1996). Guba and Lincoln (1989) refer to fairness as one criteria for achieving authenticity in interpretation. By this they suggest balance, that is that all the relevant stakeholders voices (perspectives) should be apparent in the findings because to omit these is in itself a form of bias, not through poor objectivity but by lack of inclusion and therefore marginalization (Lincoln and Guba 2000). Hence I sought information from both women and doctors to obtain a richer and more complete story.

6.9 Summary

This chapter has described two qualitative studies. The first used semi-structured interviews to explore the follow-up needs of women at different time points during their recovery. The second used a focus group to explore the opinions of doctors who regularly provide breast cancer follow-up. The results from each are presented in the next chapter and offer insight in to similarities and differences between the views of providers and users of breast cancer follow-up.

Chapter 7. PHASE ONE: EXPLORATION OF FOLLOW-UP PRACTICE RESULTS

7.1 Introduction

The following results are presented in two parts. Firstly data arising from the interviews with women attending breast cancer follow-up, secondly the data arising from the focus group with doctors providing breast cancer follow-up.

7.2 Interviews with women

7.2.1 Sample Size

Twenty-four out of thirty eight women approached took part in the study representing a response rate of 63 percent. Of the fourteen who eventually did not take part four women refused outright citing the reason that they perceived that they had no comments to make. The other 10 women stated that they were unable to participate due to sickness in the family (n=1), travelling abroad (n=2), too busy with other commitments (n= 5), or an inability to find a mutually convenient time with the interviewer because of working hours (n=2). Refusal was spread evenly across the two sites of the hospital.

7.2.2 Demographic Data

All the participants were female. Their ages ranged from 32 to 78 years, with a mean of 51 years. The time since the end of their active treatment, that is, the length of time receiving routine follow-up care, ranged from seven to 94 months. Sixteen of the women were being followed up at one site of the Trust, and eight at the other site. Demographic details are presented in Table 7.1 and serve to provide a snapshot of the types of women taking part, with regards to their age, marital status, whether they are mothers and whether they are working. All of these features could have an impact on their views of the emotional and practical implications of attending for breast cancer follow-up and allows the reader to gain a broader illustration of the women taking part.

Table 7.1: Demographic details of women interviewed

Letter denoting individual	age (years)	marital status	number of children	Months since cancer diagnosis	Work
A	32	Married	2	7	Part time
B	37	Single	1	24	Full time
C	63	Married	2	12	Retired
D	54	Married	3	17	Full time
E	46	Married	0	23	Homemaker
F	36	Single	0	15	Full time
G	70	Widowed	4	30	Retired
H	54	Single	0	11	Full time
I	78	Married	2	21	Retired
J	50	Married	3	41	Part time
K	44	Married	2	8	Full time
L	40	Single	0	10	Full time
M	54	Married	3	58	Homemaker
N	41	Divorced	3	20	Part time
O	39	Single	2	14	Part time
P	68	Widowed	4	77	Retired
Q	51	Married	0	8	Full time
R	57	Married	2	19	Homemaker
S	38	Single	0	72	Student
T	54	Widowed	3	94	Part time
U	45	Divorced	2	9	Full time
V	50	Married	2	37	Part time
W	71	Divorced	2	7	Retired
X	53	Single	0	11	Full time

7.2.3 Thematic Analysis

Constant comparative analysis generated 6 main themes overall. These were then divided further into sub themes and categories (see Table 7.2) which reflect a woman-centred approach in accordance with my chosen feminist philosophy and are presented and exemplified using the participant's own words. To identify the source of any quotations whilst also ensuring anonymity, each participant was allocated a letter of the alphabet to denote who the comment derived from. This allows the reader to appreciate that a breadth of people's comments are included, rather than citing just a handful of those who took part overall. Table 6.1 (repeated below) demonstrates which stratification band each recruit falls into enabling the reader to access the age group and time on follow-up for each of the individuals that have quotations cited.

Table 7.2: Categories, themes and sub themes arising from the constant comparative analysis *(highlighted in bold within the text)*

Theme	Sub Theme	Category
7.2.4 Personal significance of attending check-ups	Dependence on doctors	* Fear of succumbing to breast cancer * Wanting to be given the all clear * Not wanting to lose contact * Wanting to be seen by an expert * Accepting the physical check-up * Wanting to be told when to come * Accepting a specialist nurse
	Feeling vulnerable	* Lack of dignity * Lack of privacy
	Fitting in with lifestyle	* Child care * Returning to work * Caring for elderly relatives * Travelling costs
7.2.5 Care delivery	Considering others (altruism)	* Putting up with waiting * Putting up with being hurried through
	Passive acceptance of what doctors say	* Putting up with inappropriate behaviour * Feeling hindered asking questions * Accepting inadequate answers to questions
	Feeling depersonalised	* Not seeing familiar doctors (lack of continuity)
	Ongoing individual needs	* Having breast cancer at a young age * Financial difficulties
	Benefits of coming for check-ups	* Getting reassurance * Access to a specialist * Meeting other women with breast cancer
	Drawbacks of coming for check-ups	* Provokes anxiety * Frightening * Dissatisfaction with care delivery

Table 6.1: Stratification bands (phase one) [indicating patients in each band as denoted by letters of the alphabet]

	No. of months individual has been attending follow-up			
		6 – 11 months	12 – 23 months	> 24 months
Age	< 40 yrs	A L	F O	B S
	41–50 yrs	K U	E N	J V
	51-60 yrs	Q X	D R	M T
	> 61 yrs	H W	C I	G P

7.2.4 Personal significance of attending check-ups

Dependence on doctors

A key message communicated by the women was how much they depended on the doctors providing the follow-up consultation and this manifested itself in numerous ways. Clearly check-ups continue to be an important event in the woman's lives and two thirds (n=15) of women reported increased levels of anxiety in the days or weeks preceding their routine appointment. The predominant reason given for this was fear that new disease or recurrence would be found. Indeed **fear of succumbing to breast cancer**, in that it would return and no longer be curable, was a very real concern for almost every woman. The other reason cited for anxiety was an association between the hospital and bad feelings or symptoms:

> *You do get panicky and for about a week before the check up you find lumps all over the place, sort of springing to life* (participant B)
>
> *Now when I go to the hospital I get that sick feeling and I just feel physically very ill, which in itself is ridiculous* (participant X)

> *The day before I get very uptight and on the morning, well, uptight isn't the word, you just never know if someone's going to find something* (participant Q)
>
> *Just the smell of the hospital brings it all back* (participant O)

The increased anxiety was present regardless of the age of the person and the amount of time they had been on follow-up, so attending for long periods of time appears not to diminish the levels of anxiety evoked. Knowing, and fearing, that the breast cancer could return resulted in an unsurprising, yet almost obsessive, **wanting to be given the all clear** by the doctor providing the check-up. The women placed huge importance in being told they were well by the doctors, whom they perceived as knowledgeable experts. Yet such reliance on doctors can be considered misplaced because being given an all clear at one appointment does not preclude new disease returning in the coming weeks or months. Nor does it really mean that advanced disease is not already present, given the limitations in surveillance noted in chapter 3. It is interesting that the women viewed the doctors as being those most able to confirm the absence of recurrent breast cancer and hence reassure them that all was well when in reality the practice of three or six monthly visits is unlikely to capture the majority of recurrences. Most recurrences are discovered at unscheduled interval appointments and women noting signs and symptoms themselves (rather than having them found by doctors) are the first indication of recurrence in most cases (Scanlon et al 1980, Mansi et al 1988, Muss et al 1988, Loomer et al 1991, Schapira 1993, Moore et al 1999, Pivot et al 2000, Donnelly et al 2001).

Yet none of the women considered the potential of their own knowledge of their bodies or their own ability to know when something was wrong and this manifested itself by almost all of them expressing that they did **not want to lose contact** with the hospital clinic. They felt compelled to attend even though they might be more capable of finding symptoms that indicate recurrent breast cancer than the doctors. This might be because women are not aware of the inefficacy of routine follow-up in detecting new disease. Whilst women want to continue attendance, notably they have little say in how often they come and it was the doctors, not the women themselves, that determined the frequency of routine scheduled appointments. Overall the frequency with which women were being seen in clinic for follow-up care ranged from once every month to once every year, with the majority attending three monthly (see Table 7.3 below).

Table 7.3: Frequency of Visits for Follow-up

Frequency	Number
1 Monthly	1
3 Monthly	13
4 Monthly	3
6 Monthly	3
Yearly	4
TOTAL	24

Further dependence on the perceived expertise of the doctors is demonstrated when the women discussed their satisfaction with the frequency of the appointments. Over two-thirds of those being seen more regularly expressed satisfaction with the frequency of clinic visits and referred to the *'immense reassurance from knowing that there is an appointment every three months in the calendar'* (participant E). A paradox is beginning to emerge here because, coupled with the vulnerability and anxiety that attending for follow-up engenders, is the fact that women still want to come. It would seem, therefore, that the anxiety is an acceptable trade off for being seen regularly in the clinic. The frequency they were seen was not only determined by the doctors but was most likely an arbitrary figure relating to hospital protocol on follow-up. Yet it was used by the women as a measure of their wellness or risk of succumbing to breast cancer and any changes (particularly longer gaps) in the interval between check-ups provoked powerful reactions of relief that they were returning to health versus fear that the reassurance would be less often forthcoming.

A few women would even prefer to be seen more often, and all of these were on yearly follow-up. Those preferring more frequent follow-up were notably younger women, with only one person over sixty years falling in to this group. They again referred to the importance of obtaining reassurance and were concerned at the possible implications of not being examined on a frequent basis. All of these women alluded to one of the merits of regular attendance being that the clinic acted as a 'safety net' to capture any new problems that might develop.

> *When you are put on to yearly* [appointments] *you feel quite literally that you are being cast aside* (participant J)

> *I think they should look after me more, I think, because they said to me some of my lymph glands were affected, they should keep an eye on* me (participant P)

Only very few preferred to be seen less often. These women felt that having appointments further apart would indicate that their health was reverting back to normal and that their doctor was less concerned about them. These were all on 3 or 4 monthly follow-up and one patient commented

> *I mean I'm getting to the point now where I would like it to be six months, just to think that I am well again, really well again. You know, because the further apart your appointments are, obviously they are not worried, they think oh yes, she can go to six months now, that would be nice, to get to that point* (participant U)

For another woman loosing frequent contact with the hospital allowed her to forget the experience more easily.

> *I feel that the least I have to do with the hospital and everything else, I can pretend that it has never happened* (participant X).

Thus it seems that one schedule of follow-up is unlikely to suit everybody and the desire for more or less frequent visits is influenced by numerous variables, including one's age, perceived (or real) prognosis and levels of anxiety. There is a balance to be achieved for most women between being seen often to obtain reassurance versus being seen less often as a sign that the doctor is confident with your progress.

Linked with the concept of not loosing contact with the hospital, is the importance to women that the clinic is accessible, especially between scheduled appointments, if necessary. Most of the women did regard the hospital staff as accessible between routine consultations and felt comfortable contacting nurses to move their appointments forward. Of note, the staff members considered most accessible were nurses, either the clinical nurse specialists or the trial research nurses. Most commented that the doctors were not directly accessible, for example by telephone, although they could see them by moving their appointments forward and it was most commonly the nurses that facilitated and sanctioned this. Moving appointments to an earlier date required sanction from a health professional and was not something women could do themselves. Although there was rarely any difficulty doing this, it reflects the power of the hospital system in governing who can be seen and when, and the powerlessness of women, who effectively have to seek permission to attend when they want to.

> *I've got no hesitation, if there was a problem I would ring, they have always said to me, whatever time day or night, they are there for me* (participant Q)

> *I think I play the system a little. If I am worried about something I come earlier and then I know a doctor will see me because I am booked in so they have to* (participant D)

The remaining few did not feel able to access the hospital between visits and felt 'tied' to their set appointments with the doctors. These were all older women, over the age of sixty-five years.

The importance of **wanting to be seen by an expert** is further manifested in the women's comments about their general practitioners (GP's) providing routine check-ups. The majority of women did not access their general practitioner for advice or support predominantly because they considered them to be too busy or lacking in specialist knowledge. A couple of women remarked that their GP's were unfriendly and disinterested.

> *Oh no! They are bigger worriers than me, they are the biggest panic merchants, best to stay away I think! They are always checking me out, if I get a cold they say you better go for a chest x-ray. They cause more worries than they take away, so I stay well away from them* (participant A)

> *They are actually more of an obstacle* (participant C)

Of note some stated that they would access their GP for problems related to their breast cancer in between hospital visits and these were mostly the older women, over the age of fifty-five years.

> *My GP is excellent and she's really interested in me. She said she could give me a repeat prescription, but she would rather see me every 3 months just to make sure I am OK. I think that's nice* (participant R)

Specialist knowledge was an obvious advantage of attending the hospital clinic, with more women assuming that the preciseness of the surveillance and the likelihood of new disease being detected quicker were both improved by being seen by doctors with more experience of breast examination.

> *I really like my GP, but am not convinced he would know what to look for or what was due to the chemo. Those doctors at the clinic do it all the time don't they? Surely they are more likely to see something and know exactly what it's related to or whether we need to do anything like a scan or something* (participant T)

However an interesting contradiction is raised here in that whilst the women declared confidence in specialist hospital doctors examining them, over half still declared this examination was not reassuring and often cursory. This **accepting of the physical check-up** that they perceive as not very worthwhile is contradictory to the notion of desperately wanting to attend to obtain reassurance. The majority of women expressed reluctance to stop follow-up clinic attendance and yet openly admit to shortcomings with clinical efficacy in the system. It is difficult to determine if this is due to a view that some reassurance is better than none at all, especially if vulnerable and fearful of new disease occurring, or because they are passively accepting the approach the doctors provide in spite of recognising the shortcomings because as an expert, the doctor *'must know best'*.

> *I can't quite get over how brief the check-ups are. I mean the examination is so cursory. It always strikes me that how come just a manual sort of feel around is enough* (participant 0)

> *They just say fine, good, any problems, feel there, feel there, under the arms, you are doing fine, see you next year* (participant A).

> *There have been a few occasions when you think well what was the point of that, you know, I could have done that at home. I'm not convinced of the actual value of what the doctor does to you* (participant E)

In addition, several women reported inconsistencies in the way they were examined and noted that the process was quite different with different doctors.

> *The first time was very brief, and the second one was the complete opposite because they felt my liver and he wanted an ultrasound around my breast and even mammograms* (participant K)

> *There is no point when they just fiddle around very quickly, you need to feel that you have had a really good check out, because I mean I can check myself at home. I want someone who is qualified, not just for a quick feel. Last time she (the doctor), however, checked all the back of my neck, all down my back, my tummy. She gave me a thorough going over and I felt reassured when I came out* (participant F)

A few felt the examination was too focused on the physical elements and commented that

> *they assess well-being by feel, and that's it, if they can't find anything, they say that's fine* (participant L).

The women had the same doubts about efficacy of any tests or investigations ordered by the doctors as part of the check-up. Although some women found them reassuring, the majority, irrespective of age, stated the tests were not reassuring.

> *I don't really want the tests. The ultrasounds are not much cop for me and the mammogram they say is not much good either. I think the scenario of we are not going to go looking for it is probably a good one, because otherwise you could be up there all the time, you know I think I need a blood test or I ought to have a bone scan* (participant X)

Nevertheless, some of the participants were anxious to have more investigations, particularly body scans.

> *I have asked for a scan but they won't give it to me. They said what do you want a scan for, I said peace of mind. I was talking to one woman a few years ago and they gave her a body scan and she felt much better afterwards and yet they won't do it for me* (participant P)

Some admitted mixed feelings, claiming any tests bought both fear and reassurance.

> *Having a mammogram just makes it* [the appointment] *10 times worse, yet you get all mixed up, its that thing about reassurance that all is well versus the fear that it won't be* (participant J)

Given the evidence about clinical efficacy of routine scans presented in chapter 3, coupled with the fact that earlier detection of recurrent breast cancer is unlikely to impact on prognosis, the reassurance associated with these tests is misplaced and might again indicate a dependence on a biomedical model in which hearing a test result is 'all clear' is sufficient for many, despite it not necessarily representing certainty in terms of being free of recurrent disease. Again, this suggests women are not in possession of all the facts with regards to the efficacy of routine investigations. This lack of understanding led to misplaced suspicions about the motives of not doing routine investigations and many of the women were convinced that this was a cost cutting exercise to save money on expensive tests, rather than because of their lack of clinical relevance.

> *I think it is all about saving money. I mean scans are expensive and you think to yourself 'is my health being put after their pounds and pennies'* (participant X)

Placing the responsibility on the doctors for detecting any recurrent breast cancer or for giving the all clear might also be an indication that the women did not want this responsibility themselves. This is reflected in their indicating that they **wanted to be told when to come** for check ups rather than choosing this for themselves. When questioned about the appeal of an open access clinic or person-led flexibility the majority of women (n=16) felt they would prefer to be checked regularly following a set appointment system. The reason for this was their fear that otherwise they would constantly put off making an appointment and would fail to attend. Respondents preferring regular attendance were spread evenly across all age groups, although more of them had been attending follow-up for less than the mean duration of twenty-eight months. This suggests the need for the reassurance of being examined might be more prevalent nearer to completing adjuvant therapy and that the reliance on this might diminish over time as they begin to regain confidence in their ability to recover successfully from the disease.

> *It depends how motivated people would be. I think you would feel that you wouldn't come along unless there was something that you wanted to raise and sometimes there is value in it because you have an appointment you actually speak about something that you would have just carried on with otherwise* (participant E)

> *I'd probably never come. I need to have a set appointment otherwise I'd never remember to come along and I'd always find some reason for not coming* (participant L)

The above quotations are interesting because they expose a further paradox. Many women seem to want to attend the appointments, and frequently, but would not prioritise them if it were left to them to organise. Their apparent reluctance to take responsibility for their breast cancer detection indicates a loss of power and ability to take control. Such disempowerment might stem from an enforced reliance on a paternalistic health care system or might be related to persistent vulnerability, particularly early on, that leads to an ethos of *'putting your head in the sand'* (participant L). Garmarnikow (1978) likens the former to a parent-child relationship, in which the doctors take on the fatherly role (making the decisions in a paternalistic manner) and the women (or patients) become the children, with decisions being made over their heads and accepting being told what to do. Certainly some women commented that they were surprised by their total compliance, when outside of the hospital environment they successfully managed busy jobs and family life and were used to making important decisions themselves rather than deferring to others.

Only a few expressed a preference for an open access system.

> *It would be helpful. If there could be some flexible system instead of what, at the end of the day, is a very structured approach, I think that might be a benefit* (participant N)

The remaining three women were indifferent. However, some saw the benefit in a telephone follow-up system, but only in combination with coming to the hospital, not as a replacement to clinic visits.

A final contradiction to the women's explicit dependence on doctors is the fact that just over half would be **accepting of a specialist nurse** and would actually be content to replace contact with a doctor with being seen a by a nurse. Inevitably some women considered that only doctors should provide follow-up care, on the grounds that they were *'most qualified'* and *'had the most up to date knowledge'*.

> T*hey* [nurses] *are not qualified. I wouldn't come here and accept a nurse if I discovered another lump* (participant Q)

However, just over half the patients suggested that a Breast Care Nurse (a clinical nurse specialist) should provide follow-up care, as they were *'more supportive'* and had the necessary *'time', 'skills'* and *'knowledge'*.

> *They are experienced in examining but they also give the psychological support, so we would feel more at ease. The doctors haven't got the time to give you anything and I think they don't know how to approach you (*participant W*)*

> *I suppose for what they do you don't have to be a doctor, because all they do is prod and poke* (participant L)

> *A nurse-led clinic? That would be brilliant, five star* (participant R).

The remaining women suggested a combination of both doctor and Breast Care Nurse would be ideal. This suggests that it may not be a doctor that women need to see per say, but a health professional that they deem competent and supportive and that can provide the reassurance that they so obviously need.

Feeling vulnerable

Whilst, inevitably, the fear of recurrent breast cancer described above results in women feeling vulnerable, other sources of vulnerability were also described and these were associated with a **lack of dignity** and a **lack of privacy** in the clinics. With respect to lack of dignity, a third of the participants referred, unprompted, to having to wear a hospital gown for the consultation and expressed how 'vulnerable', 'naked' and 'uncomfortable' it made them feel. This was due less to the nature of the gown itself and more to its symbolic association with a lack of dignity and feeling exposed. On the whole, more of the women troubled by this were older and one stated

> *... It brings all that back. The same environment, the same gown, and that sort of exposed feeling. You try to ask a doctor questions and you are sitting there naked from the waist up and you feel all your badges of dignity, your jacket and scarf, have been taken away. How can you actually talk on an equal level, you know, about medical knowledge and technology, when you are sort of sitting there naked from the waist up* (participant G)

Interestingly, without prompting, over half of the women expressed a preference for a female doctor and this was associated with feeling self-conscious about exposing their breasts in front of a male. The remainder felt indifferent about this with the exception of just one woman who made no reference to this subject during her interview.

> *There are always all these men and you feel very self-conscious, you know because they are all looking at your breasts* (participant V)

The design of the clinic and the layout of the consulting rooms exacerbated lack of privacy. Nearly half remarked, without prompting, how unpleasant it was to wait in the cubicle in which they were seen in the Outpatients department. This was mainly due to being able to hear other consultations.

> *If I've got somebody with me I try and make sure we are talking all the time so that we can't hear what's going on. I think if you can hear somebody who has got bad news, you think oh crikey is that going to be me, and when it's not you, you feel quite selfish because you just think oh thank God it's not me* (participant C)

Fitting in with lifestyle

A final sub theme linked to the personal significance of attending check-ups related to the practicalities associated with attending clinic visits and the resultant difficulties with juggling busy lifestyles. Although, most of the women expressed that they had no such practical difficulties in attending the hospital for routine appointments, those who did experience difficulties referred to problems with arranging **child care**, **returning to work**, **caring for elderly relatives** and the burden of **travelling costs**.

> *Unfortunately at work you are only a number now and they don't care. Time off work is the most inconvenient thing* (participant N)

> *I was on a temporary contract at work and now I have such a poor sickness record so it has been a bit difficult workwise really, and also I have got young children so I have to sometimes make arrangements for them to be looked after because the clinic is always in the afternoon which isn't actually that convenient because I can't be back in time to pick them up from school* (participant U)

> *She* (the woman's mother) *is 94 and she can't walk unaided. If I get delayed in the hospital she could be alone for 3 to 4 hours and she could have a fall or something* (participant I)

7.2.5 Care delivery

Considering others (altruism)

Interestingly the women often alluded to altruistic behaviour as a reason for accepting less than satisfactory care, such as **putting up with waiting** to be seen and also with **being hurried** once in the consultation. Nearly all the women considered the time they were kept waiting prior to going in to see the doctor was acceptable, not because it was short, but because they believed it to be necessary and unavoidable.

> *It is sometimes a short wait, sometimes long, but you have to realise that there are emergencies that crop up and things that go on. They do their best not to*

> *keep you waiting unless they absolutely have to, so I think you have to be patient about these things* (participant H)
>
> *It's life, I mean I've had to do it for 5 years so I've accepted it now. If you want to have that special treatment you wait* (participant G)

However a quarter stated the time they were kept waiting was unacceptable and most of these were younger women under the age of 40 years. These women referred to a lack of communication in that they often did not know why the clinic was running behind schedule and a frustration that the doctors rarely apologised or seemed to acknowledge how long they had been sitting anxiously outside.

> *I am not naturally a moaner. But my goodness, the waits seem to get worse and worse. I don't think I have ever been seen within about two hours of my allotted time and once I was seen over three hours late and ended up getting home after 8.00pm for what was a 3.30 appointment* (participant A)

Similarly, nearly all the women, irrespective of their age, felt hurried during the consultation and that not enough time was given to them but whilst disappointed by this, there was also a recognition of the busy nature of clinics and a consequential concern about taking up more than one's fair share of time.

> *You get the feeling that they haven't got time for small talk, you have to get in there quickly before they nip off* (participant O).
>
> *I personally feel that you don't want to waste their time because there are so many other people. It's probably the way the clinic is organised, you know the rooms are in a line, you know a chain, a conveyor belt and the doctor is just coming in and going straight out and on to the next one* (participant L)
>
> *It is such a quick visit but you do feel very aware of taking more than your fair share of time because often I come and the waiting area is just packed with all these poor people, so you allow yourself to be sucked in to this how are you, plink, plink, donk, donk, you look fine, thank you very much, see you in a year* (participant W)

Putting up with unacceptably long waits and hurried consultations could be construed as further indication of disempowerment, or at least subservience, among the women. The 'superior' position of the doctors was reflected in a general culture of being grateful to be bestowed with their time and expertise and was therefore an accepted trade off against the lack of time afforded. The altruistic attitude of not wanting to take time off other women waiting might be considered one of a collection of related feminine traits such as nurturing, showing concern, deference and even sacrifice (Davies 2003). Only one of the women questioned why every person could not be given adequate time by having more doctors to staff the clinic.

> *Is it that they can't afford more doctors? There clearly are not enough to go round so why not just have more?* (participant W)

Problems associated with inadequate time in the consultation mainly revolved around failing to ask all of one's pre prepared questions or not feeling able to draw attention to apparently minor symptoms or ailments. Less than a quarter did not feel hurried and considered the time given to be about right.

> *I feel quite pleased with myself if I get in and out quickly. I think well they are obviously happy with me and I am quite happy to go out and spend the rest of my day shopping in London* (participant M)

Passive acceptance of what doctors say

Closely linked with their ongoing dependence on doctors, the women demonstrated an alarming passive acceptance of their sometimes **inappropriate behaviour**. Whilst half of the participants expressed satisfaction with the manner of the doctors they had seen, the remaining women had mixed feelings. Dissatisfaction was commonly associated with traits on the part of the doctors such as briskness, unfriendliness, disinterest and appearing to be irritated if asked questions or challenged. More women dissatisfied overall were younger, under 50 years of age.

> *Her* (the doctor) *attitude was awful, she was so blunt and hurried, the I haven't got all day approach, but he* (the doctor) *was wonderful, he leant back against the wall and looked as though if I was going to keep him an hour he wouldn't have minded* (participant K)

> *Some of the doctors do have a certain briskness and have been a little patronising, I actually had somebody slap me on the bum and tell me to have a nice Christmas so there is an element of little girlie sort of thing* (participant S)

Continuing a theme of vulnerability and/or disempowerment (subservience) the above quotation depicts grossly inappropriate behaviour on the part of the doctor and yet the women display passive acceptance and did not seem to feel angry about this experience. It is possible that this is because the behaviour was seen as a tolerable trade off to being seen by an alleged expert or because they do not wish to create a fuss or complain for fear it will jeopardise future care. This echoes findings by Leydon et al (2000) in which people with cancer stated being a 'good patient' (p910) was construed as doing what you are told. Such disempowerment may be rationalised by relying and having faith in the doctor's expertise (Leydon et al 2000). This makes quite a statement on the power held by the doctors in follow-up if the women perceive that doctors could somehow sabotage their care if they do not comply with everything that happens in the check-up regardless of its appropriateness or efficacy.

Similarly women put up with feeling **hindered in asking questions**, specifically relating to emotional concerns, during the consultation and with receiving **inadequate answers** when they did ask questions. Most of the women stated that they did not feel comfortable broaching any emotional/ psychological concerns at their routine clinic visits. Reasons given for this included that consultations were too physical, that the clinics were not oriented towards emotional needs and that they were conscious of taking up too much time. Overall the older women in the sample were more reluctant to discuss emotional concerns, believing that it was not the role of the clinic doctors to listen to these.

> *I just get the feeling that they are more concerned with your physical well being rather than your emotional well being. I mean that has been my impression all the way through really* (participant T)

This depicts an entirely biomedical model of service delivery in which the focus, as perceived by women, is detection of new disease and clinical examination. However, once again the women seemed to exhibit passive acceptance of the fact that emotional needs were commonly unmet and that little or no attention was given to these as standard practice within the follow-up clinics.

Emotional needs cited by the women included feeling worried and tearful, lack of confidence with undressing, problems with sexual relationships and low self esteem. Less than a fifth felt able to raise these sort of concerns and/or needs and this has obvious implications in that concerns that are not voiced will never be addressed and improved. Also women may be left coping with serious emotional distress and even clinical depression without receiving any therapeutic intervention or support for long periods of time. Some women also made reference to physical symptoms hindering their well being. Symptoms included fatigue, weight gain and hot flushes and the emotional distress this may cause. One woman commented

> ... *I certainly feel more embarrassed talking about something which could be deemed as vanity, I actually put on 2 stone in weight with Tamoxifen and that really upset me, in fact it was quite a major contribution to being depressed. It was the sort of feeling that I had lost control of my body. In some ways that was worse than losing half the breast, that has a name, whereas weight gain, people just think you have eaten too much* (participant V).

In contrast most women felt comfortable discussing any informational needs with doctors while only a few did not. Reasons given for any reluctance were the same as for psychological needs, with the addition of fearing looking ignorant or of asking questions perceived as irrelevant by their carers.

However, paradoxically, whilst most claimed to ask questions, half of the sample still reported unmet informational needs and unanswered questions. This suggests that the nature or depth of the response given by doctors is inadequate to fulfil the woman's need for information or that the answer was relayed but could not subsequently be recalled. Therefore appropriate communication skills and provision of opportunities to repeat salient information both seem essential to improving follow-up care. In addition several women asked the researcher questions outside of the interview when the taping had been stopped suggesting additional areas in which unmet informational needs and unanswered questions existed (see Table 7.4 below).

Table 7.4: Key areas of information deficit

Subject	Number
Tamoxifen	11
Management of hot flushes	5
Ability to have children	4
Relations with partner	2
Unresolved past grief	2
Likelihood of disease recurrence	2
Resolving weight gain	1
Cancer risk to children	1
Preventative dietary habits	1

Feeling depersonalised

The women alluded to the depersonalising affects of much of the data described so far and perhaps one of the most notable examples of this, in terms of unanimity, was the **lack of continuity** in the clinics. Nearly every woman (n=22) considered the lack of continuity provided by the doctors in clinic as unacceptable. Interestingly this was the one issue about which the women did not demonstrate passive acceptance. Most were vocal in their dissatisfaction with lack of continuity and state that they had raised this with the doctors that they had seen. This might be because lack of continuity threatened safety and women might conceivably put their safety above their emotional well-being. Continuity was considered to be important in order to enable the women to feel 'like an individual', 'a person, not just a number' and to feel the doctor knew their history and was familiar with their medical notes.

> *I don't think anyone can judge me from reading notes, a continuous face would know you as a person, not just another number* (participant Q)

> *There is always that question about who am I going to see this time. You desperately want someone who knows you and gives you time. I have seen 19 doctors in four years. You certainly hope they have read your notes!* (participant E)

> *They might remember something that we had discussed before and make it feel more personal* (participant L)

Only a very small minority of the participants did not perceive continuity as important.

> *So long as I see somebody I'm quite happy* (participant D)

Thus the desire to be treated as an individual, as well as the perceived necessity of the doctor knowing your personal medical details, was the most important issue alluded to by the women. The 'cattle market' ethos mentioned earlier (crowded waiting rooms and hurried consultations) might well be considered an acceptable trade off if the woman felt like an individual when she was eventually seen.

Ongoing individual needs

Small numbers of women without any prompting highlighted the following themes. While only a few women mentioned these areas they are important in view of the potential number of women throughout the UK who may think these issues are worth further consideration.

In terms of provision of care, three women expressed a wish for complementary therapies to play a bigger part in the follow-up care provided. In addition, two **younger women** made reference to exploring their unique needs, specifically in relation to their feeling very conscious that they were the youngest people in the ward and in clinic.

> *They were all so much older, at least a twenty year age gap between me and all the other ones there* (participant O)

Six women referred to the difficulties associated with continuing work, having less sensitive employers and also with obtaining insurance.

> *They stopped paying me so I had to think about getting the invalidity benefit which didn't even pay the rent, it was really awful. There was somewhere by outpatients that could give you advice about that, but if I hadn't found it, I don't think anybody would have come up with that information, nobody actually said how are you managing financially, it was just assumed* (participant N)

> *It's the fear of society, I mean I can't get jobs. If they needed proof of my health I'm sure I would omit having breast cancer because I don't think I would get a job. Simply, my health is not 100% and yet I work as hard as anybody else. That stigma, I can't even get insurance* (participant V).

Areas such as these might well be poorly addressed with appointments so explicitly geared towards the physical check-up of the individual and yet, such needs can be hugely important to some women and inevitably hamper their optimum recovery.

Benefits of coming for check-ups

Over half of the women considered peace of mind and **reassurance** as the main advantage of the current system of follow-up care. This was particularly pertinent for women who were nearer to finishing their treatment and had therefore had less time to recover from the experience of having breast cancer. A few of the sample felt that being able to be seen by a **specialist** at short notice was advantageous, while some mentioned that they enjoyed talking to other **women** in the waiting area and thus not feeling alone with their concerns.

Most of the women (n=21) felt that overall the clinic visits for routine follow-up care were worthwhile and that it was important to be checked in one way or another. Nearly all of the participants made specific reference to their overall confidence in the NHS Trust at which the study took place and expressed relief and satisfaction to be treated at this hospital.

> *The standard of treatment is superb, other hospitals in relation to this one all have a great deal to learn* (participant G)
>
> *If the cancer did come back I would want to go to the* [hospital under study], *I have faith in everybody, the people there are fantastic. I'd be very reluctant to go to a different hospital now* (participant C).

However, of relevance here is that half of the women also made reference to a feeling of anti-climax after treatment had finished and of feeling cast aside and on one's own after previously having had so much contact with the hospital.

Drawbacks of coming for check-ups

The perceived disadvantages of the current system of follow-up care stated by the women at the end of the interview revolved around emotional, care delivery and practical issues that have been discussed earlier and are summarised for clarity in Table 7.5 below). Key drawbacks were that the check-ups **provoked anxiety** and **fear** and a **dissatisfaction with aspects of care delivery** such as a lack of continuity. A fifth of the women reported no disadvantages.

Table 7.5: Disadvantages of the current system of follow-up care

	Number
EMOTIONAL	
High anxiety	11
Fear new disease will be found	4
Seeing other ill patients	2
Only addresses physical needs	1
Unfriendly doctor	1
CARE DELIVERY	
Lack of continuity	4
Lack of time with doctor	3
Long wait to be seen	2
PRACTICAL	
Travel long distances	1
Time off work	1

7.2.6 Summary of women's' views of follow-up care

While the majority of women felt that the check-ups were worthwhile, there are a number of personally significant factors and issues associated with care delivery that require addressing to ensure a greater person-focused approach and less dependence and vulnerability on the part of women.

7.3 Focus Group with doctors

7.3.1 Demographic Data

The details of the five participants are presented in Table 7.6.

Table 7.6: Characteristics of the focus group participants

Initial	Age	Gender	Status	Rank	Ethnic origin	Length of time on team	No. of follow-up clinics per week
J	38 years	Female	Single	SpR * Year 5	White, English	10 mths	4
S	42 years	Male	Single	SpR Year 5	White, English	5 mths	5
G	34 years	Male	Married (1 child)	SpR Year 3 Research**	White, English	7 mths	1
Ja	29 years	Male	Single	SHO ***	Asian, Indian	3 mths	2
B	54 years	Male	Married (1 child)	Visiting Consultant****	White, American	8 mths	5

*SpR – Specialist Registrar

**Specialist registrars are encouraged to gain research experience during one of their five years training. This is usually one year spent conducting a clinical trial, during which they are freed up from a large percentage of their clinical commitments

*** SHO – Senior House Officer

****As a major, specialist cancer centre, the trust attracts medical applicants from overseas. These are awarded honorary contracts after a probationary period to ensure competence and expertise. They usually remain in post for one year and are involved with clinical and research activity. This individual was given SpR Level 5 status, as he holds a consultant breast surgeon post in America.

7.3.2 Thematic Analysis

Framework analysis generated 4 main themes overall. These were then divided further into sub themes and categories (see Table 7.7), which are presented and exemplified using the participant's own words. The greater focus on biomedicine was noted throughout the analysis and the different language used by the doctors because such masculinised discourse was at odds with feminist philosophy (all but one of the participants were male). To identify the source of any quotations, the first initial of the speaker's name is used to denote each participant, and 'R' is used to denote the researchers input, as the group facilitator.

Of note, focus groups differ from one to one interviews in that there is a greater dynamic within a group and ideas are developed by the group members as the discussion is generated, that is there is a greater likelihood of the members 'bouncing' off each other in the things that they say. To reflect this I have included chunks of conversation throughout, rather than just one person's comments as in the interview analysis. In this way it can be seen how various group members respond to what someone else has said and also how their thoughts and feeling interrelate to the other group members. It also demonstrates how sub themes and categories may have emerged as a direct result of that discussion because one person's comments generate a response that might otherwise have been omitted.

Table 7.7: Categories, themes & sub themes arising from the Focus Group framework analysis *(highlighted in bold within the text)*

Theme	Sub Theme	Category
7.3.3 Organisation of Clinics	Essential Prerequisites	* Missing notes * Too few rooms * No tapes * No results
	Booking System	* Too few investigation slots * Over booking
7.3.4 Care Delivery	Inadequate Time	* Conflicting commitments
	Lack of continuity	* Knowing what happens to individuals
	Clinical examination and Investigations	* Reassurance * Cursory
	Needs of women	* Recognition of limitations * Failing to address all needs
	Frequency and Duration of Follow-up	* Haphazard nature * Discharging patients
7.3.5 Personal impact on doctors	Repetition	* Lack of fulfilment
	Helplessness (feeling vulnerable)	* Unable to cure * Referring on to others
	Needs	* Education, training & development
7.3.7 Specialist Nurses	Reliance	* Guilt * Recognition of skill * Support for nurse-led follow-up

7.3.3 Organisation of clinics

Essential Prerequisites

All of the group members concurred about the frustrations of inadequate resources during the clinic, which one individual referred to as 'the essential prerequisites'. Examples of these included **missing clinical notes**, **too few consultation rooms**, and nurses, **no dictation tapes** and **lack of available slots** to book various imaging tests. Frustrations arose not only from the inconvenience caused and the slowing down of the clinic whilst items were found, but also because absent notes affected the quality of the consultation and their knowledge and thus management of the individual clinical scenarios.

> *G: "It drives me mad when the notes are missing. They say look it up on the computer which is great until the last letter mentioning suspicion of mets hasn't reached the screen yet and you go in all cheerful and normal while they are waiting to hear the results of life changing tests".*
>
> *R: "What other resources affect the running of the clinic by their absence?*
>
> *S: "Usually there are not enough rooms, so you stand outside like a lemon waiting to jump in when someone comes out, it is just ridiculous to stand there waiting when you could be getting on with it and finishing earlier".*
>
> *J: "Sometimes you tell a patient they might have new disease but then say we'll scan you in about two weeks time because there is no earlier slot and you think for goodness sake, how am I going to explain that one to someone who is panicking and wants to know what the hell is going on".*

Hence, in the same way that the women commented about inadequate numbers of doctors in the clinics (contributing to long waiting times and rushed consultations), the doctors also perceive the clinics are under resourced. However their focus is more about practical resources and the booking system (see below) than personnel and there seems to be a clear potential for the clinics to run more efficiently if these resource issues were addressed.

One doctor did mention **inadequate nursing** support for the clinics. However interestingly he regarded the nurses as performing very biomedical tasks and makes no comment on them being delayed due to provision of psychosocial care. He also seems to hold very determined role boundaries in terms of duties that could not possibly fall in to the domain of medicine.

> *B: "I get frustrated when all the nurses disappear. It really slows you down having to sort out forms and appointments and dressings to take home, that sort of thing, because there are only two nurses between three of us and so you are lucky to spot one".*

Booking System

Another factor compounding the busy nature of the clinics are the sheer numbers of people seen. The set up of the clinic allows **'overbooking'** when all the appointment slots are taken in order to see people with new or urgent problems. This results in sometimes as many as six women with the same time slot for their appointment. In addition, the schedule is set up to allow 10 minutes for each slot but individuals will often require more than this, particularly if new symptoms are reported.

> *B: "When the clinic is hopelessly overbooked it can be a bit soul destroying. You see all these notes lining the shelf and just know that you are in for a late one".*

> *G: "You are definitely torn. You know that if you take too long with each patient that the queue will just not move fast enough".*

> *Ja: "But you can't win because if you give patients all the time in the world, the ones outside moan and scowl because they are so late coming in and have been waiting for 2 or 3 hours. But if you hurry them, then they go out feeling cheated because you have not taken enough interest in them or answered all of their questions".*

> *J: "I think there are always those you feel justified giving the time to and those that are just taking the mick. If someone asks a sensible question, say about their pathology, or about taking HRT, then I am very happy to answer it, but if*

> *they say please can you take a look at my big toe nail whilst I'm here, you feel like saying bog off"!*

Thus both the doctors and the women feel pressured by too many people in the system and are aware that more time used up by one person, potentially denies another person adequate time in their consultation. These quotations also indicate that the power base within the consultation lies with the doctors because they make the decision as to whether to answer all questions fully or to cut short the interaction time. The women indicated little opposition to this lack of control. Presumably if this power was challenged, in that a woman demanded to have more time, or indeed refused to leave the room, they would be labelled as difficult and this is a likely explanation, as well as the altruism, for the passive acceptance of being rushed that the women admitted to during the interviews.

7.3.4 Care delivery

Inadequate Time

In the same way that the women remarked on the hurried nature of the consultations, all the doctors in the focus group commented on the hectic, busy nature of the outpatient follow-up clinics and felt that this was a negative aspect of the service from both their perspectives as doctors and for the women. In their opinion the rushed schedule was compounded by several factors. Firstly, they were never all able to start clinic on time, due to other **conflicting commitments**. Sometimes individual doctors are delayed in the operating theatre, which can over run from the morning into the afternoon session. The senior house officer also has to admit and clerk new admissions arriving on the ward. If they do not arrive until the afternoon, they have no choice but to do this during clinic time. They are further restricted because routine pre operative tests such as chest x-rays need to be ordered and carried out before the departments close at 5.00pm, thus preventing these jobs being completed after clinic, in the early evening. When the doctors rush to clinic from another area, such as theatres or the ward, they are frequently forced to forgo lunch in between.

> *S: "If the theatre list is too full a.m. we are really split in two directions. I end up sending someone out to start clinic, but then I am short staffed finishing the last case. Sometimes I have arrived in clinic as late as 3.30pm and haven't*

> *failed to notice the glaring looks from everyone. It is not as if I have been sitting with my feet up, usually we have been here since 7.30, and you count yourself lucky if you grab a sandwich before you start the next thing ".*
>
> *Ja: "Absolutely. I have to clerk in all the admissions on Tuesday and Wednesday afternoons. They keep bleeping me to come down earlier but if I don't get it done I do it after clinic and end up finishing at about 8.00pm. Either that or the boss arrives for the pre op ward round and I can't present the cases because I haven't finished prepping them".*
>
> *J: "It is also a bit tough if you do arrive on time. I know I don't have theatres first on Tuesday's but sometimes I um moan because I have managed to get there on time and then I end up seeing twice as many patients as everyone else".*

Interestingly, although arriving late to the clinic may be unavoidable in some situations, the doctors may be subconsciously contributing to a subtle oppression of the women. If women see doctors rushing in late and know that time available is even shorter they may feel more deferent and conscious of taking up too much time and so may feel even more inhibited in asking their questions.

Lack of continuity

In line with the views of the women, the doctors also commented on the effects of a lack of continuity for them and the frustrations of commencing an important line of investigation with an individual, which they then do not have the opportunity to follow through and may not get to **know what happens to individuals** in their care. The system for seeing women relies on notes being placed along a desk in order of appointment times. The doctors then take the next set of notes in the queue and therefore have little control over who they see unless they specifically ask for certain individuals because they recognise a name. This lack of continuity causes frustration because of wondering what has happened to certain women and also because they might have to give bad news to people that they have not met before, and therefore have not built a rapport with.

> *J: "I find it hard because you have, um, broken the news that something could be wrong, and shattered their lives, and then you never see them again".*

> *G: "They will often see someone else for the results and it's hard from both sides. I don't like telling someone they have lung mets when I have never seen them before in my life".*

> *B: "And you don't know how much they were told by the person who ordered the tests, you don't know if they played it down or came right out and said I am sure you have secondaries and we can't cure them".*

It seems the vulnerability and concerns over safety that the women expressed are shared by the doctors conducting the consultation.

Clinical examination and investigations

Interestingly, the group members referred to a somewhat paradoxical situation with regards to clinical examinations and diagnostic investigations. On the one hand they realised the inadequacy and **cursory** nature of the clinical examination and also the rationale for not ordering routine tests. But on the other they admitted to ordering tests for their own **reassurance** or to alleviate the person's worry, even when there was no sound clinical reasons for conducting them. This behaviour might influence the dependence on these tests as expressed by the women and their perceived importance in obtaining reassurance. It seems that the doctors are responding to the vulnerability exhibited by the women. Yet paradoxically, by doing this, they continue to perpetuate the feelings of dependence on the doctors that the women clearly demonstrated. It again highlights significant power within the consultation, because the doctors have the authority to order a test or not and this implies they hold the key to detecting the presence of recurrent breast cancer, when in fact the real sensitivity of tests to achieve this in the absence of symptoms is highly questionable.

> *S: "You sometimes feel like you are just going through the motions. You have a feel and say everything is all right, but actually you don't know. If they have some disease brewing in their bones, there is no way me feeling the breast is going to make a blind bit of difference!"*

> *R: "Is it the same kind of thing with regards to x-rays and scans and bloods?"*

> *J: "I think every doctor has ordered tests when they are not absolutely necessary. You know in your heart of hearts that they probably won't show anything relevant, but you can't help having niggling doubts. You think well what if there is something there and I miss it, so you do it for your peace of mind as well as theirs".*
>
> *R: "Do you find the patients sometimes put pressure on you to investigate them even after you have explained that there is not clinical indication for them"?*
>
> *B: "Yes. The thing is they can go on and on and wont accept that you haven't done a full body scan, so you think well OK if I do that I am going to put an end to this now".*
>
> *J: "I am guilty of that too, but it drives me nuts when* (mentions a consultant surgeon by name) *orders every test under the sun for their private patients".*

Needs of Women

When questioned about the success of the follow-up clinic in terms of meeting individual woman's needs, the group reported mixed feelings about the adequacy of psychosocial care within the follow-up clinics. Whilst some members considered information needs were largely met, others disagreed.

> *G: "I actually think we do a good job in answering their questions. I spend more of the clinic talking and going through things, than I do examining as such".*
>
> *S: "I'm not sure about that. Um, I would think a lot of patients go away wishing they could have asked more or feeling that they haven't managed to get to the bottom of things".*

The suggestion by some group members that information needs are adequately addressed contradicts with what the women said in that they declared difficulties in asking questions and receiving inadequate answers when they did ask something. This might be indicative of a misunderstanding on the part of the doctor on what it is the woman actually wants to know, or a failure to communicate the information in a language that it is readily understood.

However in terms of emotional needs, the entire group **recognised their limitations** and agreed that they probably **failed to meet** these adequately for the majority of women, demonstrating that the doctors recognise the shortcomings in care as perceived also by the women. Reasons cited for this were that the clinics were too busy to spend much time on emotional support and that they had no immediate solutions and were therefore not able to intervene and "make things better". Finally they perceived that they are not well prepared to manage emotional distress and felt that the nurses would be 'better equipped' to do this (see section 6.3.7).

> *G: "I feel bad when people leave very upset or they tell you things that you just can't really do anything about. They might say I'm finding it very hard to get over all of this and you say over and over again, give it more time, it just sounds so corny, as if we are palming them off".*
>
> *Ja: "The problem is that the clinic just doesn't allow for you to sit and listen. You try to be kind, but if there is nothing concrete you can offer then you tend to hope that they will go away, sooner rather than later!"*

Sadly, although the doctors acknowledge shortcomings in their care, they do not explore any possible solutions, but merely except the problems as a fete a compli. It could be argued that allowing sub optimum care to continue not only makes their job more difficult because problems will continue to arise in women they see, but may also be construed as subconsciously conspiring to continue the oppression of women by not facilitating attention to their key needs. Instead doctors should be striving for compassion, seeing people as individuals and respecting their dignity (Davies 2003).

Frequency and duration of follow-up care

When asked for their thoughts on the frequency with which women attend for follow-up and the duration it lasts for, the group had mixed opinions. Most thought the frequency of visits every 4 to 6 months initially were about right, which concurs with the majority of the women. However a criticism was that in reality this is rarely stuck to and numerous women attend 'when it suits them', and usually more frequently than their scheduled appointments.

> *S: "I think it is totally* ***haphazard. I*** *am sure the patients just book themselves back when they want to, irrespective of when you tell them to come back".*

> *B: "I know they are anxious but when someone has come every two weeks for 3 months and there is nothing wrong with them, you do think to yourself for goodness sake, get over it".*

Once again, the doctors exhibit power within the consultation because they decide how often an individual should be seen. Someone coming back earlier is regarded as non-compliance rather than recognising that that person may know their own bodies and may be trying to meet their own needs and alleviate their fear. It also highlights a possible discrepancy between the judgements of doctors and nurses. As women cannot effectively book themselves into an earlier appointment, they are reliant on a health professional, most commonly the nurse, to do it for them. This means that the nurse has decided an earlier appointment is justified, whilst the doctors clearly believe this is not always the case and that the woman has returned inappropriately. This could be because the doctors focus on the physical examination in the clinic, judging, if there are no new symptoms, that the appointment is unnecessary, whilst the nurses might recognise the high levels of anxiety and decide a visit is worthwhile, even in the absence of notable physical symptoms.

Linked with this issue is the fact that it is quite difficult to **discharge** some people, even after ten years of follow-up. This is partly because women may be unwilling to leave with no further visits planned and partly because the doctors are anxious not to discharge if something may be wrong.

> *B: "You have that doubt at the back of your mind. If I let them go, will they get a recurrence the next month".*

7.3.5 Personal impact on doctors

Repetition

One unpopular aspect of the clinic that arose in the discussion was its repetitive nature, both in terms of the clinical scenarios and the questions that women ask. Group members referred to the monotony of performing the same routine clinical examination and answering the same questions many times in one clinic session. This leads to a certain **lack of fulfilment** in attending follow-up clinics, more so for those who were committed to several a week and might help to explain the lack of a 'personal touch' that so many of the women commented on.

> *J: "The clinic can be painfully repetitious at times. You can become a bit robotic. Hello, any problems, can I examine you, thank you, see you in a year".*
>
> *B: "I think because the issues are similar for most people the same old questions come up time and time again. I have lost count of how many times I have explained why we don't do body scans, how Tamoxifen works, why the breast is red after radiotherapy, why there is numbness after surgery etcetera etcetera etcetera etcetera".*

Interestingly reluctance on the part of the doctors to repeat information over and over implies that their needs may sometimes take precedence over those of the women. This is a form of power because ultimately the doctors control what is covered during the consultation.

Helplessness (feeling vulnerable)

When asked about aspects of the clinic that they find difficult, two group members reported anxiety when they have discovered secondary disease, not just because metastatic breast disease **cannot be cured**, but in particular the feelings of helplessness that this situation evoked.

> Ja: "*There is certainly an element of impotency. If they have metastatic disease then they don't need a surgeon, so we* ***refer on*** *and send them off to the medics and have no hand in how they will do".*

> G: *"I find myself saying well there are several approaches to treating this but the oncologists will tell you all about that. You feel as if you are palming them off. Then they will say but you can do something can't you, and I say the old chestnut, oh yes, well we can always treat this, but treat is not the same as cure, so I deliberately avoid that word".*

Needs

The group members were asked if the clinics in any way facilitated their **education and training** needs as doctors. The more experienced doctors stated that generally this was not the case, especially in terms of routine clinical examinations and recognising suspicious symptoms. However they did recognise the importance of being able to see the late results of breast reconstruction.

> J: *"I enjoy seeing how things heal over time. Seeing reconstructions years down the road is educational. You can get a feel for what will happen given time and then you can explain to new patients what will happen to them".*

> S: *"Yes, I think you need to see late effects as a surgeon and to understand that what you do at the time will not stay like that forever".*

The most junior member of the team did feel the clinics were educational. This was partly because he had less experience in examining breast tissue post cancer treatments. The other aspect was referred to as 'spontaneous learning' when he would see something for the first time or listen to case history discussions and debates about the best course of action in certain clinical scenarios.

> Ja: *"You know that things will feel different after scarring and radiotherapy, but you need to build up confidence* [in breast examination], *otherwise you think every lump and bump is recurrence".*

One group member commented on the value in seeing problems resolving completely over years as this gave him confidence that people do get better and that the multiple aspects of morbidity experienced by women can heal given time.

> G: *"You say things will be better in time, and it sounds a bit corny, but actually they do. It is really nice to see people years down the line and they*

> *are truly fine. They have no pain, no hot flushes, no recurrence and can lead normal and stress free lives; well at least as far as the breast cancer goes".*

Interestingly the women in the first study did not mention the needs of the doctors at all, except in acknowledging that they are busy.

7.3.6 Specialist Nurses

Reliance on specialist nurses

Every member of the group praised the input of the specialist nurses in to the clinics. These included clinical nurse specialists in breast care, but also research nurses and chemotherapy nurses. They admitted to some **guilt** at over reliance on these nurses for many aspects of care and agreed that the clinics would function poorly without them. There was a unanimous **recognition of skills** that nurses have and specific aspects of care that were valued by the group were emotional care, the ability to explain things in lay terms, their wide ranging knowledge and their ability to solve practical dilemmas.

> S: "*The specialist nurses are my life line. I can hardly remember them not being able to answer things for me or get things done"*

> *B: "If a patient cries, well it's call* (states the name of a clinical nurse specialist). *Get her down quick!"*

Davies (2003 p736) refers to the above as 'cleaning up' after the doctors. However, there was acknowledgement that this reliance can sometimes be abused in that specialist nurses are 'used' by the doctors to 'get the patient out more quickly', and are sometimes called at towards the end of the clinic to facilitate the doctors 'escaping more easily'. Once again this is enlightening about role boundaries and the perceived superiority of doctors over nurses. There is an ethos that the specialist nurse is called down (summoned) to the clinic at the discretion of the doctors and hence is answerable to their needs and demands. Such behaviour has been deemed as doctors 'doing dominance' and nurses 'doing deference' (Davies (2003 p722).

> *Ja: "I hope they don't mind me saying it, but you do tend to rely on them when the patient is taking ages. I say why don't you speak to our specialist nurse*

> *and she can go through all your questions. You feel a bit mean but you are also relieved when they pop their heads around the door".*

All of the group members were **supportive of nurse-led follow-up** and saw no difficulties arising from nurses adopting this role. Reasons for this affirmation were cited as their skills in psychosocial care and communicating and their ability to explain a variety of issues relating to breast cancer. They also commented on the permanent positions these nurses hold and therefore their greater likelihood of offering continuity and also their being involved at all stages of the disease management and all treatment modalities, thus being familiar with all members of the interdisciplinary team.

> *R: "Do you thing follow-up care could be provided by a specialist breast care nurse"?*
>
> *J: "God yes, of course, I don't know why more CNS's don't take it on. You would probably do it a thousand times better...."*
>
> *B: "And I bet the patients would prefer it as well. They much prefer talking to you anyway".*

7.4 Summary

The doctors display agreement with the women interviewed in the first study in that they highlight a number of issues with care delivery that require addressing to ensure a greater person-focused approach and potentially more optimum care. Specifically there was concurrence on the hurried nature of the clinics, lack of continuity, lack of resources, questionable efficacy of routine investigations and poor attention to psychosocial care, although with different focuses on the potential victims and impact of these. In addition to this, they remind us of the need to take into account the views of those providing the consultation and how this provision meets their training needs as well as how it makes them feel. Imbalances of power inevitably exist between users and providers of follow-up and these will impact on perception of the quality of care by both parties.

Chapter 8. PHASE TWO: DEVELOPMENT OF THE NURSE-LED FOLLOW-UP CLINIC

8.1 Introduction

This chapter describes the process of preparation and training I went through in order to carry out consultations in a nurse-led breast cancer follow-up clinic. I spent time considering the model of nurse-led care that I intended to evaluate and discussed this with clinical and academic colleagues. The rationale in the first instance was to develop a nurse-led version of the follow-up model run by doctors in order to check feasibility and acceptability. Hence the protocol (see below) standardises traditional medical approaches to follow-up and retains a clinical focus on disease detection. I wanted to determine ways in which the same model of care given by a doctor and a nurse could vary. It was not my intention to develop an alternative model of follow-up care but I hoped that if I was able to successfully demonstrate that nurses could provide a level of follow-up care that was at least as good as that provided by doctors and was acceptable to women, I could then go on to develop alternative models in the future. In fact approaches to breast cancer follow-up changed during the period of the study when the National Institute of Clinical Excellence (NICE 2002) produced an updated document on breast cancer service guidance that stated long-term follow-up has not been shown to offer any clinical benefit to women and thus check ups should continue for only two to three years (except if clinical trial protocols require longer). Thus moves to shorten (or even cease) follow-up provision have largely refocused ideas for models of service delivery in this setting. Nevertheless, prior to these changes and in view of the desire by the women to retain follow-up but with improved attention to continuity of care and emotional support, it seemed prudent and imaginative to evaluate care delivered by a specialist nurse. At the time of designing this study nurse-led clinics were much less prevalent and so I also wanted to explore the tensions and challenges of extending nurse-led care into areas traditionally undertaken by doctors.

Prior to evaluating the nurse-led care, I had to undergo a process of preparation for this new extended role. This process consisted of three main elements: development of a protocol for the intervention (including defining practice boundaries), training and learning the skills and establishing the practicalities of the nurse-led clinic. The preparatory work took place over a period of ten months in total, during which time field notes were kept to record the processes and experiences involved (see figure 8.1).

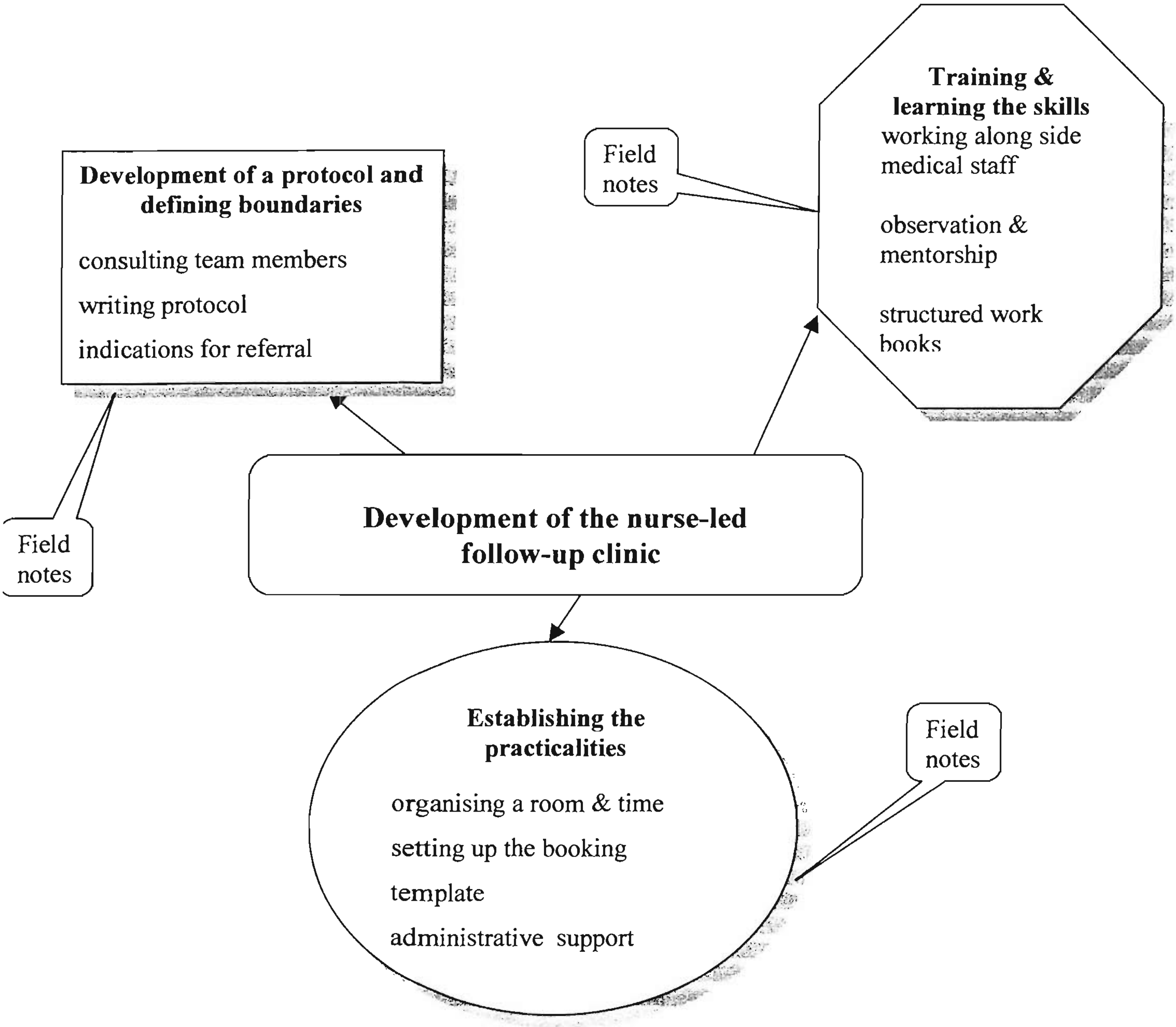


Figure 8.1 Illustration of research design of Phase Two

8.2 Use of Field Notes

Reflexivity is a core tenet of feminist methodology, by focusing on acknowledging and reacting to my feelings about running the nurse-led clinic I became integrated in the research encounter. I thus used reflexive field notes as a way of achieving an expansion of understanding that might be deemed central to the production of knowledge. Field notes are essential to remembering thoughts, feelings and observations about the research setting that might otherwise be forgotten (Lofland 1971). They can take several forms and in my case they consisted of personal reflections on activities during the research and served as a running description of the process of preparing for undertaking nurse-led follow-up, including protocol writing, training and putting it into practice. I took the notes in two ways. The first was dictating pertinent entries in to a dictaphone that I carried during training and whilst conducting the nurse-led clinic (for the purpose of dictating entries for the medical notes). I transcribed these recordings at a later date. The other way was to type entries directly on my office computer the same day as the event in question (whilst my memory was still clear) when time allowed. I then saved these to a disc for transcribing at a later date. I decided to keep the field notes because the concept of nurses extending role into activity traditionally performed by doctors was relatively new at the time of training and I wanted to capture the effect of this process on the nurse (myself) and to explore further what extended role activity might mean for the individual nurse taking part. Looking back my notes achieved this focus in that they largely pertain to my feelings (good and bad) and personal impressions about the preparatory process rather than to statements of facts.

8.3 Development of a protocol for the intervention & defining boundaries

As discussed in Chapter 3, practice of breast cancer follow-up is diverse and variation exists, not only with regards to duration and frequency of appointments, but also to the nature of clinical examination performed. A key concern I had was ensuring safety of practice by adherence to the hospital guidelines on breast cancer follow-up. Yet a search of the local breast unit policies revealed no such guidelines in existence. I decided that a protocol for the clinical follow-up consultation should be written and agreed by all professionals practising it, including the doctors. Thus safety was enhanced in that if litigation problems arose, the woman would be unable to claim practice would be different had they been seen by a member of the medical team, instead of by the nurse. This consistency of practice was deemed especially important as women found to have incurable metastatic disease could, understandably, react angrily and, albeit mistakenly, perceive that it would have been detected earlier and thus be more curable if a doctor had been responsible for their follow-up care. Interestingly there was disparity and disagreement between medical oncologists and surgeons on the breast unit as to what constituted best practice for a follow-up examination and this resulted in three drafts being written before agreement was eventually reached. The main area of contention was clinical examination of the spine and abdomen for bone and liver metastases respectively. Whilst some doctors felt these should be included to ensure completeness and attention to detail, others felt they were so unlikely to reveal the suspicion of recurrent disease without any symptoms present, that they did not include them unless the woman specifically drew attention to concerns relating to these areas. The field notes capture the effect of this on me. The final protocol is presented in Figure 8.2.

> *Banging my head against a wall comes to mind.* [name of consultant surgeon] *and* [name of consultant oncologist] *can't agree with each other on what we should all be doing in the examination. When I write down what one has said the other asks me why I put that in and back round we go again.* Page 2

As well as standardising practice in the follow-up clinics, the protocol details practice boundaries for the specialist nurse, in that it is clear which clinical scenarios cannot be managed by myself and when referral back to the medical team is required.

Frequency and Duration:

Follow-up will be provided to patients after completion of adjuvant treatment for breast cancer 3 monthly for 2 years, then 6 monthly until the end of the 5th year post diagnosis, then 1 yearly until the end of the 10th year post diagnosis.

Investigations:

Mammography will be performed at the end of the 1st year post diagnosis for all patients.

Patients with Ductal Carcinoma in Situ (DCIS) will then receive annual mammograms.
Patients with invasive carcinoma will have a mammogram every 2 years.
No other investigations will be performed routinely on asymptommatic patients.

Medication:

Patients receiving adjuvant Tamoxifen will continue to take it for 5 years. If any unresolved problems are reported by the patient whilst continuing Tamoxifen for this duration, the patient will be referred back to the medical team.

Clinical Procedure:

At each clinic visit, the following clinical examination will be performed:

- palpation and examination of breast/chest wall on side affected by cancer
- palpation and examination of contralateral breast
- palpation and examination of bilateral axilla
- examination of supraclavicular nodes
- examination of neck and spine for tenderness
- palpation of liver

Indication for Referral back to Medical Team [for patients seen by a specialist nurse]:

The patient should be referred back to the medical team immediately for any of the following indications:

- detection of a new lump on the side of the affected breast or on the contralateral side
- detection of abnormality at 'routine' mammography
- detection of skin changes (other than those post radiotherapy treatment) such as new skin nodules, puckering, peau d'orange.
- detection of new nipple changes on either side, such as retraction, discharge or scaling
- detection of palpable axillary or supraclavicular lymph nodes
- reported spinal tenderness
- detection of possible mass in liver
- detection/ reporting of jaundice
- reporting of new bone pain which is persistent, unresolved and worsening
- detection/ reporting of shortness of breath
- detection/ reporting of distended abdomen or pelvic ascites
- reporting excessive, unplanned weight loss
- reporting of persistent headaches
- reporting of any sudden, unexplained physical episode

Figure 8.2: PROTOCOL FOR BREAST CANCER FOLLOW-UP

Of note, this protocol was compiled within a medical model, in that it contains details only relevant to clinical care (examinations and investigations). References to providing support, information and emotional care to the women were omitted at this stage because the protocol served as a guideline for *safe* clinical practice rather than optimum holistic practice. I was reluctant to include details pertaining to emotional and informational care because this may have influenced the 'natural' behaviour of the doctors or myself in the clinic. Instead it was agreed by all team members that a clinical protocol should be followed but the context of delivery of that care (the exact content of the discussion and how we communicated and answered questions) would be left to the judgement of the professional in the consultation at that time.

8.4 Training and learning the skills

A period of six months training occurred during which time I shadowed senior doctors from medical and surgical teams on the breast unit and documented the numbers of women seen, the nature of their clinical concerns and the outcomes. Initially techniques for examination were demonstrated by the doctor and then practised myself with the woman's consent. Later I conducted the initial examination and presented the findings to the training doctor who then checked for accuracy and conferment. Towards the end of the training period the hospital introduced training tools for nurses extending their remit of practice called Role Development Profiles (RDP). These are structured packs that enable the 'student' to work through acquisition of knowledge, skills and theory in a formalised, documented but flexible way. It involves some core information on extending the scope of individual practice and some customised sections referring to the knowledge and skills required for the extended role, as well as forms documenting assessment and evidence of attainment. I therefore compiled a Role Development Profile (Appendix J) for breast cancer follow-up consultations and examinations and completed all the relevant paperwork to demonstrate completion of training, appropriate mentor supervision, fulfilment of objectives and 'permission' to perform this extended role from nursing management. The knowledge and skills identified as essential to this extended role were agreed by a working party of three medical consultants from the breast unit (one oncologist and two surgeons), two specialist breast care nurses, and a practice development nurse and are presented in Tables 8.1 and 8.2.

Table 8.1 Essential Knowledge Areas for Undertaking Breast Cancer Follow-up

1) The normal anatomy and physiology of the breast, chest wall and axilla
2) The pathogenesis and natural history of breast cancer
3) Principles of examination of the natural breast, a reconstructed breast, the chest wall, axilla and regional lymph nodes in the context of follow-up consultations
4) Differences between a normal, untreated breast and axilla versus a treated area
5) Treatment modalities and aims of management of early breast cancer including:
   ☐ Surgical treatment options (indications, complications and after care)
   ☐ Reconstruction techniques (complications and after care)
   ☐ Medical treatment modalities (chemotherapy, radiotherapy, endocrine therapy) including rationale for use, duration, indications, complications and short and long term side effects
6) Pathological variables and their prognostic significance
7) Patterns of presentation of local recurrence and primary target sites for metastatic breast cancer
8) Relevant symptamology with respect to possible metastatic disease
9) Clinical detection and appropriate investigation of new presenting symptoms to identify local and distant metastatic disease
10) Indications for referral to the medical team
11) Treatment modalities and aims of management of advanced breast cancer
12) Early and late complications of loco regional and systemic treatment of breast cancer including:
   ☐ Strategies for the management of treatment induced symptoms (e.g. hot flushes, vaginal dryness, skin and hair changes, erythema, seroma, lymphoedema, amenorrhea, chronic pain)
   ☐ Appropriateness of the use of hormone therapy following the diagnosis and treatment of breast cancer
13) Local protocols for follow-up surveillance and screening imaging, including frequency, duration and content
14) Accountability with regard to documentation of the follow-up consultation, including correspondence to the General Practitioner
15) Key issues relevant to survivorship following breast cancer (e.g. emotional needs, altered body image and related concerns, altered fertility, significance of family history) and appropriate psychological care of the individual
16) Professional and legal implications of conducting routine follow-up consultations and examinations for people who have completed treatment for breast cancer

Table 8.2: Essential Skills for Undertaking Breast Cancer Follow-up

1) Take a relevant clinical history
2) Interpret the relevance of the person's medical history with regards to breast cancer (including prognostic implications)
3) Conduct clinical examination of the normal breast, the post treatment breast and the reconstructed breast
4) Recognise clinical variations between a treated and untreated breast and axilla
5) Interpret and assess the relevance of symptoms reported in the follow-up consultation
6) Clinically detect potential local recurrence in the breast or axilla
7) Recognise the signs and symptoms of potential distant metastatic breast cancer
8) Explain the selection of and process of investigations for the detection of metastatic disease to the individual
9) Initiate referrals (as appropriate) to medical staff and other members of the multidisciplinary team for specialist intervention (including psychological care)
10) Interpret and explain the relevance of the person's family history of breast cancer
11) Provide the individual with appropriate emotional support in response to their needs
12) Recognise expected physiological changes in keeping with breast cancer treatment
13) Recognise and act on complications of treatment (short and long term)
14) Educate and provide accurate advice and information to people
15) Correctly and accurately complete documentation, including dictation of a letter to the General Practitioner (with appropriate terminology and content)

When the clinic initially commenced nurses working in the hospital where the study took place were not able to sign request forms for ordering radiological investigations such as annual mammograms. This illustrates the traditional subordination that nurses have to doctors because of differences in the tasks which each have the authority to undertake. In many ways doctors demonstrate dominance by choosing (or not) to confer authority (and provide the training) to undertake such tasks. Nurses, meanwhile, demonstrate deference waiting for such authority to be bestowed (Davies 2003).

Not being able to order tests posed a difficulty in that a doctor had to be found to complete the form, but had not then examined the woman themselves and was not privy to the relevant clinical details. Therefore a Role Development Profile was completed for ordering diagnostic investigations (see Appendix K). Authority to order routine diagnostic investigations was given following successful completion of the RDP and attendance at a study day, both of which were assessed by clinical leaders of the radiation protection and diagnostic radiology departments.

Field notes kept during the period of training capture my feelings during this training time and recount daunting but enjoyable experiences.

> *It's weird to feel like a novice again. I feel nervous with the registrar watching me and self conscious.* Page 3
>
> *A great clinic today. Really enjoyable. Found two new lumps correctly, one quite deep in the axilla, that the registrar had trouble locating. A great boost to my confidence.* Page 6
>
> *It is quite awkward learning whilst physically touching breasts. I am not used to hands on practice anymore and it feels quite invasive, especially as they* [the women] *are letting me train on them and putting up with being examined twice.* Page 5
>
> *It makes such a difference being able to fill in my own mammo forms. It saves time and I don't have to run to another room to find a doctor to do it, but it also makes me feel more credible because I can sort out everything for the patient there and then.* Page 8

8.5 Establishing the practicalities of the nurse-led clinic

The planning of the practical logistics of the nurse-led clinic was held in conjunction with the nurse manager of the Outpatients Department. It was decided that the clinic would be based with Outpatients in order to facilitate easy access to the notes, consulting rooms and the medical team. The clinic was set up to run on a Tuesday afternoon alongside an existing breast cancer follow-up clinic run by one of the consultant surgeons and his team. An appointment template was set up that allowed 15 consultation slots between 2.10pm and 4.30pm at ten-minute intervals. To prevent non-trial participants being booked in error or participants being given appointments during the nurse's annual leave, only I had access to making bookings for the clinic. Unfortunately, reliance on only one nurse meant people had to be cancelled and rebooked during unavoidable absence such as sickness, although this actually happened only once during the two years that the clinic ran.

I was responsible for dictating a clinic letter to summarise the consultation, one copy of which is stored in the clinical notes and one is forwarded to the General Practitioner. The secretary attached to the consultant surgeon's clinic running alongside the nurse-led clinic assumed responsibility for typing up these dictations. As the women were accessed from the medical clinic, no extra workload was encountered for the secretary, that is the number of women seen overall was not altered with the instigation of the trial. Completed letters were sent to me via the internal mail service for checking and signing and were then posted out or filed in the notes accordingly by the same secretary.

Within the existing system, if a doctor in the clinic ordered an investigation, the hard copy of the results were sent to the relevant secretary who would then show them to any doctor from that clinic so that they could be communicated to the woman, recorded in the notes and acted upon if necessary. However, for the women I saw, I chose to keep my own record of all investigations ordered so that I became personally responsible for checking the results. Results were easily accessible, as all such clinical details are available by password access on the hospital clinical information system. Adoption of this approach meant that all women seen by me retained their contact with me and were not exposed to medical input routinely, for example for test results, as this would have enabled them to make comparisons between health professionals, which may, in turn, have influenced their questionnaire entries. Although it did not always go so smoothly.

> *Team communication is frustrating. A woman I saw had her bone scan results come back showing wide spread disease. The registrar called her back to clinic early and saw her without even telling me anything about it, even though she could see I had dictated the last clinic letter.* Page 7

8.6 Doing it for real

I was struck by the differences between the roles of the traditional clinical nurse specialist (CNS) and the extended role within the nurse-led follow-up clinic. Nearly fifteen years experience as a nurse specialist in breast care and eight years within this breast unit, had resulted in me being established as someone with vast knowledge of this client group and someone that both doctors and nurses approached with questions and for advice pertaining to people with breast cancer. However the nurse-led clinic role felt very different in several ways. Firstly there was a loss of confidence in my ability and secondly a much greater feeling of isolation. As the senior clinical nurse specialist with seven breast unit nurse specialist colleagues there existed a notable team approach to sharing work and supporting each other with difficult or complex cases. In the clinic no such team existed at first and, unable to slot easily in to either the team of doctors, or the outpatient staff nurses, there was an unmistakable feeling of not quite fitting in. However over time the doctors became much more accepting and included me in discussions about women and the overall running of the clinic.

Similarly, both of these groups had difficulty in relating to the new role as well. The doctors would initially ask for input pertaining to the clinical nurse specialist function, such as fitting a breast prosthesis, and this was simply not feasible with several women waiting to be seen. On most occasions another clinical nurse specialist could be paged to attend instead but in their absence it was very pressured having to effectively wear both hats and provide two types of service. My field notes capture the frustration.

> *It is hard juggling the two hats of a researcher and a CNS. It seems the latter role often takes priority down in outpatients. Women stop me in the waiting area as a CNS, and ask if they can seem me there and then, which is very difficult if I have a queue of four or five nurse-led clinic attendees waiting as well. The doctors are the same and just expect me to be free when they want to ask me something.* Page 8

> *I realise how reliant on* [name of CNS colleague] *being there as well. She was off sick today which meant there was no CNS to cover the clinic. Although the*

> *doctors convey support for the nurse-led clinic, this soon changed when no one answered the bleep. I have been juggling women with both hats on all afternoon, rushing to see someone on the ward if there is the slightest gap between my clinic appointments. It feels very unfair, it is 7.25pm and I am exhausted.* Page 6

Interestingly, this echoes the sentiments of the doctors who stated that they rely on the presence of the nurse specialist in clinic. This reflects that upon adopting the medical role of providing follow-up consultations, I began experiencing some of the same frustrations as the doctors. Reflecting back I can see that role tension was probably inevitable. As well as fulfilling the role of a nurse specialist, and a researcher, I was also trying to replicate a medical model of follow-up that focused on a clinical examination rather than on psychosocial care, which is a central tenet of the nurse specialist role. It is interesting how by adopting the traditional model of medical follow-up I quickly became pressured in to assuming a distance akin to the doctors and could have been equally at risk of failing to meet emotional needs of women because of this pressure.

> *I saw a very sad woman today. Her husband died recently and she is lonely and frightened. I wanted to spend time with her and arrange to see her again, but the pressure of people waiting to be seen and the fact that protocol states she doesn't need to be seen again for 3 months meant I sent her away feeling I had not done all I could. I felt fed up and guilty about this all afternoon and my service feels like a token in the clinic, but almost never like that in my CNS role* Page 9

Davies (2003) asserts that an important attribute of nursing is caring, which includes giving comfort, showing concern and making emotional contact. Interestingly these might also be considered feminine traits, whilst medicine exhibits more masculine traits such as technical proficiency, rationality and objectivity (Davies 2003). Thus it is feasible that by consciously choosing to adopt the medical model of care delivery in this setting (one of examination and checking for the presence of new disease) my caring (nursing) qualities were challenged and sometimes subjugated to the medical tasks. Other authors have identified similar themes and the possible tensions arising from the caring ethos of nursing versus the curing ethos of medicine (Maclean 1974, Gamarnikow 1978). Interestingly, I had witnessed doctors sometimes failing to attend to the caring component, particularly on ward rounds, in my nurse specialist role. Having exhibited behaviour such as discussing an individual's operation in front of them but without including them, I would adopt an advocacy role and would effectively use my caring skills to 'clean up' after the doctors had left by attending to the woman's emotional and informational needs. Thus these skills were inherent in my practice prior to undertaking the extended role of follow-up provision and in spite of sometimes being compromised, remained apparent in my nurse-led care.

> [Name of woman] *clearly doesn't care much about the cancer side of the visit as such. We spent the whole time talking about her husband who has ca oesophagus. She just needed to ask me things and talk about it. I was thinking is this right and relevant for a breast cancer follow-up check, but on her way out she said it had been the most useful and helpful half hour she had spent in months and I knew then that I had been a good nurse even if we had digressed!* Page 11

> [In response to the question what was best about the clinic] *Seeing* [name of nurse]. *As soon as I walk in I feel better. Her smile, her calmness, knowing she cares about me and will look after me. All wonderful.* Page 7

Further difficulties arose from the attitude of the staff nurses in outpatient clinics. Despite explaining the new role on numerous occasions, they were largely unable to make the distinction between it and the nurse specialist role. This manifested itself most commonly with finding a room for me in which to see women. The nurses always chose to give the doctors priority for the consultation rooms and would even interrupt a nurse-led consultation to attempt to secure the room back again for the doctor's use. This illustrates an interesting power play because in this case it was other nurses who denied me access to rooms and thus rendered me powerless (or certainly restricted) but perhaps this resulted in their deference to doctors.

> *Although the clinic is just accepted by the women and the docs, the other nurses seem to miss the point. Although I have explained, several times now, they often ask me what exactly I am doing with these women and why.* Page 5

> *I am definitely not seen as important as the doctors, even though I am seeing exactly the same cohort of patients, at the same time for the same reasons! I have to battle for a clinic room every week and they keep offering me the information room which has sofas in it, even though I have explained this is inappropriate for a clinical examination.* Page 4

> *I used a room allocated to the SHO* [senior house office] *today because he was late and hadn't arrived. But then when he came, they kept knocking on the door and asking me whether I would be much longer!* Page 7

I noticed an interesting change in my use of the space once in the room. Perhaps as a result of leading the consultation, I always sat down to talk to the women after the clinical examination. In my nurse specialist role the doctor commonly led the consultation, choosing when to include me in the discussion. If they had taken the last remaining chair I would inevitably stand over the person whilst talking to them. Davies (2003) refers to this as a form of dominance, in that I was dominated by the doctors and knew my place in the hierarchy but then asserted myself (albeit uncomfortably) over the women by standing over them. Davies (2003) asserts that by sitting down, I placed myself on an equal footing with the women and diminished size and dominant posturing. I was struck by how a hierarchical relationship with the doctors could affect my behaviour to the women in this way and how the absence of that hierarchy (namely me taking charge of the consultation in follow-up) prevented this behaviour on my part.

Another notable difference in the two roles revolved around the level of responsibility accorded to each. Whereas the clinical nurse specialist is responsible for responding to questions and reacting appropriately to symptoms reported, there is not a direct responsibility for the safety of each individual. Within the clinic this had changed because of the possibility of finding new disease with each examination. The potential to give someone the all clear or to tell them of a suspected finding translated as having enormous influence over their emotional well being and equated far more with the notion of having 'their life in your hands'. This was an interesting and important distinction for me between the medical and nursing roles and gave insight to possible stresses that doctors carry differently to nurses by the virtue of this responsibility for deciding on medical care.

> *The women are hanging on my every word as I examine. I have noticed they watch your face intently as you touch them. I am sure they are looking for any non-verbals that will give away your impressions. I find myself avoiding eye contact if I think I have felt something until I am sure and ready to discuss it with them.* Page 7

> *I knew as soon as she took off her bra that she had local recurrence, quite extensive as well. I put off telling her while I performed full examination, knowing that she would be devastated by the news. It is quite hard having to tell her myself about what* ***I*** *have found. Normally I just pick up the pieces after the doctors tell people what* ***they*** *have found.* Page 8

> *One thing I have really noticed is you can't use the old line, what did the doctors tell you. This was always useful to find out how much they knew, to buy some time and to check out you are coming from the same place.* Page 6

Being accorded the authority to order diagnostic investigations greatly enhanced autonomy and independent working. However the inability to prescribe medications caused further frustrations and sometimes slowed down the clinic. Examples of this included when the woman asked for more Tamoxifen, or when drugs such as antibiotics were required.

> *I saw someone today who clearly had a fungal infection in the fold of both breasts. I knew exactly what it was and what to treat it with but I still had to make her wait for 25 minutes before* [name of consultant surgeon] *saw her, diagnosed what I had said and then wrote her a prescription. After all that I dictated the clinic letter and explained the condition and the treatment to her anyway.* Page 10

Providing follow-up consultations was a unique experience for me and raised interesting issues as to the nature of extended roles within advanced nursing practice.

One of these was the sense of vulnerability that things could go wrong. Much more so than in specialist nursing there was an acute awareness of the possible litigation involved with this work. This made me much more empathetic to the notion of ordering unnecessary investigations to 'cover myself' that the doctors admitted to during the focus group. I had concerns and a lack of confidence early on as to the safety of clinical examination and whether important findings would be missed due to the novelty of the role for the post holder. This is epitomised in the case history below.

> *Emily had been to see me for her three monthly checks up as usual and I had not detected any abnormalities. Just two weeks later, whilst I was on a day off she called my CNS colleague and reported noticing blood in her bra cup. My colleague arranged for her to come to the surgical clinic where she was seen by a visiting registrar from Malaysia. This doctor detected two 2cms lumps, one in each breast that she deemed highly suspicious and proceeded to take nine core biopsies of the two areas. When I heard about it after the weekend I was devastated. I couldn't imagine how I could have missed not just one moderately sized lump, but two. I immediately went to see the Consultant surgeon to talk it through and share my concerns as well as to tell him my confidence was shattered! He was great. We talked it all through, exactly what I had done. Unbeknown to me at that time he already had concerns about the practice of the registrar and the number of 'false alarms' she had had. He advised me to wait for the biopsy results. Three days later they returned all clear, all nine of them, and showed fibrous tissue only. I rushed to see the consultant with the results in hand. I then called Emily to give her the good news. I was nervous that she would have lost all confidence in me. She was so relieved when I told her and said she had not slept all weekend. I asked her if she was still happy to continue seeing me. She said she never wanted to see another doctor! I arranged for her to see the consultant with me when the bruising had gone down, really to reassure all of us that there was nothing to find and then I slept the best I had done for a week too that night!*

My experience leads me to believe that knowledge about aspects of litigation and protection, such as vicarious liability, are crucial for nurses extending their role.

Nurses are all too often ignorant about the differences between personal, professional and criminal culpability and it was not until I had had the scare described above that I realised the necessity to understand litigation issues and ensure that I was practising appropriately.

Interestingly, I found it difficult performing clinical examinations whilst not wearing a uniform. As a CNS I had worn my own clothes for over ten years but did not perform ‘hands on’ clinical care within this role. Perhaps it was reflective of my need to in some way separate the aspects of listening and providing support with touching breasts, but I can recall awkwardness at first and wondering if a uniform would be appropriate. My medical colleagues largely chose not to wear white coats and so were also examining whilst in their own clothes. When I asked them if they were comfortable with this any reluctance was only based on cleanliness and infection control, for example when managing open wounds. There was no other dilemma on their part.

Another key issue was the necessity for me to have a huge breadth and depth of breast cancer knowledge. I documented many areas that women asked questions about ranging from treatments to rehabilitation, lifestyle changes to insurance, prognosis to genetics. I have grave doubts as to whether I could have performed so highly and with so much patient satisfaction if I did not command this specific expert knowledge. For me this highlights the crucial importance of site specific knowledge. I am aware of a former theatre nurse who is now a nurse practitioner in breast cancer care providing follow-up care. She is a competent, ‘hands on’ clinician but admits difficulties in fielding the range of questions she faces without a sound background in this clinical area, and more frequently need to defer questions, for example about hormone replacement therapy, to a medical colleague.

An enormous dilemma for me revolved around how necessary it was to keep to the specific focus of the breast cancer follow-up consultation if this was not actually the key issue for the woman at that time. I encountered several examples of consultations when the woman needed time, support and information in areas quite removed from breast cancer care, but certainly related to nursing care and input. One woman’s husband was in the terminal stages of cancer of the oesophagus and she wanted to discuss his treatment and plans to be admitted to a hospice. Although this clearly encompassed oncology nursing care, it is arguably not relevant for discussion in a breast cancer follow-up clinic. Another example was even less clear cut, as it related to a woman who was suffering domestic abuse by her mentally ill son. She arrived to clinic one day quite literally covered in bruises and was too tender for me to be able to examine her properly. Her profound distress appealed to my nursing values and we spoke at length about the difficulties of her situation and possible interventions that she could pursue. I was very cognisant of the fact that the content had completely drifted from breast cancer surveillance, yet also knew that we had had a meaningful and highly valuable consultation for which she expressed gratitude with a hand written thank you letter the next day.

A short while after completing the data collection for the randomised study, I left the hospital in which it had taken place. All of the participants had seen me for a minimum of one year by then and the earliest recruits had seen me for over two years. I found it surprisingly harder to end these relationships than those with people I had encountered in my traditional CNS role. The loss somehow seemed greater with the clinic patients. I reflected if this was due to the quite intense relationship we had had on a one-to-one basis. In the traditional role some women would be more dependent than others but would still have input from other members of the health care team, such as doctors and my fellow specialist nurses. Within the nurse-led clinic no other staff were involved and the regular certainty of appointments led to familiarity and closeness on both sides. I felt guilty at ending the relationship knowing I would be placing them back in the medical led follow-up clinics and that the things that they had come to value from me, such as continuity, would be lost.

In summary, this work has exposed the multiple difficulties with implementing nurse-led follow-up. These are as follows:

- Overcoming professional practice boundaries, such as being able to order mammograms and routine prescribing of items such as Tamoxifen.
- Poor nursing support for the role in terms of being given fair access to rooms, outpatient clinic nursing staff and medical notes clerks.

- The difficulties associated with developing and demonstrating clinical credibility, particularly when no accredited training course exists for the extended task in question.

- Medico legal implications of extended role and the necessity to ensure appropriate cover but also knowledge of relevant legalities such as vicarious liability.

- Adequate numbers of staff trained to do the extended role is crucial because otherwise the system will not support the post holder taking holiday or going off sick.

- There remains the question of remuneration for nurses in an extended role. Arguably they should be rewarded for acquiring new skills but performance of tasks alone does not a superior nurse make.

8.7 Summary

The ease with which the nurse-led clinic ran did improve over time. I gained in confidence, the doctors were accepting and appreciative of the contribution it made. Overall the experience was enormously rewarding and satisfying and there was a very real sense of disappointment when I left my post at the hospital, thus bringing the nurse input into breast cancer follow-up consultations to a close.

The following section contains the data arising from the randomised controlled trial. General patient characteristics at randomisation are presented, followed by statistical and descriptive data for each of the two questionnaires in turn.

Chapter 9. PHASE THREE: RANDOMISED CONTROLLED TRIAL COMPARING NURSE-LED AND MEDICAL FOLLOW-UP RESEARCH DESIGN

9.1 Introduction

The third study evaluated a nurse-led model of breast cancer follow-up using a randomised controlled clinical trial approach. Analysis of the data from the two explorative studies in phase one identified areas that a specialist nurse might develop or improve upon. The purpose was to evaluate the outcomes of care for women attending nurse-led follow-up compared to conventional medical care in terms of quality of life and satisfaction, as reported by the women. Specifically of interest were differences between the health professionals with respect to addressing the gaps and meeting the needs exposed in the phase one studies. Assumptions that nursing may provide benefits need to be formally tested. Data were collected using postal questionnaires and the findings from this study enabled suggestions to be made for improving care in this clinical setting, crafting a new model and ensuring the needs of people attending breast cancer follow-up are met more adequately in the future.

The research design is described next in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al 2001) and as such includes information pertaining to the null hypothesis, aims and objectives, the study population with inclusion and exclusion criteria, sample size estimations, randomization allocation, outcome measures, reliability and validity and a trial profile. Information pertaining to the effects of the intervention, measures of precision and descriptive and inferential statistics are presented in the following chapter.

9.2 Null hypothesis

A hypothesis is a prediction of the relationship between two or more variables and hypotheses are framed in terms of their being no relationship between the variables (Devane et al 2004). Thus a null hypothesis (H_0) assumes this lack of relationship unless the trial generates evidence to the contrary.

The null hypothesis (H_0) for this trial was: *'there is no difference in the levels of satisfaction, as reported by women, between those receiving follow-up provided by a nurse versus those receiving follow-up provided by a doctor'.*

9.3 Aims

The aims of the study were:

i) To ascertain the disadvantages to individual quality of life and satisfaction with care resulting from nurse-led or traditional medical breast cancer follow-up

ii) To ascertain the benefits to individual quality of life and satisfaction with care resulting from nurse-led or traditional medical breast cancer follow-up

9.4 Objectives

The objectives of the study were:

i) to compare the outcomes of provision of breast cancer follow-up by doctors and a specialist nurse

ii) to further identify subsequent care needs after treatment is over for those that remain free of further disease

iii) to identify alternative models of breast cancer follow-up care

9.5 Randomised Controlled Trial

In order to meet the objective of comparing outcomes of care given by two different professional groups a randomised controlled trial was used. The purpose was to ascertain the benefits and disadvantages to individual quality of life and satisfaction with care resulting from nurse-led (intervention) or traditional medical (control) breast cancer follow-up, thus comparing the outcomes of provision of breast cancer follow-up by the different health professionals.

A randomised controlled trial (RCT) is a method employed in experimental research in which an intervention is introduced to the subjects and its effects noted, thus enabling comparison of subject behaviours and beliefs under the various conditions being investigated. Randomization is defined as the process of assigning some thing or someone (in this case the women) to a condition (in this case follow-up after breast cancer) in such a way that every person has an equal probability of being assigned to any particular condition (Polit et al 2003). By randomizing in this way, the two groups are likely to be identical to begin with, thus the only difference is the application of the intervention, (in this case exposure to nurse-led rather than conventional medical breast cancer follow-up). Random assignment removes the potential of bias (Kunz and Oxman 1998). This method serves to enhance theories of causation because in rigorously designed randomised controlled trials, it is highly likely that only the intervention can be responsible for the results. Causation can never be absolutely established as such but is inferred from repeated succession of findings (Pawson and Tilley 2004). Randomization can therefore be considered as perhaps the only method that attempts to control, outside of laboratory settings, all possible extraneous variables and thus are perhaps the best way to compare the effectiveness of different interventions (Altman 1996). The study involved women being randomised to traditional medical or nurse-led follow-up.

This meant both professionals providing the same clinical consultation according to protocol (see figure 8.2), so that any differences between the two interventions were as a result of differences between the attitudes, communication and approaches of the doctors and nurses, rather than the structure of the consultation per say. Eligible people were approached in person and by letter informing them of the nature of the study. The women were randomised at point of entry in to the study and allocation of consenting participants to either group was made by an independent randomisation service, the Randomisation Office, within the local Department of Epidemiology. In practice this involved me ringing the randomisation office with the name, hospital number and date of birth of the woman who had agreed to be randomised. I was then given a recruit number of that individual and told if she had been randomly allocated to see a doctor or specialist nurse for follow-up. Concealing random allocation in this way prevents subversion and bias towards either group by the investigator or the participants (Kunz and Oxman 1998).

In randomised studies it is important to ensure that the research setting for each group is constant and that conditions are the same for all participants (Carter 1991). In this study the nurse-led clinic was set up alongside the medical clinic. Both ran in the same suite of rooms, within the same outpatient department on the same afternoon and both allocated women ten minute appointments. However, initially more time was afforded to the nurse because a full complement of patients was not achieved straight away as recruitment was slower at the commencement of the study. The control group received medical care from one of a group of 6 doctors, 1 consultant, 1 visiting consultant, 3 specialist registrars or 1 senior house officer. Close proximity of the nurse-led clinic to the medical clinic allowed exchange of questions and information and also ensured the doctors were close by if anything was required by the nurse which they were prohibited in doing, such as prescribing Tamoxifen. It also ensured prompt referral back to the medical team if evidence of recurrent or systemic disease was discovered.

A potential weakness of randomised controlled trials are that they result in conflict between the goals of therapy and the goals of experimentation, and between the researcher's role of scientific investigator versus health care professional (Schafer 1982). The researcher is subject to conflict of interests if the need to recruit adequate numbers of participants competes with their ability to ensure the well being of all of their patients. This is further compounded because the design of randomised studies precludes them from permitting any individualised tailoring of treatment protocols without sacrificing scientific rigour (Schafer 1982). Similarly the randomised selection of the intervention (especially if it is a drug treatment) may discourage participants entering the trial because they are fearful that one may be superior. They may also be reluctant to accept treatment that the doctor has not personally chosen and expressed a preference for as the best for them, given all of their personal circumstances at that time (Polit et al 2003). Another criticism of this method is that randomised trials produce evidence at a population level, rather than at an individual level, which might be acceptable to testing new medication, but is less relevant to capturing experiences of health care (Dingwall et al 1998). As these authors go on to say, a randomised controlled trial will not distinguish between equity (fairness of access to the service) and humanity (how people are treated). A service could be efficient and equitable but its users may perceive they have been treated badly. For example, women receiving breast cancer follow-up may perceive they have been seen on time and thoroughly examined, but that little attention was given to their emotional and informational concerns, leading to dissatisfaction with the service overall.

9.6 Population and Sampling

Women for this phase of the study were recruited from surgical clinics, under the lead of one consultant breast surgeon at the London branch of the NHS Trust hosting the study. People were considered eligible for the study according to pre-set inclusion criteria as follows:

- they had received all treatment for breast cancer at the NHS Trust hosting the study and were currently completing their final adjuvant therapy prior to commencing routine follow-up care or were at their first post treatment visit;
- they had had treatment for Stage I or II [see appendix L for explanation of breast cancer stages) breast cancer at initial diagnosis
- they were asymptomatic at the time of randomisation (to ensure their follow-up is routine and not influenced by any present symptoms);
- they were not experiencing any adverse healing problems secondary to undergoing breast reconstruction;
- they were under the care of one specified consultant breast surgeon;
- they were able to understand and read English (in order to be able to complete the questionnaires successfully).

Exclusion criteria included:

- they had had one or more treatments at another hospital
- they had already attended for two or more routine follow-up outpatient appointments
- they had Stage III or IV breast cancer
- they had reported symptoms and/or were already undergoing investigation for recurrent disease
- they had ongoing problems with healing from surgery or required further breast reconstructive surgery

- they were under the care of another consultant
- they were unable to understand and read English sufficiently to complete the questionnaires

Men were not excluded but none appeared in the sample. The above criteria were more specific than those set for the qualitative interviews described in chapter 6 to ensure clinical appropriateness for nurse-led follow-up. As the interviews involved eliciting people's views on breast cancer follow-up, the clinical stage of the disease at diagnosis was irrelevant, as long as they remained well at the time of interview. However in the randomised trial, clinical problems such as unhealed surgical sites would have theoretically precluded nurse-led care because of their practice limitations such as not being able to prescribe antibiotics in the presence of infection.

The women were selected via the clinic lists using continuous simple random sampling. This is a form of probability sampling, in which each member of the population has an equal chance of being selected (Polit et al 2003, Hedges 2004). I established a sampling frame, that is a list of the elements of the population from which the sample was drawn. In this case the list consisted of women meeting the eligibility criteria stated above. All outpatient clinic lists were printed off and worked through during the period of recruitment and each attendee was looked up on the hospital computerised notes system to check if they met the eligibility criteria. Thereafter it is believed that all eligible women were approached to take part in the study. In this way researcher bias is removed and the sample can be considered representative (Field and Morse 1992), in that all eligible patients have an equal opportunity to take part. Eligible women were posted a letter explaining the study and a consent form, along with a stamped return envelope (see appendix M).

Using data from the qualitative interviews with women, a statistician calculated the sample size required to achieve statistical significance, that is for me to look for a difference between the group exposed to the input of nurse-led care and the other group not exposed to nurse-led follow-up. Randomised trials have to be large enough to ensure that true differences between the interventions are not overwhelmed by chance effects of the allocation process (Devane et al 2004). When the phrase "statistical significance" is used, it means the difference is not likely to be due to chance. The ability to statistically detect a difference when the difference truly exists (that is, not due to chance) is called the power of the test.

I estimated how large a difference between the 2 groups would be observed, both from data achieved in the qualitative interviews with women in phase one, and from my experience as a specialist nurse (knowing I could provide continuity and had the skills to broach complex emotional concerns). From the qualitative interviews in phase one, 92% of women felt that continuity of the professional they saw in the follow-up clinic was unacceptable. This was deemed inordinately high, thus for the trial it was decided that it would be desirable to measure a reduction to 50% for this key endpoint. In theory, as the only nurse in the trial, I should have achieved 100% continuity thus those deeming it unacceptable could have been zero. However, such an expected difference was too large and would have resulted in a very small sample size to demonstrate it. In addition, most nurse-led follow-up would realistically be provided by a team of nurses, thereby suggesting improvements in continuity over doctors could be expected, but would not be as great as those that might be seen with just one nurse. I wanted to attempt to demonstrate that a reduction in those deeming continuity was unacceptable to 50% would correlate with significantly improved satisfaction. In order to reliably detect a fall in the proportion who felt that continuity of the professional they saw in the follow-up clinic was unacceptable from 92% to 50% (reaching significance at the 5% level with a 'best' power of 90%) 54 women in total would need to be randomised (27 in each group).

For a second important endpoint, 79% of women in the qualitative interviews felt that they were unable to raise emotional concerns in the follow-up clinic. I wanted to attempt to demonstrate that a reduction in those unable to raise emotional concerns to 40% would correlate with significantly improved satisfaction. Using the sample size estimate of 54 women obtained for the unacceptable continuity endpoint (27 in each group), this would provide 85% power in order to detect a reduction in the proportion who felt that they were unable to raise emotional concerns in the follow-up clinic from 79% to 40% (at the 5% significance level). This was considered a reasonable improvement to determine significant changes to emotional care arising from nurse-led follow-up. I had a cut off date for searching clinics for possible recruits and had aimed to reach 70 participants by this time (exceeding 54 to allow for drop-outs) but in fact reached 80 recruits (40 in each randomisation arm) at the close and this was deemed sufficient numbers for meaningful analysis. When expected differences are large, it does not take a particularly large sample to ensure that the differences will actually be revealed in statistical analysis.

Randomisation took place over a period of 18 months during which time a total of 3129 women and 4 men were seen in the clinics from which eligible participants were identified and of these 156 women and no men met the eligibility criteria. Most women were not eligible either because they had already been attending for follow-up for longer periods of time or because they had higher stage disease. Others had ongoing surgical problems or required medical intervention at follow-up as a result of being recruited into other clinical trials (usually drug therapy trials), the protocols of which dictated the follow-up schedule. Of these 156 eligible women, 40 did not reply to the invitation letter and 36 refused to participate. This represented an accrual of 53% of eligible women. Of the 36 women refusing to be randomised, 23 cited reasons for refusal. The reasons for refusal are presented in Table 9.1 below. The predominant reason related to concerns about the safety of being examined by a nurse and the belief that they would be in 'safer hands' with a doctor. Some questioned whether the nurse would be adequately trained and maintained that clinical examination was the exclusive remit of a doctor. Another reason for refusal was practical in that a few women felt that the questionnaires would be too time consuming within their busy lives. Finally, a few women mentioned that they had already taken part in more than one clinical trial relating to their breast cancer diagnosis and treatment and felt that they had had enough of questionnaires at that time. The remaining 80 patients were randomly allocated to receive either nurse-led (n = 40) or conventional medical follow-up (n=40).

Table 9.1: Reasons for Refusals to Participate

Reason for Refusal	No. of patients (n=23) (%)
Prefer to be examined by a doctor	9 (39)
Concerns about competence of specialist nurse	6 (26)
Too busy, lack of time	5 (22)
Over involvement in clinical trials & data collection	3 (13)

9.7 Methods of Data Collection

Two questionnaires were used in the randomised controlled trial. The first was chosen to capture the subsequent care needs after treatment is over for those women that remain free of further disease and to explore further their possible ongoing needs and preferences. The second was chosen to capture the relative merits of the two health care professionals providing follow-up in terms of how satisfied the women were with each (see also Table 9.2).

Table 9.2: Outcome Measures of the questionnaires

Data Collection Tool	**Outcome Measures**
Functional Assessment of Cancer Therapy [Breast] (FACT-B)	1) Quality of life in relation to the multi-dimensional effects of breast cancer treatments
'Your Views of Follow-up Care'	1) Satisfaction with health professional 2) Continuity of care 3) Ability to raise emotional and informational needs within the consultation

Both of these semi-structured questionnaires used contain mainly closed questions with fixed alternative replies. The purpose of using questions with such a high degree of structure is to ensure comparability of responses and to facilitate analysis (Polit et al 2003). Closed questions also ensure completion is quick and easy, even if the tool remains quite long. However in addition participants were given the opportunity to add comments throughout by use of free text spaces provided. Inclusion of some open-ended questions and free text boxes allows subjects the opportunity to express more detailed opinions and to communicate responses in their own words (Polit et al 2003, Moser and Kalton 2004). This is particularly useful if subjects are being invited to comment on personal experiences and feelings, although the amount and content of the information provided can vary considerably between respondents (Moser and Kalton 2004). Citing a range of alternatives within the responses helps to avoid leading the respondent. However a drawback is that answers may be forced into a category in which they do not really belong (Moser and Kalton 2004). Utilisation of a 'tick box' style means that questions are more likely to be completed because they are less laborious and time consuming for the respondent.

The advantages of both questionnaires included that neither was too long or detailed, thus facilitating manageable completion and avoidance of putting people off filling them out. Both had questions that were worded in simple, legible language, and avoided the use of vague or ambiguous terms as well as leading and presumptive questions (Moser and Kalton 2004). Finally, both had been previously piloted and tested, thus enhancing their validity and reliability.

The questionnaires were administered by post on the day of the follow-up appointment or the day after. Earlier plans to deliver the questionnaires to each subject by hand at the time of their attendance were abandoned because it was not feasible for the researcher to see each individual if they were not seen on time or if appointment of patients in each arm of the trial coincided. The postal questionnaires were personally addressed to improve response rates and encourage opening of the letters. The questionnaires were administered on recruitment to the study (baseline) and then at every three monthly routine outpatient follow-up visit for one year, resulting in five of each questionnaire per subject. A reminder letter (Appendix N) was sent each time to explain to the participants of the reason for continuing the data collection over several appointments.

General advantages of using self-administered questionnaires are firstly that they are less costly, in terms of resources and time, and are therefore more practical to administer to large numbers of participants. Secondly, they permit complete anonymity which is particularly relevant when asking participants to comment on the service provided by the researcher, their institution or colleagues because users may be reluctant to criticise services that they continue to rely on for their ongoing follow-up care. In the same way, questionnaires eliminate interviewer bias (Burnard and Morrison 1990, Polit et al 2003). Questionnaires collect data quickly and efficiently and are amenable to statistical analysis.

Weaknesses of questionnaires as a data collection method are that whilst they achieve anonymity, the researcher may have no personal contact with the subjects and cannot therefore probe in depth issues further or check understanding and clarify any ambiguity. (However in this study, the researcher did have access to the participants in the nurse-led arm and did therefore discuss general elements raised on the questionnaires during the routine follow-up consultation). Clarification may be crucial because of an underlying assumption that the respondents will attach the same meaning to each of the questions, interpret them in the same way and that this will also coincide with the meanings that the researcher intends from each question. However in reality this may not be so and questions may be misunderstood. Clearly the questionnaire must be suitable to collect the data necessary to test the hypothesis of the study and must include questions that have a direct bearing on the variables under study (Barker 1991). Further the respondents are restrained by closed questions in that there is a 'forced' choice of response. Finally, postal questionnaires rely on the recipients having a corresponding level of literacy skills and being fluent in the written language used (in this case English).

Postal questionnaires may achieve poor response rates because recruits are not motivated to complete them at home and take the trouble to return them (Barker 1991). They can also be subject to responder self selection bias, in that people return them because they have something particularly good or bad to say about their experiences, but are less likely to if they are indifferent or ambivalent about the study subject. To minimise these problems, stamped addressed envelopes were included, along with the reminder explanatory letter referred to earlier and patients were also verbally prompted to return them whilst attending each appointment.

9.7.1 Data Analysis

All of the data was entered into the computer by myself. To capture any errors made during this process a further 40% of the questionnaires were re-input by a secretary to ensure consistency of findings. A computerised statistical package, Statistical Package for the Social Sciences (SPSS) Version 11 was used for analysis of the questionnaires. This package enables tailored programming in which columns are labelled with each question in the order in which they appear on the questionnaire. The data comprising questionnaire responses is entered directly, moving along the columns through each question in turn. Values were applied to missing data (999) and not applicable questions (99). In addition the free text answers were subjected to descriptive statistics and an inductive analysis was carried out in order to identify predominant themes. This involved coding the data into categories according to the comments detailed by the participants. The use of an inductive approach on data enables the themes to be drawn from the participants' perspectives, rather than emphasizing the researcher's preconceived ideas. It was also thought to be useful to provide descriptive statistics of the themes generated and, therefore, the numbers of responses in each category were quantified. Coding is arguable never truly free of the values, assumptions and theoretical perspectives of the researchers, although applying statistical analysis can be said to add credibility to the data retrieved.

9.7.2 Functional Assessment of Cancer Therapy [Breast] Questionnaire

The Functional Assessment of Cancer Therapy [Breast] (FACT-B) (see Appendix P) is one of a series of questionnaires developed 10 years ago with the aim of capturing multi-dimensional quality of life issues specific to a variety of different cancers, including breast cancer. It consists of five sections highly relevant to patient's values. These are physical well-being, social/family well-being, emotional well-being, functional well-being and additional (breast specific) concerns. Respondents are asked to indicate how true individual statements are, by circling fixed alternative replies ranging from 'not at all' to 'very much'. This tool was chosen because of its explicit pertinence to quality of life issues relevant to breast cancer treatments and rehabilitation. Its multi-dimensional design ensures coverage of a range of subject areas that are specifically relevant to the needs of women *following* treatment for breast cancer. Examples include ongoing pain, swollen arm, fear of recurrence and weight gain. As an established tool, the FACT-B involved patient input in its question development, has been widely validated, is considered reliable and extensively tested, and demonstrates ease of administration, brevity and sensitivity to changes in clinical status over time (Brady et al 1997). This questionnaire was completed at five time points, baseline (pre randomisation), then at 3, 6, 9 and 12 months in to follow-up. The number of women completing FACT-B questionnaires at each time point is shown in table 9.3. Overall excellent response rates were achieved with 372 out of a maximum of 400 questionnaires being returned (see also figure 9.1 for a summary).

Table 9.3 Number of FACT-B questionnaires available at each time point, according to randomised follow-up group

Months from randomisation	**Professional**		**Total (%)**
	Nurse (%)	**Doctor (%)**	
Baseline	40 (100)	40 (100)	80 (100)
3	38 (95)	38 (95)	76 (95)
6	35 (87.5)	39 (97.5)	74 (92.5)
9	37 (92.5)	35 (87.5)	72 (90)
12	36 (90)	34 (85)	70 (87.5)
Total	186	186	372

Reasons elicited for non-completion of the questionnaire during the earlier time points predominantly related to the health status of the individual at that time. For example, women complained of symptoms such as severe tiredness and hot flushes, and cited these as resulting in them feeling disinclined to complete the questionnaire. As time progressed the numbers of completed questionnaires decreased, and women less commonly cited reasons as to why they had failed to complete them. This was probably reflective of their repetition and the demands of completing them three monthly for a year. A few women commented that they had nothing more to add and felt that they had stated all of their thoughts and feelings at previous time points, thus negating the inclination to complete them again during the latter time points of the study. In addition the loss of some questionnaires occurred as a result of some women withdrawing from the study (all at different time points) (see table 9.4) due to, among other reasons, the discovery of recurrent, systemic disease. Altogether 5 women developed progressive disease during the course of the study, 3 of which were receiving nurse-led follow-up and 2 were being seen by doctors. All of these women were then seen by medical teams (usually oncologists, as oppose to surgeons) to undergo staging investigations and commencement of appropriate treatment. At the time of writing all but one of the women remained alive.

Table 9.4 Number of and reasons for withdrawal from the study after randomisation

Reason for Withdrawal	**Professional**		**TOTAL**
	Nurse	**Doctor**	
Underwent revision surgery to reconstruction	1	0	1
Developed ipsilateral skin recurrence	0	1	1
Developed contralateral new primary breast carcinoma	1	0	1
Developed bone metastases	2	1	3
Developed lung metastases	2	3	5
Withdrew to commence private health care	0	1	1
Withdrew by choice, questionnaires too tedious	0	1	1
Total *	6	7	13

* *Total reflects number of episodes, rather than number of women, as more than one participant developed metastatic disease at two sites simultaneously*

Method of Statistical Analysis

The FACT-B questionnaire was analysed according to the method recommended in the FACT-B scoring manual. Histograms were produced to check for skewed distribution of the subscale scores (Appendix Q). Subscale scores for each section of the questionnaire were obtained by totalling the scores for each item, after reversing the scores for any negatively phrased questions (by subtracting the individual item score from 4). Where at least 50% of the items for any particular subscale were completed, the subscale total was pro-rated by multiplying the sum of the subscale by the number of items in the subscale, and then dividing by the number of items completed as shown below.

Subscale score = (Sum of item scores) x (number of items in subscale) / (number of items answered)

Some subsections of the FACT-B also included a single item that asked how much that particular well-being scale affected the woman's quality of life (measured on a 5-point Likert scale from 1=not at all to 5=very much so). These scales were not re-scored before summarising, and so a high score indicates poorer quality of life.

The distributions of subscale scores and quality of life scales in the FACT-B Questionnaire were highly skewed. When plotting the scores, a bell-shaped curve indicates normal distribution. In normal distribution about 95% of the observations will lie within two standard deviations of its mean. A standard deviation is a measure of dispersion (Hedges 2004). However in general means and standard deviations are considered less representative for highly skewed distributions because the asymmetrical pattern of the distribution of responses leads to the results being influenced by minority extremes at each end of the distribution curve. Therefore the results were summarised using medians and interquartile ranges (IQR), rather than means and standard deviations. Consequently, the non-parametric Mann-Whitney test was used to compare distributions of subscale scores and quality of life scales between the two groups, as this is unaffected by the shape of the distribution.

In addition, to determining the differences in subset scores *between* each group, further analysis was carried out to investigate changes over time *within* each group, that is the trend from first observation at baseline to final observation at twelve months. This was done because differences at baseline were noted for the subset items physical well-being, physical well-being and quality of life, emotional well-being and additional concerns. Differences between the groups at baseline make subsequent differences in comparisons difficult to assess, thus in order to enable assessment of changes over time *within* each group, so that the impact of being seen by each professional would be apparent regardless of the starting points, further analysis was carried out.

As the data were skewed non-parametric methods of analysis are preferred. Changes in subscale scores from baseline to each time point were calculated, and summarised using medians and interquartile ranges (IQR). The Wilcoxon signed ranks test was used to test for change in scores from baseline to each time point within each randomised group. The Mann-Whitney test was used to compare distributions of change in scores between the randomised groups, separately for each time point. One problem with analysing each time point separately is that the issue of multiple significance testing arises. It would be preferable to carry out an overall test for trend in the scores across time, but there is no non-parametric equivalent of a trend test. Therefore, ignoring the skewed nature of the data, mean scores were compared over the 5 time points in an analysis of variance (ANOVA), for each randomised group separately. Trend in mean subscale scores was assessed in the ANOVA using the F test for trend. However, the ANOVA results should be interpreted with caution because of the highly skewed nature of the data. Graphs are also presented, showing median scores at each time point separately for women randomised to nurse or doctor-led follow-up. A cut-off of p=0.01 was used in these analyses to indicate statistical significance, as a large number of significance tests were carried out, and therefore there is an issue of multiple testing (i.e. increased likelihood of some results being significant by chance).

9.7.3 'Your Views of Follow-up Care' Questionnaire

The second questionnaire was entitled 'Your Views of Follow-up Care', adapted from other validated existing questionnaires (Wolf et al 1978, Thomas et al 1996, Faithfull 1999) and developed by in-house colleagues for a study evaluating nurse-led follow-up of patients with lung cancer (see Appendix R). Aimed at assessing service delivery, rather than quality of life per se, this questionnaire consists of sections on organisation of care, information and advice, personal experience of follow-up care and satisfaction with follow-up care. Respondents are asked to indicate responses to individual statements, by ticking fixed alternative replies ranging from 'strongly disagree' to 'strongly agree' and marking a line on one question containing a numerical measurable visual analogue scale. Both positive and negative statement are included to ensure the subject thinks about each response and avoid merely ticking the same fixed reply for every question. In addition, open-ended questions elicited what had been particularly good and bad about their care, satisfaction with frequency of visits, aspects that were missing and preference for any health care professional. Finally, some supplementary questions with fixed alternative replies and tick boxes were added to ensure coverage of key themes identified in phase one, such as having adequate time devoted to the consultation. This tool was chosen because of its previous use in the same research setting on patients undergoing follow-up after cancer treatment. Hence it had been subjected to piloting and subsequent amendments (Moore et al 2002) enhancing reliability and validity. This questionnaire was completed at five time points, 3, 6, 9, 12 and 15 months in to follow-up. No baseline (pre randomisation) was possible because the questionnaire evaluated perceptions of follow-up, which no participants had experienced at randomisation because they were recruited towards the end of their final treatment, before they commenced routine follow-up care. The number of women completing questionnaires at each time point is shown in table 9.5. Overall excellent response rates were achieved with 371 out of a maximum of 400 questionnaires being returned and reasons for non-responders and withdrawal are explained earlier in section 9.7.1 (see also figure 9.1 for a summary).

Table 9.5 Number of 'Your Views of Follow-up Care' questionnaires available at each time point, according to randomised follow-up group.

Months from randomisation	**Professional**		**TOTAL (%)**
	Nurse (%)	**Doctor (%)**	
3	40 (100)	40 (100)	80 (100)
6	37 (92.5)	38 (95)	75 (94)
9	34 (85)	39 (97.5)	73 (91)
12	38 (95)	35 (87.5)	73 (91)
15	38 (95)	34 (85)	70 (87.5)
Total	185	186	371

Method of Statistical Analysis

To analyse the 'Your Views of Follow-up Care' questionnaire, all of the questions were first re-coded from a scale of 1-5 to a scale of 0-4 by subtracting 1. For each item in each section a score of 0 was allocated to the responses *"strongly agree"* or *"completely satisfied"* ranging to a score of 4 for the responses *"strongly disagree"* or *"not at all satisfied"* respectively. A negative response to an individual question is defined using scores 3 and 4 (that is "disagree" or "strongly disagree") for positively phrased questions. For example 'My appointments or phone calls have been arranged to suit my convenience'. Conversely a negative response for negatively phrased questions is defined using categories 0 and 1 (“strongly agree” and “agree”). For example ‘I have been kept waiting for my appointments or phone calls’.

Subscale scores for each section of the questionnaire were obtained by totalling the scores for each item, after reversing the scores for any negatively-phrased questions (by subtracting the individual item score from 5). There were no missing items on the satisfaction questionnaires, and so no adjustment for missing data was necessary.

The five main sections were:

- Organisation of Care (Section A)
- Information and Advice (Section B)
- Personal Experience of Care (Section C)
- Satisfaction with Care (Section D)
- Supplementary questions

Initially histograms of the distributions of the subscale scores were produced. As with the FACT B questionnaire, these were highly skewed (see Appendix S). Therefore the results were summarised using medians and interquartile ranges (IQR). Medians are representative of the whole picture because they occur half way along the distribution. IQR ensure responses between the range of 25% and 75% are summarised. Consequently, the non-parametric Mann-Whitney test was used to compare distributions of subscale scores between the two groups, as this is unaffected by the shape of the distribution.

In addition to determining the differences in satisfaction scores *between* each group, further analysis was carried out to investigate changes over time *within* each group, that is the trend from first observation at three months to final observation at fifteen months. This was done in order to enable assessment of increases and decreases in satisfaction over time within each group so that the impact of being seen by each professional would be apparent regardless of the starting points of each group. Changes in subscale scores from baseline to each time point were calculated, and summarised using medians and interquartile ranges (IQR). The Wilcoxon signed ranks test was used to test for change in scores from baseline to each time point within each randomised group. The Mann-Whitney test was used to compare distributions of change in scores between the randomised groups, separately for each time point. One problem with analysing each time point separately is that the issue of multiple significance testing arises. It would be preferable to carry out an overall test for trend in the scores across time, but there is no non-parametric equivalent of a trend test. Therefore, ignoring the skewed nature of the data, mean scores were compared over the 5 time points in an analysis of variance (ANOVA), for each randomised group separately. Trend in mean subscale scores was assessed in the ANOVA using the F test for trend. However, the ANOVA results should be interpreted with caution because of the highly skewed nature of the data. Graphs are also presented, showing median scores at each time point separately for women randomised to nurse or doctor-led follow-up. A cut-off of p=0.01 was used in these analyses to indicate statistical significance, as a large number of significance tests were carried out, and therefore there is an issue of multiple testing (i.e. increased likelihood of some results being significant by chance).

Section E of the questionnaire contained open questions with space for free text responses. This qualitative data is presented separately. Question E11 asking women how they would rate their support during follow-up overall was analysed following measurement with a ruler of points marked on a visual analogue scale with a range of 0 to 100 millimetres.

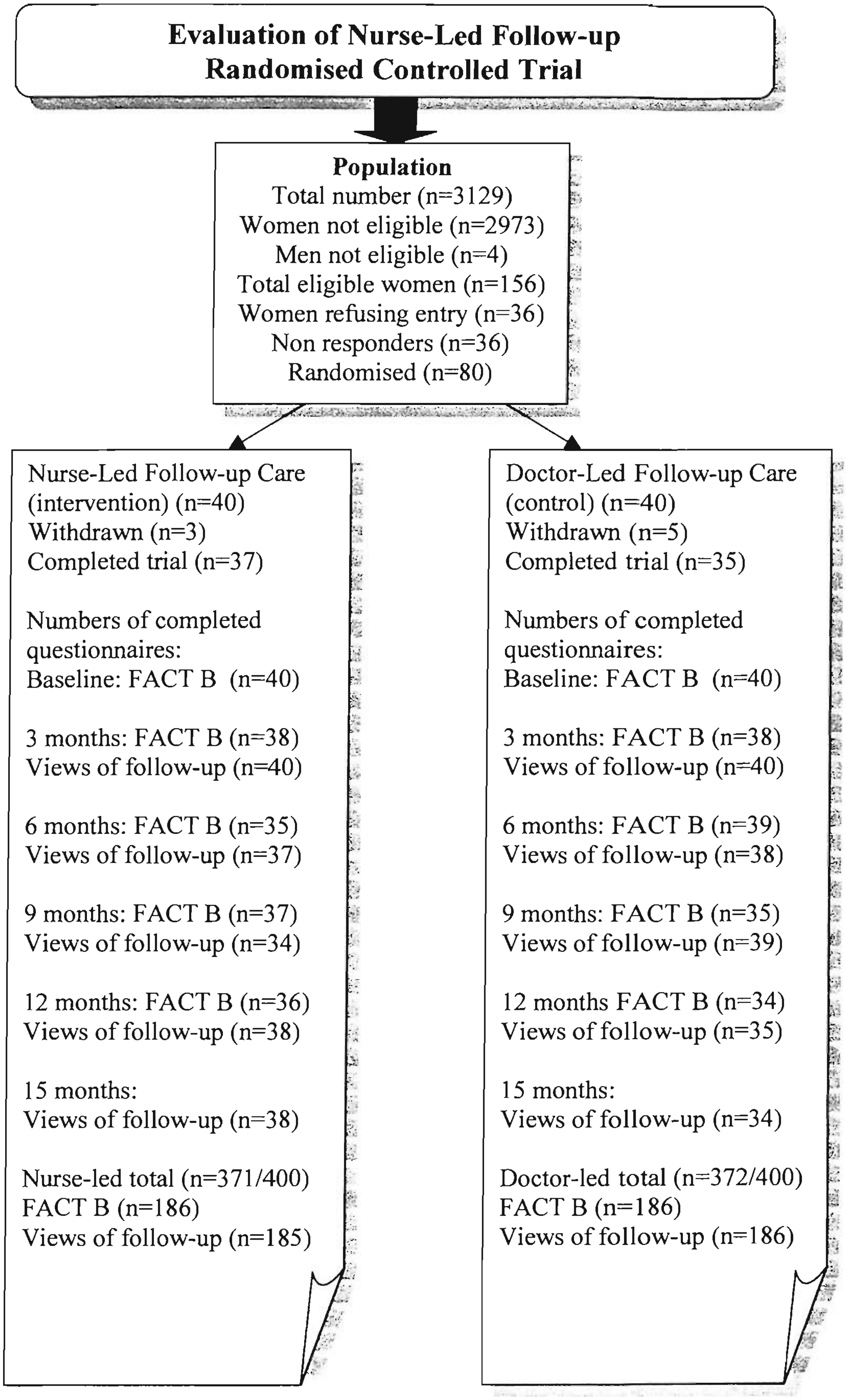


Figure 9.1 Illustration of research design for phase Three

9.8 Ethical Considerations

Approval for the randomised study was obtained from the Committee for Clinical Research (CCR) and the Local Research Ethics Committee (LREC) within the Trust. Agreement was also sought from the Surgical Consultant and from the Clinical Head of the breast unit.

Potential recruits were notified during the consent process that their decision to refuse or to terminate participation would not affect the attitudes of any of their carers (see appendix M for invitation letter and consent form). Confidentiality was also assured thus guaranteeing that any information provided by the subject would not be made accessible to parties other than those involved in the research. The women are referred to by their randomisation within the results to protect their identity. All of the completed questionnaires were securely stored and will be destroyed on successful completion of this thesis.

Consent for copyright use of the FACT-B questionnaire used in phase two was sought in writing from the originators of the tool in America (see appendix T). This was received with no restrictions but a request to share data arising from use of the tool with its authors.

To ensure equity of care in the RCT and safety with regards to referring patients in the nurse-led group back for medical intervention in the presence of new symptoms, a new protocol arm was developed. This was written in collaboration with medical and nursing staff and was formerly adopted as the Breast Unit Follow-up Protocol (for all health care professionals) prior to commencement of randomisation (see Figure 8.2 in preceding chapter). The protocol contained guidance on frequency and duration of follow-up consultations and investigations, use of adjuvant endocrine therapies, the procedure for clinical examination at each visit and criteria for prompt review by the medical team.

9.8.1 Reliability and Validity

A research design has to ensure reliability and validity and these are interrelated concepts that cannot be considered independently of each other (Eby 1993). Reliability refers to attempts to maximise the accuracy of the study, in that it is concerned with the extent to which a measure gives consistent results (Nolan and Behi 1995). The higher the level of reliability the greater the confidence we can have in the results. In order to achieve statistical reliability (that the results are due to the intervention rather than chance) a sufficiently large sample size was used. Questionnaires were chosen for their clarity and lack of ambiguous wording in an attempt to prevent unreliable answers resulting from misinterpretation of the questions.

Validity concerns whether the study has correctly measured what it is supposed to measure. This can be difficult with tools that collect data on human behaviour and attitudes because the results will depend on numerous variables, such as the respondents' candour, their willingness to answer and the absence of stereotyped answers. Content validity (the representativeness of the questions) was addressed by using previously validated questionnaires and by referring back to the extensive literature review to ensure all important areas relating to breast cancer follow-up had been captured in the questions.

Internal validity (whether differences in the observed effects can be attributed to differences in the intervention) was improved with randomisation. As the women were randomly assigned, each experienced the same test conditions and research instruments, the same history and chance of selection (Cook and Campbell 2004b). Thus randomisation should ensure that comparison groups of sufficient size differ only in their exposure to the intervention concerned (McKee at al 1999) (in this case doctor or nurse-led follow-up). External validity (the extent to which the results are generalisable to all potential recipients) can be threatened when the outcome of the intervention is dependent on the person providing it. The outcomes of both the doctor-led and nurse-led follow-up clinics may have resulted from the characteristics and personal skills of the doctors and nurse taking part (Black 1996), rather than from differences in the practice of medicine and nursing per say. It is possible that the nature of the research setting (a highly specialist and acclaimed cancer hospital) led to the women, doctors and myself not being representative of all users and providers of breast cancer follow-up clinics.

9.8.2 Bias

Bias can be defined as a distortion in the estimate of an effect measure, which can lead to an error in assigning a relationship between the variables (Meininger, 1998). Selection bias concerns whether the participants are representative of the study population. The total cohort of eligible people commencing breast cancer follow-up within one hospital consultant surgeon's caseload was approached to take part in the randomised study. It is acknowledged that these may not have been representative of the population as a whole as they were drawn from a limited geographical area in South East England, only one hospital and one consultant. Further control over the selected population was imposed by the inclusion and exclusion criteria. However, as women are excluded or refuse to participate the study population becomes a progressively smaller subset of the reference population, in principle increasing the scope for selection bias and raising doubts about generalisability. It is possible that those women who refused to participate had a worse perception (even if this was not the reality) of their prognosis and so felt safer seeing a doctor for follow-up, suggesting that women who did agree to be randomised already had greater confidence in their recovery and thus potentially less need from the follow-up consultation.

Confounding bias occurs when the relationship under investigation is interrelated with another confounding factor. Randomisation will also help to eliminate confounding bias. The use of randomisation after recruitment allowed for random distribution of important characteristics to both groups (Brink and Wood 1998). I was cognisant of the potential for bias within the RCT because I was known as a clinical nurse specialist to the women and the doctors in the unit in which the study was conducted and I would also be the nurse conducting the nurse-led follow-up and as such was evaluating myself.

9.9 Paradigmatic approach

As explained in chapter 6, a research paradigm relates to the set of philosophical assumptions that guide the researcher's approach to inquiry and refers to the use of theory to focus the inquiry and to facilitate the development of outcomes. The philosophical approach underpinning the explorative studies in phase one was feminist methodology but I was keen to explore and adopt other approaches that would relate to a quantitative study, whilst also complementing the feminist theory that I found I related to so well. Adoption of two philosophical approaches contributed to my development and understanding and served to enrich my research practice because I was able to learn valuable lessons from each.

Whilst exploring different theoretical approaches to underpin the randomised trial I was struck by my personal ability to relate to a post positivist stance. Post-positivism refers to a more contemporary school of theory that retains some underlying principles developed earlier by positivist theorists but is less radical and extreme in its thinking. Positivist theory is placed in a scientific paradigm that aspires to valid, reliable and, crucially, objective development of knowledge. Historically positivism has been strongly associated with 'hard' sciences such as physics and chemistry, similarly clinical and medical research has been dominated by this approach. Proponents of this theory assert that wholly objective accounts of the world can be achieved. In other words there is an underlying assumption that facts (truth) can transcend opinion and personal bias (Denzin and Lincoln 1987) and reality can be captured and understood. Thus truth in the eyes of positivist inquirers is achieved through verification and replication of observable findings (empiricism) and arises from directly perceivable processes (Clark 1998). Two fundamental implications of this approach are firstly, that researchers are deemed to be neutral, detached observers, separated from all stages of the research process to ensure objectivity, and secondly that subjective phenomena such as human meanings and experiences are considered beyond the scope of positivist research.

The later emergence of post-positivism refuted these ideas, proposing instead that only *partially* objective accounts of the world can be produced because no research method is ever one hundred percent free of any flaws. Hence reality can only be approximated. Undeniably, post-positivistic research evolved in direct response to the obvious limitations of an approach that denies the importance of the subjective and experiential aspects of individual people (Clark 1998). Of note, such limitations will inevitably hold inadequacies for nursing research as well because mechanistic views of human experience are incongruent with holistic, individualised nursing care.

Post-positivism commonly relies on multiple methods to capture as much of reality as possible (Ford-Gilboe et al 1995) and attempts verification of theories and ideas by using traditional evaluation criteria. Post-positivist researchers contend that triangulation is a framework that fits with their philosophy in that it deepens understanding of *different* aspects of the issues, rather than convergence on just one fixed point (Seale 1999). They contend that individual research questions should be answered with appropriate research methods for that question and specific methods could not answer every type of problem pertaining to human experiences (Ford-Gilboe et al 1995, Clark 1998). In accordance with the philosophical beliefs underpinning post-positivism, triangulation of quantitative and qualitative methods suggests the researcher's recognition that there exists a diversity of truths (facts), and as such different forms of inquiry are needed to access them (Clark 1998).

As a research paradigm it applies a more deductive model in which propositions logically deduced from existing theory and knowledge are operationalised in the research study (as opposed to inductive models where the researchers begin with few preconceptions). Importantly, post-positivist research does not exclude either the facts (or truths) arising from quantitative data or those emerging from the experiences and beliefs of individuals. Accordingly, post-positivist research maintains the positivist elements of quantification and search for causal factors but also incorporates subjectivity and meaning thus allowing researchers to advocate a pragmatic combination of quantitative *and* qualitative measures (Seale 1999). Science is still deemed to require logical reasoning and evidence, but rather than confining such proof to that which can be directly perceived (the positivist approach), post-positivists accept the importance of inferable forms of evidence, such as the self-reports inherent in interviews and questionnaires (Clark 1998). Quantification is employed to reinforce the data and to test hypothesis across samples but complex statistical measures are seldom used as part of the structured analysis (Denzin and Lincoln 1998). Qualitative input is facilitated by use of methodology that captures individual points of view and secures rich and meaningful descriptions, lending support to subsequently formed arguments.

My own background as a researcher and clinician, as well as my personality, identifies with an objective, scientific stance. As a nurse working in an oncology setting, I had always retained a cynicism of unproven cancer treatments and of people making claims about cure without any evidence to support them. I have encountered examples of this from within and without traditional medicine. Women with breast cancer have frequently told me about unscrupulous alternative therapists who sell therapies with unproven benefits at exorbitant prices whilst guaranteeing cure. I have witnessed first hand the bitter disappointment that results in the realisation that cure has not been achieved and I have felt frustrated that such approaches are not subjected to rigorous evaluation, yet remain available with no body of evidence to support their use.

Working in a breast cancer setting for fifteen years, I have had extensive previous experience of randomised controlled trials (recruiting to them, explaining them and conducting them) and was familiar with this choice of methodology. Previous training in scientific, quantitative approaches had established a belief in their recognised, valued contribution to knowledge. Treatment for breast cancer, in terms of availability of superior chemotherapy drugs and new endocrine therapies, has progressed significantly in the last ten years and we have witnessed a significant improvement in mortality figures as a result. I am starkly aware of the substantial contribution that randomised controlled trials have made to knowledge and progress. Therefore I considered my study, in which a primary aim is to compare care from two different health professionals, was highly suited to a randomised, controlled design and it sat appropriately within my own philosophy of research based on quantification and empiricism. In addition, an important tenet of post-positivism is adoption of an experience based and interpretive approach to research, used to effect clinical change. This is deemed integral to improving the quality of care given to people receiving follow-up care after treatment for breast cancer. Hence, post-positivistic philosophy was adopted as an underlying approach for this study because, in contrast to positivism, the researcher is not seen as being wholly detached from the inquiry, and instead is recognised as shaping the process in some way (Clark 1998). Nevertheless the approach remains underpinned by contemporary empirical research activity (Ford-Gilboe et al 1995).

Post-positivist and feminist research (described in chapter 5) are complementary because, although the latter is less fundamental, both approaches retain the criteria of objectivity and empiricism. Feminist methodology can be conceptualised as complementary to and located within the post-positivist research movement (Webb 1993). Both represent reformulation of the nature of objectivity and involve the kinds of inquiry suited to 'real world' studies (Robson 2001). Another model of interpretive theory, examples of feminist research emerged in the modernist phase of qualitative research development, at a time when post-positivism also functioned as a powerful paradigm. As qualitative researchers strove to be seen as rigorous as their quantitative counterparts, work in this period 'clothed itself in the language and rhetoric of post-positivist discourse' (Denzin and Lincoln 1998 p17).

The two philosophies balance the recognised problems inherent in each. Exclusive adoption of post-positivism as a predominantly scientific paradigm could have limitations when researching people because humans are complex and unique with multiple experiences, perceptions and values that may not be comprehensively captured by purely scientific or quantitative approaches (Polit et al 2003). Feminist theory relates to nursing, which has been characterised by a humanistic philosophy, giving value to personal meaning, subjectivity and understanding (Playle 1995) but may be limited by an inability to develop a scientific underpinning to ensure credibility when generating new knowledge. Post-positivist and feminist theories encompass qualitative and quantitative, experimental and naturalistic research strategies, embroiled in a realist ontological framework. Multiple methodology, endorsed by both philosophies, facilitated objective and subjective data collection and was successfully employed to enrich my understanding of the follow-up needs of women after completion of treatment for breast cancer.

9.10 Summary

This chapter has described the randomised controlled trial that was designed to compare follow-up provision by doctors versus myself, a specialist nurse. The trial involved administration of two questionnaires, subjected to both quantitative and qualitative analysis. The results of the randomised controlled trial are presented next.

Chapter 10. PHASE THREE: RANDOMISED CONTROLLED TRIAL COMPARING NURSE-LED AND MEDICAL FOLLOW-UP RESULTS

10.1 Introduction

This chapter presents the data collected during the randomised controlled trial. General demographic details are presented first, followed by the results pertaining to each of the questionnaires' (Functional Assessment of Cancer Therapy [Breast] (FACT-B) and 'Your Views of Follow-up Care) in turn.

10.2 Patient Characteristics at Randomisation

The demographic and clinical data of the two randomised groups is presented in Table 10.1. The characteristics of each were compared using the chi-squared ($\chi 2$) test (a non-assuming test of statistical significance between two categories). The exceptions were age, where mean ages were compared using the t-test and diagnosis, where Fisher's exact test is used because small numbers in one of the categories invalidates the $\chi 2$ test.

Characteristics are largely distributed similarly between the two groups with the exception of age, where there were more younger women and the mean age was lower in women in the conventional follow-up group (p=0.04). Because of this weak significance at baseline the analyses of both questionnaires was repeated adjusting for age. This made no difference to the results and all results that were found to be significant in the unadjusted analysis remained significant in the adjusted analysis.

Table 10.1: Characteristics of the women at randomisation

	Nurse-led Follow-up n=40 (%)	Medical Follow-up n=40 (%)	Test statistic*	p-value
Gender:			N/A	N/A
Female	40 (100)	40 (100)		
Male	0 (0)	0 (0)		
Age (years):				
30 – 39	0 (0)	6 (15.0)		
40 – 49	1 (2.5)	9 (22.5)		
50 – 59	26 (65.0)	18 (45.0)		
60 – 69	10 (25.0)	3 (7.5)		
70 –79	2 (5.0)	1 (2.5)		
80 – 89	1 (2.5)	3 (7.5)		
Mean (SD)	57.7 (7.3)	52.8 (12.8)	2.10	0.04
Diagnosis:			N/A	0.43
Invasive breast carcinoma	35 (87.5)	38 (95.0)		
In situ breast carcinoma	5 (12.5)	2 (5.0)		
Stage:			0.09	0.77
I	33 (82.5)	33 (82.5)		
II	7 (17.5)	7 (17.5)		
Treatment:			0.96	0.62
Breast conserving surgery	30 (75.0)	26 (65.0)		
Mastectomy only	3 (7.5)	4 (10.0)		
Mastectomy with reconstruction	7 (17.5)	10 (25.0)		
Chemotherapy	14 (35.0)	18 (45.0)	0.47	0.49
Radiotherapy	32 (80.0)	28 (70.0)	0.60	0.44
Endocrine therapy	31 (77.5)	33 (82.5)	0.08	0.78

N/A = not available

It was not possible to carry out a significance test for gender as all patients were female (comparing 100% with 100% implies a p-value of >0.99)

* Test statistic and p-value correspond to $\chi 2$ test, except for:

age, where mean ages were compared using t-test

diagnosis, where Fisher's exact test is used (where only a p-value is calculated – i.e. no test statistic).

10.3 Functional Assessment of Cancer Therapy [Breast] (FACT-B) questionnaires: Quantitative Results

Physical well-being

The difference in subscale scores for physical well-being was statistically significant at baseline and at 6 months, with women receiving nurse-led follow-up reporting higher levels of physical well-being (see table 10.3). Also, levels of physical well-being appear to improve over time, particularly in the women who received doctor-led follow-up.

Table 10.3 Comparison of subscale scores for physical well-being between women receiving nurse-led and doctor-led follow-up.

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) subscale score for physical well-being**	**n**	**Median (IQR) subscale score for physical well-being**	
Baseline	40	25.5 (22.0-27.0)	40	20.5 (19.0-25.0)	0.004
3	38	26.0 (23.0-27.0)	38	23.5 (20.7-26.0)	0.081
6	35	26.0 (24.0-27.0)	39	25.0 (18.0-26.0)	0.024
9	37	26.0 (24.0-28.0)	35	26.0 (22.0-27.0)	0.216
12	36	27.0 (25.2-28.0)	34	27.0 (24.0-28.0)	0.761

High score for physical well-being = high level of well-being

The difference in scores for the question "How much does your physical well-being affect your quality of life?" was statistically significant at baseline and at 6, 9 and 12 months, with women receiving nurse-led follow-up reporting lower levels, that is a decreased extent to which physical well-being affects their quality of life (see table 10.4).

Table 10.4 Comparison of scores for how much quality of life (QL) is affected by physical well-being between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) score for physical QL**	**n**	**Median (IQR) score for physical QL**	
Baseline	40	2.0 (1.2-4.0)	39	4.0 (3.0-5.0)	0.012
3	38	4.0 (1.0-5.0)	38	4.0 (2.5-5.0)	0.925
6	35	4.0 (1.0-5.0)	39	5.0 (4.0-5.0)	0.030
9	37	4.0 (2.0-5.0)	35	5.0 (4.0-5.0)	0.017
12	36	4.0 (1.5-5.0)	34	5.0 (4.0-5.0)	0.024

High score for physical QL = increased extent to which physical well-being affects QL

In the additional analysis, mean subscale scores for physical well-being showed a statistically significant increase over time in the ANOVA, in both the nurse-led and doctor-led follow-up groups (F test for trend: p=0.009 for nurse and p<0.001 for doctor). Scores representing how physical well-being affects quality of life (QL) were similar over time for the nurse group, but showed a statistically significant increase over time in the doctor group (F test for trend: p=0.155 for nurse and p=0.007 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in tables 10.5 and 10.6.

It can be seen that there were highly statistically significant changes in physical well-being score from baseline to all of the time points in the women who received doctor-led follow-up (table 10.5). In the nurse arm there was a statistically significant change in physical well-being score from baseline to 12 months (table 10.5). Also, the changes in physical well-being scores from baseline were statistically significantly different between the randomised groups at 3 and 12 months (table 10.5). Changes in scores describing how much quality of life (QL) is affected by physical well-being were less significant (table 10.6). In the nurse arm, change in physical QL scores was significant at 12 months, and there were no significant changes in the doctor group (table 10.6). In addition, the distributions of change in physical QL scores were very similar between the randomised groups (table 10.6).

Table 10.5 Comparison of change in subscale scores for physical well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for physical well-being	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for physical well-being**	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	
3	0 (-2, 2)	0.935	3 (0, 4)	<0.001	0.002
6	0 (-2, 2)	0.490	3 (0, 6)	0.002	0.019
9	0 (-5, 2.5)	0.032	5 (0, 7)	<0.001	0.013
12	1 (0, 3)	0.002	6 (2, 8)	<0.001	0.001

High score for physical well-being = high level of well-being

+ve score for change = increase over time

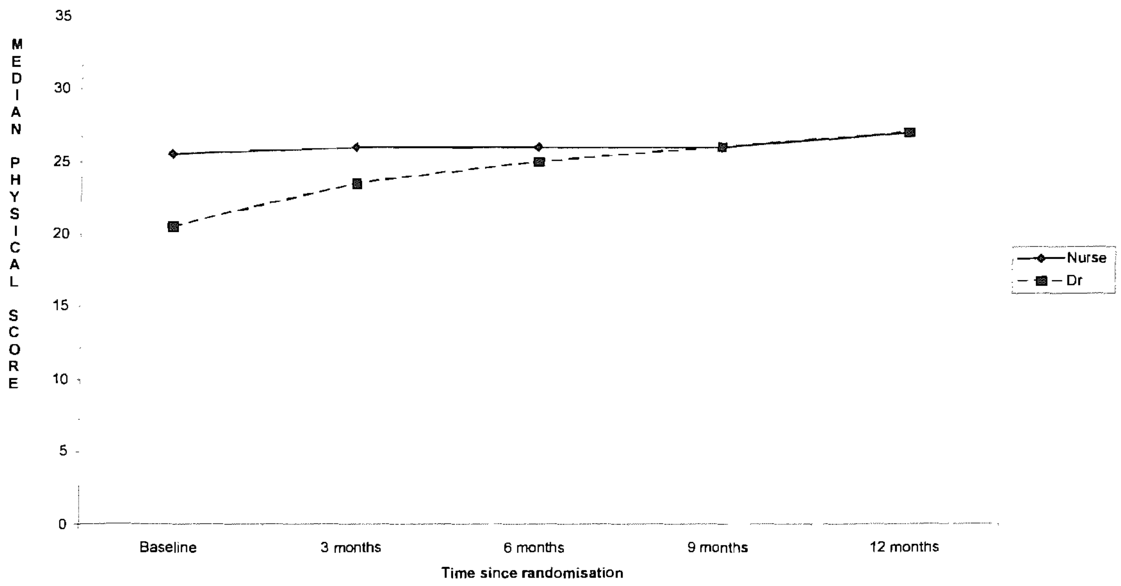
Table 10.6 Comparison of change in scores for how much quality of life (QL) is affected by physical well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for physical QL	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for physical QL**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	0 (0, 2)	0.014	0 (-1, 1)	0.873	0.046
6	0 (0, 2)	0.037	0 (0, 1)	0.023	0.722
9	0 (0, 1.5)	0.042	0 (0, 2)	0.043	0.705
12	0 (0, 2)	0.008	0 (0, 1.5)	0.055	0.532

High score for physical QL = increased extent to which physical well-being affects QL

+ve score for change = increase over time

Graph 1: Change in median subscale scores for physical well-being from FACT-B



Social/Family well-being

The difference in subscale scores for social/family well-being was statistically significant at 6, 9 and 12 months, with women receiving nurse-led follow-up reporting higher levels of social/family well-being (see table 10.7). Also, although levels of social/family well-being appeared to remain stable over time in the women who received nurse-led follow-up, there was some evidence of a decline in the women who received doctor-led follow-up.

Table 10.7 Comparison of subscale scores for social/family well-being between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) subscale score for social well-being**	**n**	**Median (IQR) subscale score for social well-being**	
Baseline	40	23.0 (16.1-27.7)	39	21.0 (18.0-25.0)	0.264
3	38	23.9 (18.7-27.0)	37	22.0 (17.0-26.0)	0.206
6	35	23.8 (16.3-26.0)	39	20.0 (16.0-23.0)	0.044
9	37	22.4 (16.2-26.7)	35	17.0 (14.0-24.0)	0.032
12	36	24.0 (18.0-27.0)	34	16.7 (14.0-24.0)	0.011

High score for social well-being = high level of well-being

There were no statistically significant differences in scores for the question "How much does your social/family well-being affect your quality of life?" at any time points (see table 10.8).

Table 10.8 Comparison of scores for how much quality of life (QL) is affected by social/family well-being between women receiving nurse-led & doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) score for social QL**	**n**	**Median (IQR) score for social QL**	
Baseline	39	5.0 (4.0-5.0)	39	4.0 (4.0-5.0)	0.482
3	38	4.0 (3.0-5.0)	38	4.0 (4.0-5.0)	0.292
6	35	4.0 (3.0-5.0)	37	4.0 (4.0-5.0)	0.947
9	37	4.0 (4.0-5.0)	35	4.0 (4.0-5.0)	0.718
12	36	4.0 (4.0-5.0)	34	4.0 (4.0-5.0)	0.220

High score for social QL = increased extent to which social/family well-being affects QL

In the additional analyses, mean subscale scores for social well-being showed no statistically significant trend over time in the ANOVA, in either the nurse-led or doctor-led follow-up groups (F test for trend: p>0.99 for nurse and p=0.116 for doctor). Scores representing how social well-being affects quality of life (QL) were similar over time for both randomised groups (F test for trend: p=0.512 for nurse and p=0.423 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in tables 10.9 and 10.10. From these tables it can be seen that there were no statistically significant changes in social subscale scores (well-being or QL) from baseline to any of the time points. Also, the changes in scores from baseline were very similar between the randomised groups.

Table 10.9 Comparison of change in subscale scores for social/family well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for social well-being	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for social well-being**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	0 (-2, 2)	0.526	0 (-1, 1)	0.505	0.923
6	0 (-2, 2.5)	0.698	-1 (-3, 2)	0.057	0.437
9	-1 (-2, 3)	0.829	-1 (-7, 2)	0.066	0.360
12	0 (-2, 2)	0.836	-1.5 (-5.8, 2)	0.021	0.138

High score for social well-being = high level of well-being

+ve score for change = increase over time

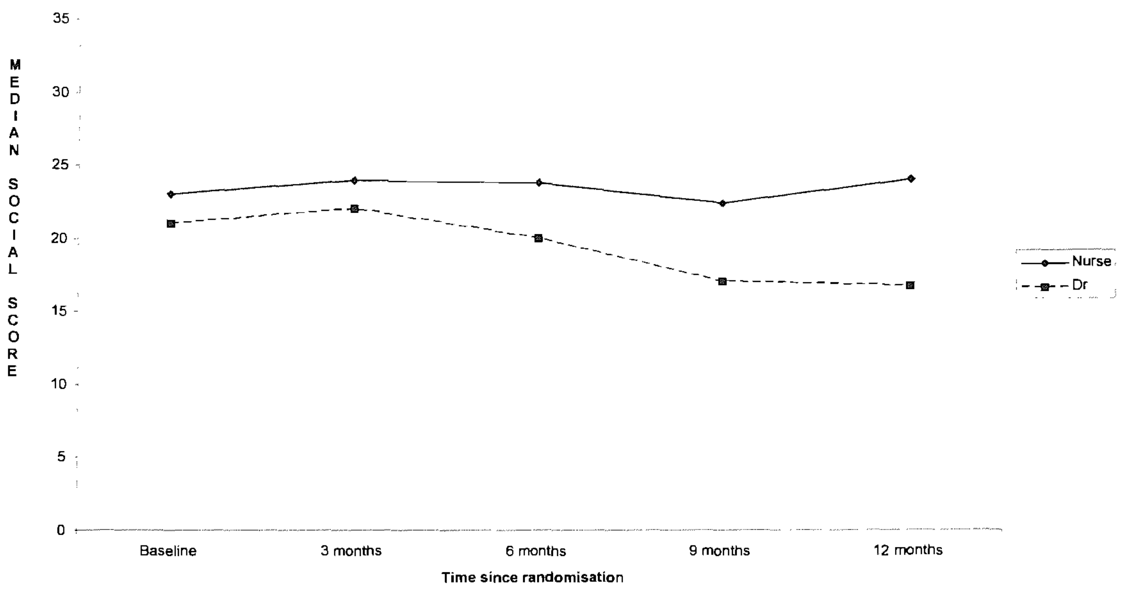
Table 10.10 Comparison of change in scores for how much quality of life (QL) is affected by social/family well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for social QL	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for social QL**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	0 (-1, 0)	0.090	0 (0, 1)	0.307	0.018
6	0 (-1, 0)	0.480	0 (-1, 1)	0.974	0.572
9	0 (-1, 0)	0.211	0 (-1, 0)	0.763	0.319
12	0 (-1, 0)	0.033	0 (-1, 1)	0.528	0.086

High score for social QL = increased extent to which social/family well-being affects QL

+ve score for change = increase over time

Graph 2: Change in median subscale scores for social well-being from FACT-B



Emotional well-being

The difference in subscale scores for emotional well-being was statistically significant at 6 and 9 months, with women receiving nurse-led follow-up reporting higher levels of emotional well-being (see table 10.11). Also, levels of emotional well-being appeared to remain stable over time in both groups of women.

Table 10.11 Comparison of subscale scores for emotional well-being between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) subscale score for emotional well-being**	**n**	**Median (IQR) subscale score for emotional well-being**	
Baseline	40	20.0 (16.0-23.0)	40	18.0 (10.0-21.0)	0.079
3	38	20.0 (16.0-24.0)	38	20.0 (13.7-21.0)	0.186
6	35	21.0 (17.0-22.0)	39	19.0 (10.0-21.0)	0.011
9	37	21.0 (14.5-23.0)	35	18.0 (12.0-21.0)	0.037
12	36	20.0 (16.2-22.0)	34	20.0 (15.0-22.0)	0.435

High score for emotional well-being = high level of well-being

There were no statistically significant difference in scores for the question "How much does your emotional well-being affect your quality of life?" at any time points (see table 10.12).

Table 10.12 Comparison of scores for how much quality of life (QL) is affected by emotional well-being between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) score for emotional QL**	**n**	**Median (IQR) score for emotional QL**	
Baseline	40	4.0 (3.2-5.0)	40	5.0 (3.0-5.0)	0.522
3	38	5.0 (3.0-5.0)	38	4.0 (3.0-5.0)	0.394
6	35	4.0 (3.0-5.0)	39	4.0 (3.0-4.0)	0.086
9	37	4.0 (3.5-5.0)	35	4.0 (3.0-4.0)	0.152
12	36	4.0 (4.0-5.0)	34	4.0 (3.7-4.0)	0.211

High score for emotional QL = increased extent to which emotional well-being affects QL

In the additional analyses, mean subscale scores for emotional well-being showed no statistically significant trend over time in the ANOVA, in either the nurse-led or doctor-led follow-up groups (F test for trend: p=0.849 for nurse and p=0.332 for doctor). Scores representing how emotional well-being affects quality of life (QL) were similar over time for the nurse group, but showed a statistically significance increase over time in the doctor group (F test for trend: p=0.203 for nurse and p=0.012 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in tables 10.13 and 10.14. From these it can be seen that there were no statistically significant changes in emotional subscale scores (well-being or QL) from baseline to any of the time points. Also, the changes in scores from baseline were very similar between the randomised groups.

Table 10.13 Comparison of change in subscale scores for emotional well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for emotional well-being	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for emotional well-being**	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	
3	0 (-2, 2)	0.890	0 (-0.2, 3)	0.034	0.454
6	1 (-1, 2)	0.477	0 (-2, 1)	0.864	0.598
9	0 (-2, 1.5)	0.877	1 (-2, 3)	0.164	0.204
12	0 (-1.7, 2.7)	0.860	2 (-2, 3)	0.014	0.092

High score for emotional well-being = high level of well-being

+ve score for change = increase over time

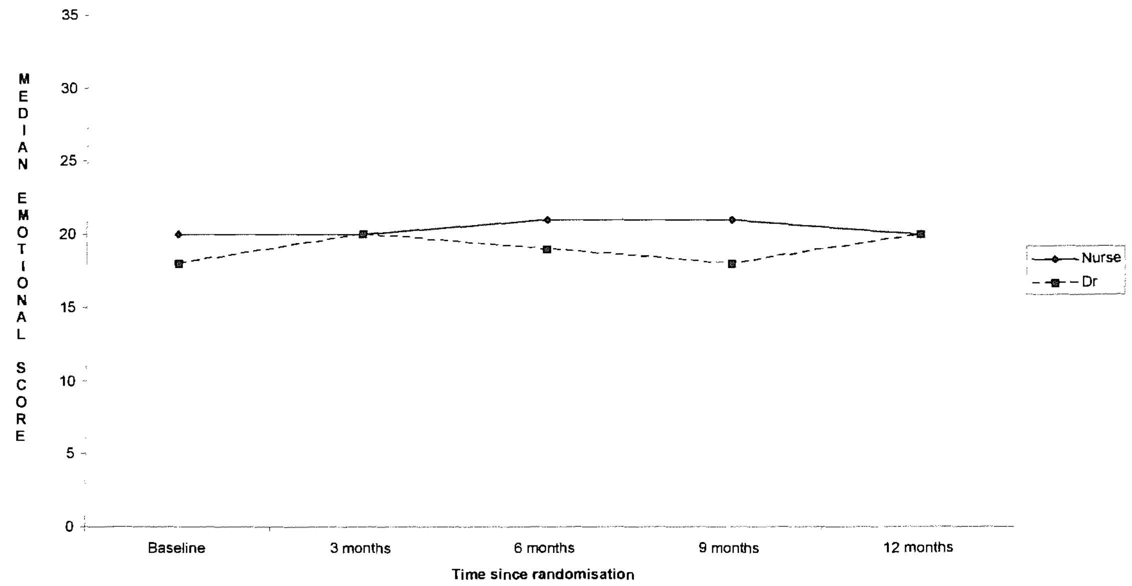
Table 10.14 Comparison of change in scores for how much quality of life (QL) is affected by emotional well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for emotional QL	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for emotional QL**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	0 (-1, 1)	0.382	0 (0, 0)	0.771	0.531
6	0 (-1, 1)	0.724	0 (0, 1)	0.273	0.278
9	0 (-1, 1)	0.360	0 (0, 1)	0.064	0.519
12	0 (-1, 1)	0.241	0 (0, 1)	0.038	0.586

High score for emotional QL = increased extent to which emotional well-being affects QL

+ve score for change = increase over time

Graph 3: Change in median subscale scores for emotional well-being from FACT-B



Functional well-being

There were no statistically significant differences in subscale scores for functional well-being at any time points (see table 10.15). Also, levels of functional well-being appeared to remain stable over time in both groups of women.

Table 10.15 Comparison of subscale scores for functional well-being between women receiving nurse-led and doctor-led follow-up.

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) subscale score for functional well-being**	n	**Median (IQR) subscale score for functional well-being**	
Baseline	40	20.0 (14.0-25.0)	40	21.0 (13.5-25.0)	0.896
3	38	20.5 (16.0-25.2)	38	23.0 (18.0-25.4)	0.281
6	35	20.0 (16.8-25.0)	39	19.0 (11.0-24.0)	0.359
9	37	22.4 (19.3-26.0)	35	22.0 (10.0-25.0)	0.263
12	36	22.0 (19.0-26.0)	34	22.0 (19.0-27.0)	0.777

High score for functional well-being = high level of well-being

There were no statistically significant difference in scores for the question "How much does your functional well-being affect your quality of life?" at any time points (see table 10.16).

Table 10.16 Comparison of scores for how much quality of life (QL) is affected by functional well-being between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) score for functional QL**	**n**	**Median (IQR) score for functional QL**	
Baseline	40	4.0 (4.0-5.0)	40	5.0 (3.0-5.0)	0.856
3	38	4.0 (4.0-5.0)	38	4.0 (3.0-5.0)	0.956
6	35	4.0 (3.0-5.0)	39	4.0 (3.0-4.0)	0.348
9	37	4.0 (3.5-5.0)	35	4.0 (3.0-4.0)	0.249
12	36	4.0 (3.2-4.0)	34	4.0 (3.7-4.0)	0.834

High score for functional QL = increased extent to which functional well-being affects QL

In the additional analyses, mean subscale scores for functional well-being showed no statistically significant trend over time in the ANOVA, in either the nurse-led or doctor-led follow-up groups (F test for trend: p=0.008 for nurse and p=0.370 for doctor). Scores representing how functional well-being affects quality of life (QL) were similar over time for both randomised groups (F test for trend: p=0.024 for nurse and p=0.137 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in tables 10.17 and 10.18. It can be seen that there was a statistically significant change in functional well-being score from baseline to 12 months in the women who received nurse-led follow-up, and from baseline to 3 months in the doctor arm (table 10.17). However, the distributions of changes in functional well-being scores from baseline were similar between the randomised groups (table 10.17). Changes in scores describing how much quality of life (QL) is affected by functional well-being were significant at 12 months for the nurse group and at 9 months for the doctor arm (table 10.18). The distributions of change in functional QL scores were very similar between the randomised groups.

Table 10.17 Comparison of change in subscale scores for functional well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for emotional well-being	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for emotional well-being**	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	
3	1 (-3, 4)	0.296	1 (0, 4)	0.003	0.395
6	1 (-1, 2)	0.365	0 (-5, 2.3)	0.888	0.769
9	1 (-1, 6.3)	0.013	0 (-3, 4)	0.278	0.296
12	1 (0.2, 6.2)	0.005	3 (-1, 6)	0.044	0.846

High score for functional well-being = high level of well-being

+ve score for change = increase over time

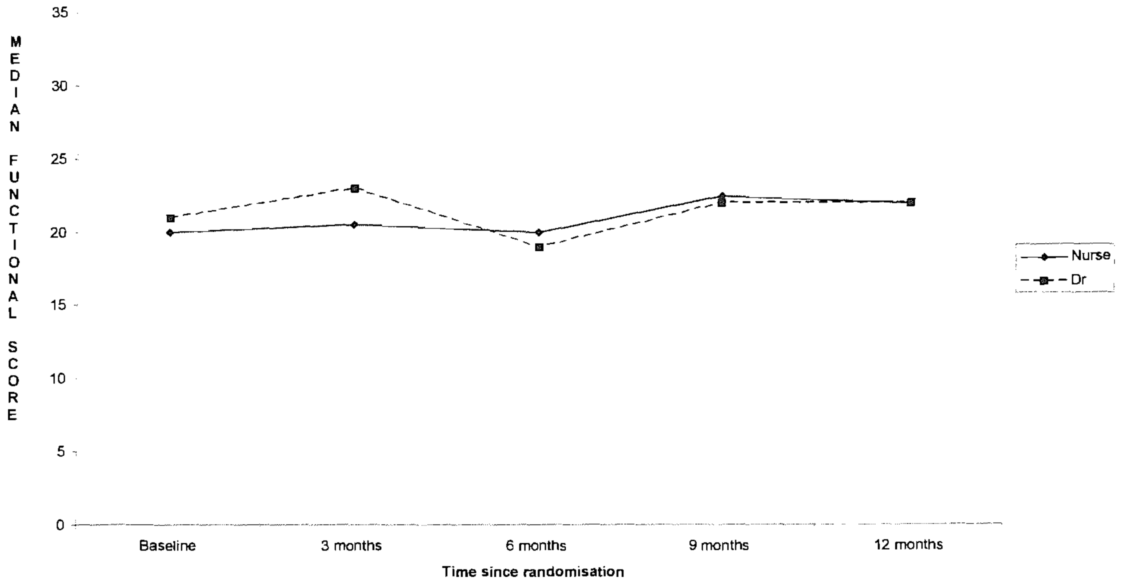
Table 10.18 Comparison of change in scores for how much quality of life (QL) is affected by functional well-being between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	Professional				Mann-Whitney test p-value (comparing nurse vs. doctor)
	Nurse		Doctor		
	Median (IQR) change in subscale score for functional QL	Wilcoxon signed ranks test p-value (comparing each time point with baseline)	Median (IQR) change in subscale score for functional QL	Wilcoxon signed ranks test p-value (comparing each time point with baseline)	
3	0 (-1, 0.2)	0.472	0 (0, 0)	0.359	0.586
6	-1 (-1, 0)	0.105	-1 (-1, 0)	0.014	0.688
9	-1 (-1, 0)	0.019	-1 (-1, 0)	0.004	0.948
12	-0.5 (-1, 0)	0.004	-1 (-1, 0)	0.087	0.929

High score for functional QL = increased extent to which functional well-being affects QL

+ve score for change = increase over time

Graph 4: Change in median subscale scores for functional well-being from FACT-B



Additional Concerns

The difference in subscale scores for additional concerns was statistically significant at baseline and 6 months, with patients receiving nurse-led follow-up reporting lower levels of additional concerns (see table 10.19). Also, levels of additional concerns appeared to improve over time in both groups of patients.

Table 10.19 Comparison of subscale scores for additional concerns between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) subscale score for additional concerns**	**n**	**Median (IQR) subscale score for additional concerns**	
Baseline	40	26.0 (19.0-31.7)	40	21.0 (15.0-25.0)	0.004
3	36	27.0 (22.0-32.0)	38	24.0 (18.5-28.2)	0.076
6	35	29.0 (23.0-32.0)	39	24.0 (19.0-28.0)	0.010
9	37	29.0 (18.5-32.0)	35	25.0 (18.0-30.0)	0.337
12	36	29.0 (24.0-31.9)	34	26.5 (21.7-31.2)	0.572

High score for additional concerns = low level of concerns

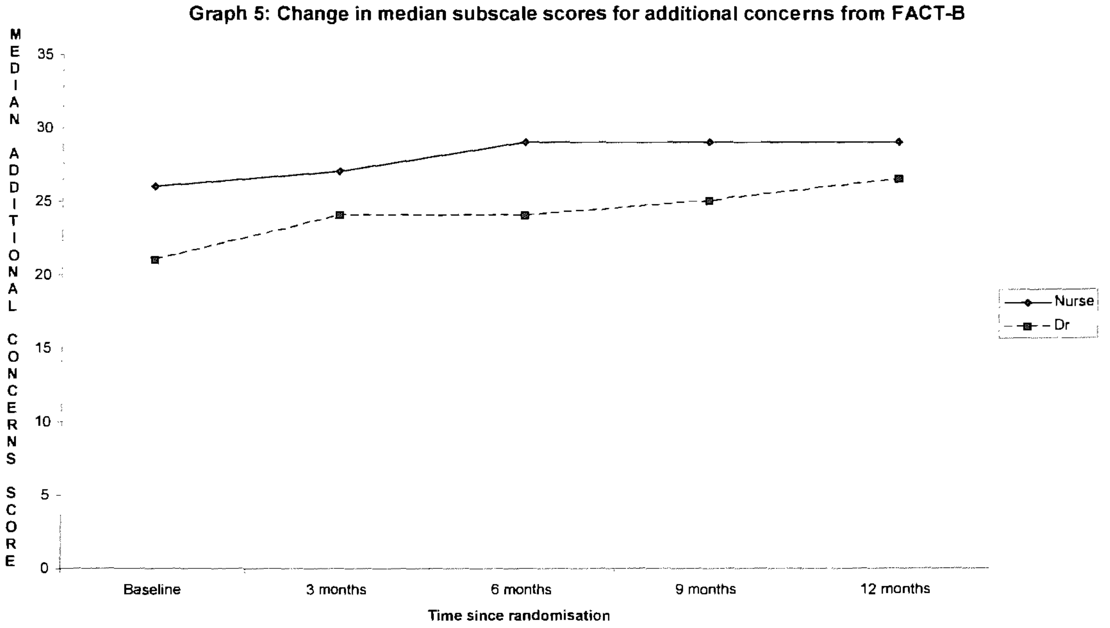
In the additional analyses, mean subscale scores showed a statistically significant trend over time in the ANOVA in the doctor-led follow-up group (F test for trend: p=0.348 for nurse and p=0.001 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.20. It can be seen that there were highly statistically significant changes in additional concerns from baseline to all of the time points in the women who received doctor-led follow-up (table 10.20). Also, the changes in scores for additional concerns were statistically significantly different between the randomised groups at 9 and 12 months (table 10.20).

Table 10.20 Comparison of change in subscale scores for additional concerns between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for additional concerns	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for additional concerns**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	1 (-1, 3)	0.380	2 (1, 3)	0.001	0.087
6	2 (0, 3)	0.020	4 (0, 8)	0.004	0.043
9	0 (-3, 4)	0.789	6 (1, 8)	<0.001	0.001
12	1 (-2.7, 4)	0.253	6 (3, 7)	<0.001	<0.001

High score for additional concerns = low level of concerns

+ve score for change = increase over time



Graph 5: Change in median subscale scores for additional concerns from FACT-B

Supplementary Questions

The difference in subscale scores for supplementary questions was statistically significant at baseline and 6 months, with women receiving nurse-led follow-up reporting lower levels (see table 10.21). Also, levels of concerns for supplementary questions appeared to improve over time, particularly for women who received doctor-led follow-up.

Table 10.21 Comparison of subscale scores for supplementary questions between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) subscale score for supplementary questions**	**N**	**Median (IQR) subscale score for supplementary questions**	
Baseline	40	16.5 (14.0-19.0)	40	12.5 (7.0-15.7)	0.001
3	36	16.0 (14.0-21.0)	38	17.0 (9.7-18.0)	0.143
6	35	18.0 (16.0-20.0)	39	16.0 (9.0-19.0)	0.024
9	37	18.0 (11.0-20.0)	35	16.0 (9.0-20.0)	0.537
12	36	17.0 (12.5-20.0)	34	17.5 (12.7-20.2)	0.791

High score for supplementary questions = low level of concerns

In the additional analyses, mean subscale scores for supplementary questions well-being showed a statistically significant trend over time in the ANOVA in the doctor-led follow-up group (F test for trend: p=0.952 for nurse and p=0.001 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.22. It can be seen that there were highly statistically significant changes in scores for supplementary questions from baseline to all of the time points in the women who received doctor-led follow-up (table 10.22). Also, the changes in scores for supplementary questions were statistically significantly different between the randomised groups at 9 and 12 months (table 10.22).

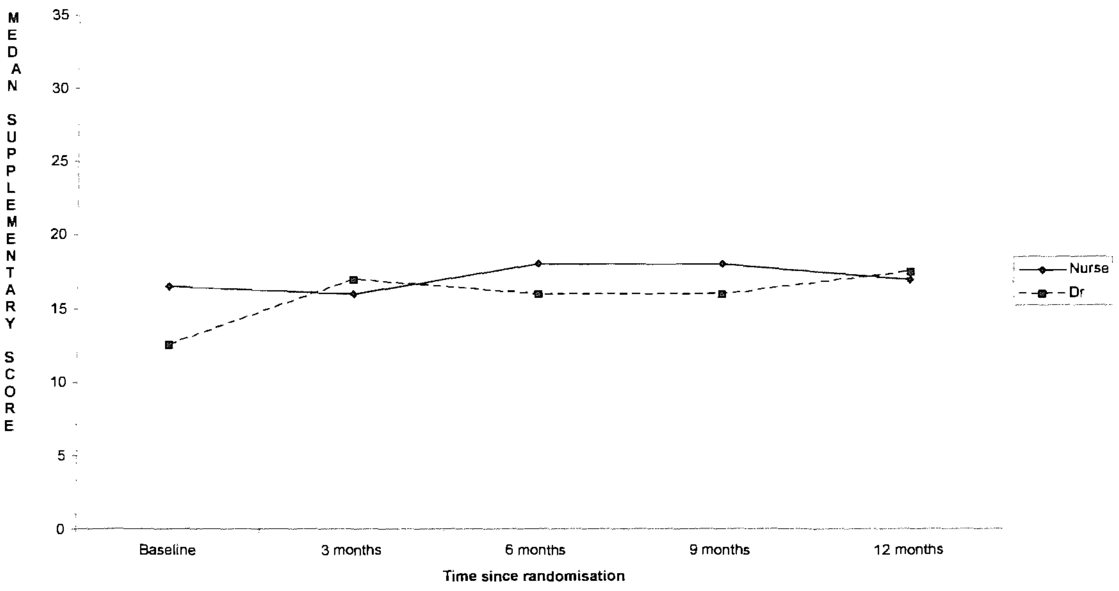
Table 10.22 Comparison of change in subscale scores for supplementary questions between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for supplementary questions	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for supplementary questions**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
3	0 (-1.7, 1)	0.870	2 (0, 4)	0.002	0.011
6	1 (-1, 2)	0.292	2 (0,5)	<0.001	0.020
9	0 (-2, 2)	0.853	4 (1, 7)	<0.001	<0.001
12	1 (-3, 1)	0.608	5 (0, 9)	<0.001	<0.001

High score for supplementary questions = low level of concerns

+ve score for change = increase over time

Graph 6: Change in median subscale scores for supplementary questions from FACT-B



10.4 Your Views of Follow-up Care' questionnaire

10.4.1 Quantitative results from 'Your Views of Follow-up Care' questionnaire

The women were asked to complete questionnaires at 3, 6, 9, 12 and 15 months after randomisation, detailing their satisfaction with the follow-up care received.

The difference in percentage of negative responses for the questionnaire overall was highly statistically significant, with women receiving nurse-led follow-up reporting much lower levels of dissatisfaction, at each time point (p<0.001) (see table 10.23). Also, while the proportion of negative responses for the nurse-led follow-up women remains stable over time, in the doctor-led group women appear to become less satisfied over time.

Table 10.23 Comparison of % negative responses for ***overall questionnaire*** between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	N	**Median (IQR) % -ve responses: all questionnaire**	**n**	**Median (IQR) % -ve responses: all questionnaire**	
3	40	2.1 (0-3.7)	40	25.5 (4.2-55.3)	<0.001
6	37	2.1 (0-2.1)	38	27.7 (10.1-50.0)	<0.001
9	34	0 (0-2.1)	39	36.2 (14.9-61.7)	<0.001
12	38	2.1 (0-2.1)	35	46.8 (21.3-59.6)	<0.001
15	36	2.1 (0-2.1)	34	45.7 (25.0-60.6)	<0.001

Section A: Organisation of care

The difference in subscale scores for section A (organisation of care) was statistically significant at each time point, with women receiving nurse-led follow-up reporting higher levels of satisfaction (see table 10.24). Also, there was some suggestion of increasing satisfaction over time for the women receiving nurse-led follow-up, and the reverse for women who were followed-up by the doctor.

Table 10.24. Comparison of subscale scores for Section A: Organisation of care between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) subscale score for section A**	**n**	**Median (IQR) Subscale score for Section A**	
3	40	27.0 (25.0-28.0)	40	17.5 (12.0-22.7)	<0.001
6	37	28.0 (27.0-30.0)	38	16.0 (12.7-18.0)	<0.001
9	34	29.0 (27.7-31.2)	39	14.0 (11.0-20.0)	<0.001
12	38	29.0 (28.0-31.0)	35	13.0 (11.0-17.0)	<0.001
15	36	30.5 (29.0-31.0)	34	12.0 (11.0-16.2)	<0.001

High subscale score = high level of satisfaction

In the additional analysis, mean subscale scores for organisation of care showed a highly statistically significant increase over time in the nurse-led group and a highly statistically significant decreasing trend in the doctor arm (ANOVA F test for trend: $p<0.001$ for nurse and $p<0.001$ for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.25. From this it can be seen that there were highly statistically significant increases in section A subscale scores from baseline to all of the time points in the women who received nurse-led follow-up, and significant decreases at all time points except 3 months in the doctor group. Also, the changes in satisfaction scores from baseline were highly statistically significantly different between the randomised groups at all time points.

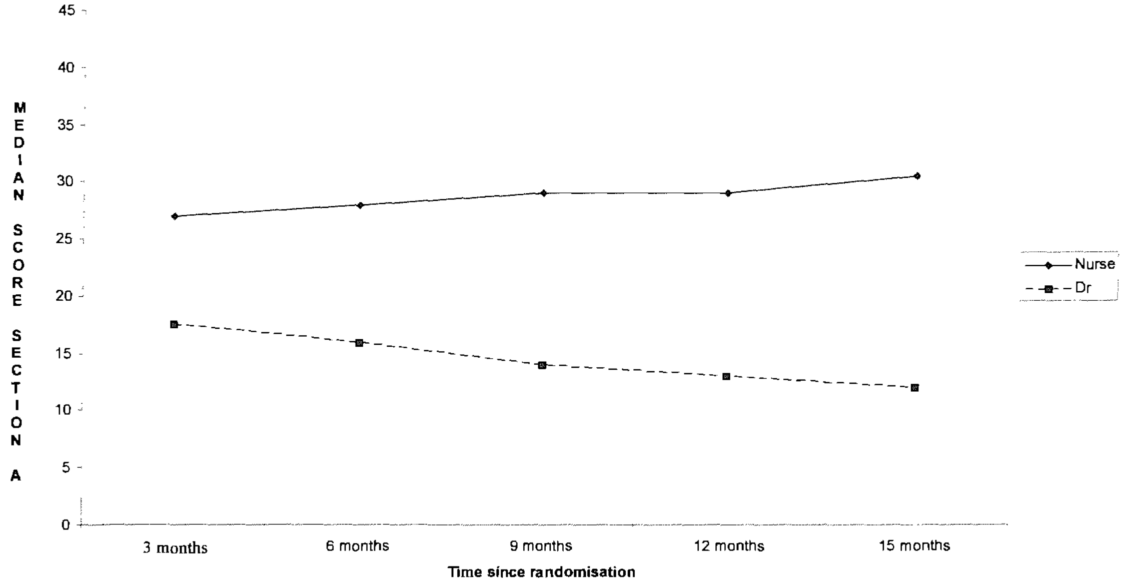
Table 10.25 Comparison of change in subscale scores for section A: organisation of care between women receiving nurse-led and doctor-led follow-up

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for section A	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for section A**	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	
6	2 (0, 3)	0.002	-0.5 (-4, 1)	0.022	<0.001
9	2 (0, 4.2)	<0.001	-2 (-4, 0)	<0.001	<0.001
12	3 (1.7, 5)	<0.001	-3 (-5, 0)	<0.001	<0.001
15	4 (2, 5)	<0.001	-3 (-7, -1)	<0.001	<0.001

High subscale score = high level of satisfaction

+ve score for change = increase over time

Graph 7: Change in median subscale scores for section A: Organisation of from 'Your Views of Follow-up' Questionnaire



Section B: Information and advice

The difference in subscale scores for section B (information and advice) was statistically significant at each time point, with women receiving nurse-led follow-up reporting higher levels of satisfaction (see table 10.8). Also, there was some suggestion of increasing dissatisfaction over time for the women receiving doctor-led follow-up.

Table 10.26 Comparison of subscale scores for Section B: Information and advice between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) subscale score for section B**	**n**	**Median (IQR) subscale score for section B**	
3	40	37.0 (34.0-38.0)	40	23.0 (17.0-36.0)	<0.001
6	37	38.0 (34.0-41.0)	38	22.0 (17.7-29.2)	<0.001
9	34	38.0 (35.0-42.0)	39	18.0 (14.0-28.0)	<0.001
12	38	38.0 (36.0-41.2)	35	17.0 (14.0-22.0)	<0.001
15	36	39.0 (37.0-41.7)	34	20.0 (14.5-24.5)	<0.001

High subscale score = high level of satisfaction

In the additional analysis, mean subscale scores for section B: information and advice showed a highly statistically significant increase over time in the nurse-led group and a highly statistically significant decreasing trend in the doctor arm (ANOVA F test for trend: p=0.007 for nurse and p<0.001 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.27. From this it can be seen that there were highly statistically significant decreases in section B subscale scores from baseline to 6, 9 and 12 months in the women who received doctor-led follow-up. Also, the changes in satisfaction scores from baseline were highly statistically significantly different between the randomised groups at all time points.

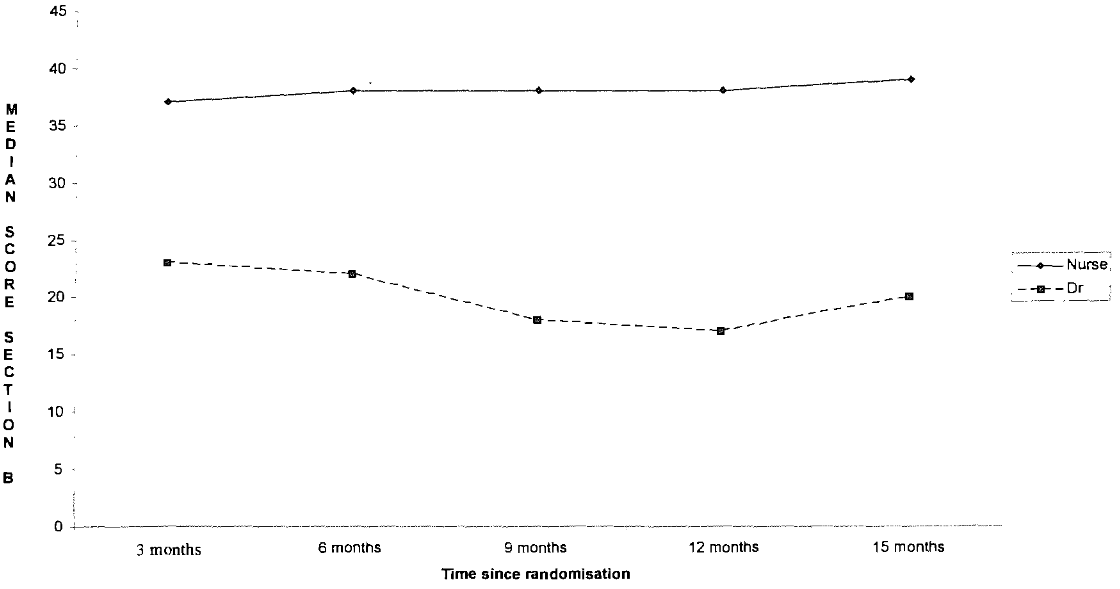
Table 10.27 Comparison of change in subscale scores for section B: information and advice between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for section B	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for section B**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
6	2 (-0.5, 6)	0.026	-2 (-3.7, 1.2)	0.042	0.001
9	1.5 (-2, 6)	0.019	-1 (-7, 6)	<0.001	<0.001
12	3 (-2, 5)	0.076	-4 (-8, 1)	0.001	<0.001
15	3 (-0.7, 5)	0.011	-4 (-10.7, 0)	<0.001	<0.001

High subscale score = high level of satisfaction

+ve score for change = increase over time

Graph 8: Change in median subscale scores for section B: Information and from 'Your views of follow-up' questionnaire



Section C: Personal experience of care

The difference in subscale scores for section C (personal experience of care) was statistically significant at each time point, with women receiving nurse-led follow-up reporting higher levels of satisfaction (see table 10.28). Also, there was some suggestion of increasing satisfaction over time for the women receiving nurse-led follow-up, and the reverse for women followed-up by the doctor.

Table 10.28 Comparison of subscale scores for Section C: Personal experience of care between women receiving nurse-led and doctor-led follow-up.

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) Subscale score for Section C**	**N**	**Median (IQR) Subscale score for section C**	
3	40	39.5 (36.0-42.0)	40	26.5 (15.2-37.0)	<0.001
6	37	40.0 (35.0-43.0)	38	18.5 (13.0-33.2)	<0.001
9	34	41.0 (38.0-42.0)	39	21.0 (13.0-29.0)	<0.001
12	38	41.0 (40.0-42.0)	35	15.0 (13.0-22.0)	<0.001
15	36	42.0 (41.0-43.0)	34	17.0 (13.0-22.5)	<0.001

High subscale score = high level of satisfaction

In the additional analysis, mean subscale scores for section C: personal experience of care showed a highly statistically significant increase over time in the nurse-led group and a highly statistically significant decreasing trend in the doctor arm (ANOVA F test for trend: p<0.001 for nurse and p<0.001 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.29. From this it can be seen that there were highly statistically significant increases in section C subscale scores from baseline to 6, 9 and 12 months in the women who received nurse-led follow-up, and highly significant decreases in satisfaction scores from baseline to 9 and 12 months in the doctor group. Also, the changes in satisfaction scores from baseline were highly statistically significantly different between the randomised groups at all time points.

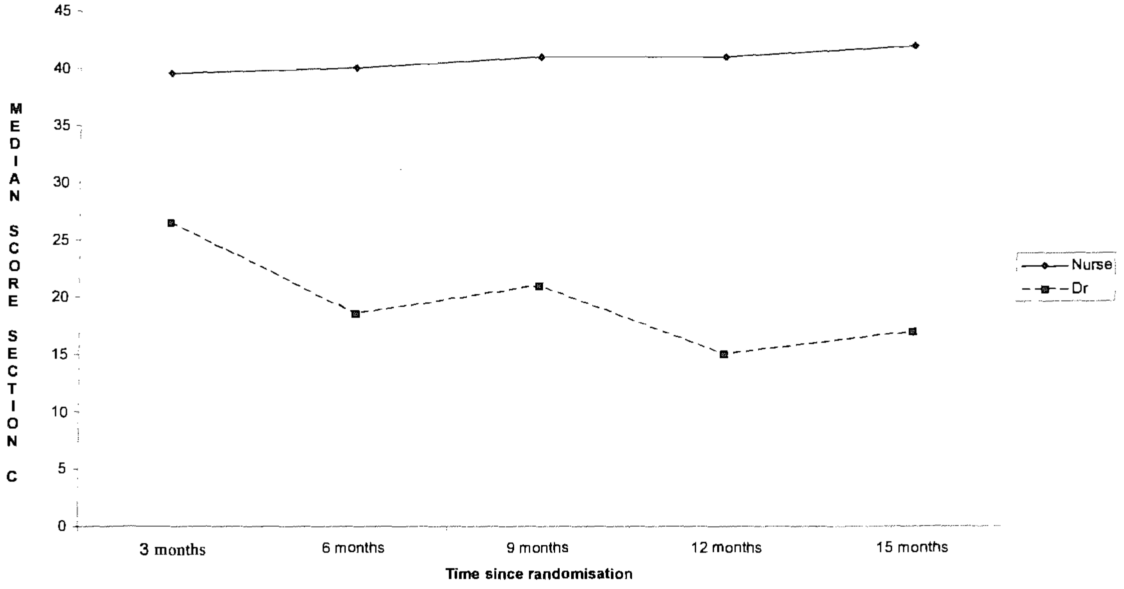
Table 10.29 Comparison of change in subscale scores for section C: personal experience of care between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for section C	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for section C**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
6	1 (-1, 4)	0.031	-1 (-4, 1)	0.081	0.005
9	1 (0, 5)	0.002	-1 (-5, 2)	0.011	<0.001
12	2 (0, 5)	<0.001	-5 (-10, 0)	<0.001	<0.001
15	3 (1, 6)	<0.001	-8 (-12.2, -2.2)	<0.001	<0.001

High subscale score = high level of satisfaction

+ve score for change = increase over time

Graph 9: Change in median subscale scores for section C: Personal experience of from 'Your views of follow-up' questionnaire



Section D: Satisfaction with care

The pattern of differences in subscale scores for section D (satisfaction with care) resembles the same as that found overall. Statistically significant differences at each time point remain, with women receiving nurse-led follow-up reporting higher levels of satisfaction (see table 10.30). Also, there was some suggestion of increasing satisfaction over time for the women receiving nurse-led follow-up, and the reverse for women followed-up by the doctor.

Table 10.30 Comparison of subscale scores for Section D: Satisfaction with care between women receiving nurse-led and doctor-led follow-up

Time point (months)	**Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) subscale score for section D**	**n**	**Median (IQR) subscale score for section D**	
3	40	39.0 (33.0-42.0)	40	24.0 (18.0-35.7)	<0.001
6	37	39.0 (34.5-43.5)	38	23.0 (20.0-32.2)	<0.001
9	34	39.0 (38.0-42.0)	39	22.0 (17.0-31.0)	<0.001
12	38	41.0 (39.0-44.0)	35	19.0 (17.0-22.0)	<0.001
15	36	42.0 (40.2-44.0)	34	21.0 (16.7-24.2)	<0.001

High subscale score = high level of satisfaction

In the additional analysis, mean subscale scores for section D: satisfaction with care showed a highly statistically significant increase over time in the nurse-led group and a highly statistically significant decreasing trend in the doctor arm (ANOVA F test for trend: p<0.001 for nurse and p<0.001 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.31. From this it can be seen that there were highly statistically significant increases in section C subscale scores from baseline to 9 and 12 months in the women who received nurse-led follow-up, and significant decreases in satisfaction scores from baseline to 6, 9 and 12 months in the doctor group. Also, the changes in satisfaction scores from baseline were highly statistically significantly different between the randomised groups at 6, 9 and 12 months.

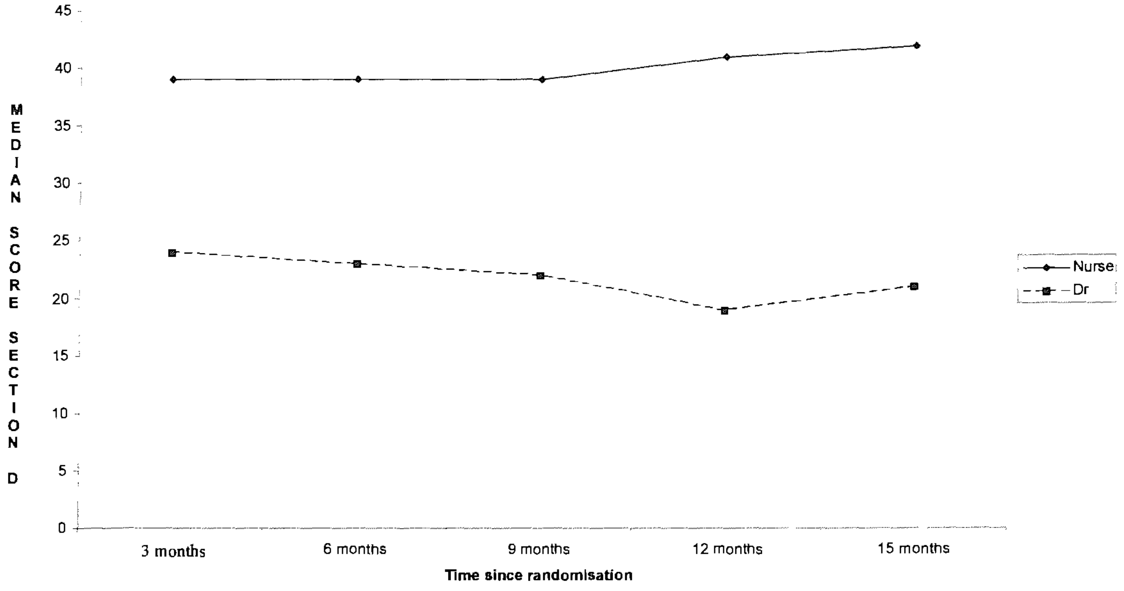
Table 10.31 Comparison of change in subscale scores for section D: satisfaction with care between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for section D	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for section D**	**Wilcoxon signed ranks test** **p-value (comparing each time point with baseline)**	
6	1 (-1, 8)	0.044	0 (-3.2, 1.2)	0.314	0.064
9	1.5 (-1, 7.7)	0.013	-2 (-5, 6)	0.003	<0.001
12	3.5 (0.7, 7.7)	<0.001	-2 (-10, 0)	<0.001	<0.001
15	3.5 (0, 9.7)	<0.001	-4 (-8, -1)	<0.001	<0.001

High subscale score = high level of satisfaction

+ve score for change = increase over time

Graph 10 Change in median subscale scores for section D: Satisfaction with From 'Your views of follow-up' questionnaire



Section E: Question 11 - Overall how would you rate the support you have received?

The difference in subscale scores for section E (rating of support received on a visual analogue scale) was statistically significant at each time point, with women receiving nurse-led follow-up reporting higher levels of satisfaction with support received (see table 10.32).

Table 10.32 Comparison of scores for Section E, question11: Overall how would you rate the support you have received?

Time point (months)	**.1 Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) score for section E Qu 3**	**n**	**Median (IQR) score for section E Qu 3**	
3	40	9.0 (7.2-10.0)	40	8.0 (6.0-9.0)	0.008
6	37	10.0 (9.0-10.0)	38	7.0 (6.0-10.0)	<0.001
9	34	10.0 (9.0-10.0)	39	7.0 (6.0-9.0)	<0.001
12	38	10.0 (9.0-10.0)	35	7.0 (6.0-9.0)	<0.001
15	36	10.0 (9.0-10.0)	34	6.0 (6.0-8.2)	<0.001

High score = high level of satisfaction with support received.

Supplementary Section

The difference in subscale scores for the supplementary section was statistically significant at each time point, with women receiving nurse-led follow-up reporting higher levels of satisfaction (see table 10.33). Also, there was some suggestion of increasing dissatisfaction over time for the women receiving doctor-led follow-up.

Table 10.33 Comparison of subscale scores for the supplementary section of the questionnaire between women receiving nurse-led and doctor-led follow-up

Time point (months)	**.2 Professional**				**Mann-Whitney test p-value**
	Nurse		**Doctor**		
	n	**Median (IQR) subscale score for supplementary section**	**n**	**Median (IQR) subscale score for supplementary section**	
3	40	19.0 (16.2-20.0)	40	13.0 (9.0-18.7)	<0.001
6	37	20.0 (18.0-20.0)	38	14.0 (9.0-16.0)	<0.001
9	34	20.0 (18.0-20.0)	39	12.0 (8.0-15.0)	<0.001
12	38	20.0 (18.0-20.0)	35	9.0 (8.0-13.0)	<0.001
15	36	20.0 (20.0-20.0)	34	9.5 (8.0-12.2)	<0.001

High subscale score = high level of satisfaction

In the additional analysis, mean subscale scores for the supplementary section showed a highly statistically significant increase over time in the nurse-led group and a highly statistically significant decreasing trend in the doctor arm (ANOVA F test for trend: p<0.001 for nurse and p=0.003 for doctor). Results of the analysis of change in scores from baseline to each time point are shown in table 10.34. From this it can be seen that there was a highly statistically significant increase in the supplementary section subscale scores from baseline to 12 months in the women who received nurse-led follow-up, and highly significant decreases in satisfaction scores from baseline to 9 and 12 months in the doctor group. Also, the changes in satisfaction scores from baseline were highly statistically significantly different between the randomised groups at 9 and 12 months.

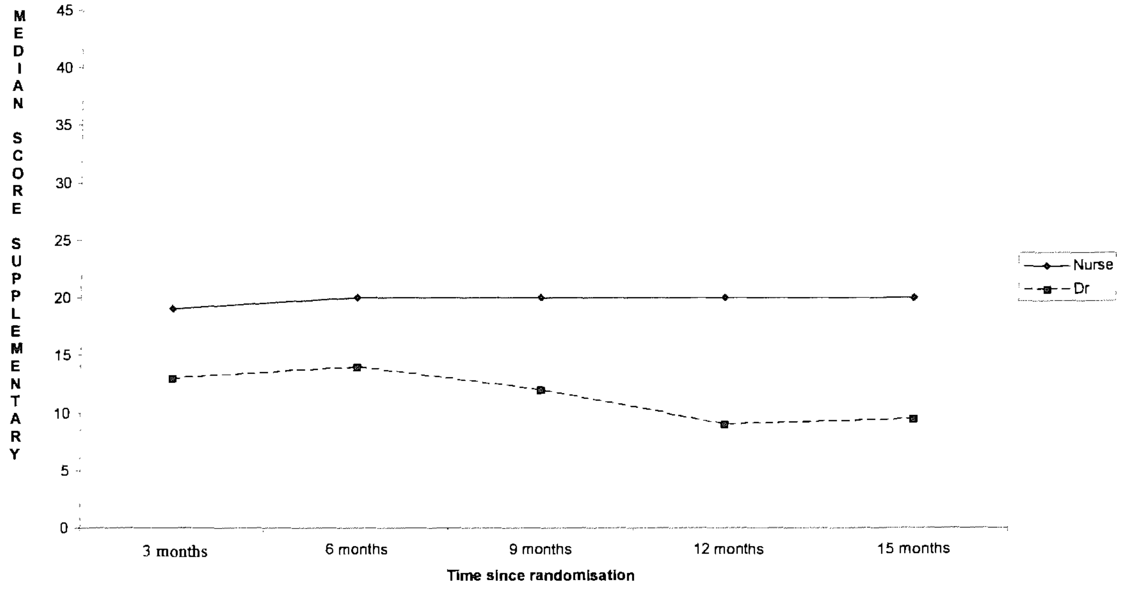
Table 10.34 Comparison of change in subscale scores for the supplementary section between women receiving nurse-led and doctor-led follow-up.

Change from baseline to time point	**Professional**				**Mann-Whitney test p-value (comparing nurse vs. doctor)**
	Nurse		**Doctor**		
	Median (IQR) change in subscale score for supplementary section	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	**Median (IQR) change in subscale score for supplementary section**	**Wilcoxon signed ranks test p-value (comparing each time point with baseline)**	
6	0 (-0.5, 1)	0.394	0 (-2.2, 1)	0.345	0.400
9	0 (0, 1)	0.053	0 (-4, 1)	0.034	0.016
12	0 (0, 2)	0.048	0 (-4, 0)	0.001	0.002
15	1 (0, 4)	0.002	-0.5 (-7, 0)	0.001	<0.001

High subscale score = high level of satisfaction

+ve score for change = increase over time

Graph 11 Change in median subscale scores for supplementary from 'Your views of follow-up' questionnaire



10.4.2 Qualitative results from patient satisfaction questionnaires (Section E)

[to indicate which professional a participant saw, D denotes doctor and N denotes nurse]*

Needs and Problems

The participants were asked to state things that were particularly troubling them since their last visit and then to comment on how these had been addressed by the doctor or specialist nurse in the follow-up consultation. At time point one (that is the first follow-up visit almost immediately after completing treatments such as surgery, chemotherapy and radiotherapy and having just commenced endocrine therapy) 80 responses were received, of which 4 omitted this question, leaving 76 replies relating to troubles/ problems. The most frequently mentioned problem, cited by a quarter of the women, was fear of the cancer recurring and an associated fear of dying from the disease so it seems that this remains an overriding concern for the majority of women.

> *How do I know if the cancer is elsewhere? No one will tell me if I have been cured* (participant 11) D
>
> *I get very stressed about the cancer coming back again. And if stress triggered it in the first place, I am not free of stress now* (participant 30) N
>
> *You always worry if the cancer will come back, and will it be in a more serious form* (participant 44) N

The next three most common problems, receiving nearly the same number of responses as each other were all within the physical domain. These were firstly hot flushes and night sweats, presumably resulting more from ovarian damage caused by chemotherapy as most women would have only been on Tamoxifen short periods of time at this point. Whilst hot flushes can occur instantly when starting endocrine therapy, they are more commonly progressive, worsening with prolonged exposure to the drug.

> *The hot flushes, particularly unbearable at night* (participant 53) N
>
> *Hot flushes ++++. You just cannot describe the over heating sensation*
>
> (participant 70) D

Secondly pain, numbness and stiffness at the operation site, including the breast and chest wall area, the armpit and the upper arm and shoulder, presumably because less time had passed for healing at this early stage in their recovery. As healing tends to improve over time it is likely that this would feature less significantly in women who had been on follow-up for a couple of years or more.

> *I am very tight over my scar line* (participant 21) *N*

> *My stiff arm and the awful tenderness in the affected breast* (participant 29) *D*

Thirdly, severe and persisting tiredness and a lack of energy.

> *I get tired so easily* (participant 73) *N*

> *No energy for anything. I seem to be always tired* (participant 66) *D*

Other frequently cited problems were worry about family members coping with everything that had happened to their loved one, and worry about them, specifically daughters getting breast cancer, because their mothers had.

> *The thought of my daughter getting breast cancer and how on earth my husband would cope with that as well* (participant 39) *N*

Thus problems cited correlate with the literature and revolve around fear of new disease, treatment related physical side effects and concerns for family members.

A few women mentioned weight gain. Three problems were mentioned each by only one respondent, which were a recurrent seroma, coping with the shopping and cleaning and nausea. Only four women stated that they had no problems or troubles to report.

At time point two, that is six months after commencing routine follow-up, 75 responses were received, of which 3 omitted this question, leaving 72 comments in total. The four most frequently occurring problems overall remained the same as at time point one, those of fear of recurrent disease, hot flushes, pain at the operation site and tiredness/ lack of energy. However the rank ordering of these had changed, with hot flushes being the worst problem and fear of recurrence scoring less numbers of responses than the other three problems. This might indicate lessening fear of recurrence as more time passes and might also be indicative of the notion that physical symptoms become more troublesome (and wearying) the longer they persist without resolution. A few problems were again mentioned each by only one or two women, such as poor sleep patterns, high stress levels, dry skin and self consciousness when meeting people. Eleven women now stated that they had no problems or troubles, nearly a threefold improvement from time point one.

At time point three, that is approximately nine months after commencing routine follow-up, 73 responses were received, of which 7 omitted this question, leaving 66 comments in total. Once again, four most frequently occurring problems were fear of recurrent disease, hot flushes, pain and tiredness/ lack of energy. However, hot flushes become more significant, scoring significantly higher than the others in terms of the number of times it is cited. The numbers of women citing tiredness and lack of energy as a main trouble had depleted to less than a fifth, whilst the prevalence of those citing pain remained proportionately the same as the previous time points. However here the nature of the pain had notably changed from post operative to pain to that the women more commonly associated with the radiotherapy.

> *My breast is so hard and tender and red since the radiation* (participant 58) D

Proportionately a few more women reported weight gain and similarly a few more reported having no problems than at the previous time points. Five women mentioned low mood and anxiety for the first time, all of which were being followed up by doctors.

> *I feel very down a lot of the time. I am sure my anxieties are irrational but I can't help feeling continually low and vulnerable* (participant 17) N

Some women continued to cite family members as their main problem, but not in terms of their coping as at baseline but only in relation to them, specifically daughters and granddaughters, getting breast cancer as a result of a hereditary risk.

> *I cannot stop thinking about my daughter and whether she will get it. Not much of a legacy from your mum is it?*(participant 22) D

At time point four, that is twelve months after commencing routine follow-up, 73 responses were received, of which 11 omitted this question, leaving 62 comments in total. Interestingly here, the highest ranking score pertained to having no worries or troubles to report, with over a quarter of the women stating this.

> *Nothing, everything has improved now* (participant 60) *D*

> *Everything has healed, I have my bounce well and truly back* (participant3) *N*

However, nearly as many women continued to report hot flushes and fear of recurrent disease. Proportionately far fewer women continued to suffer from tiredness/lack of energy or pain/tenderness in the affected area than at previous time points. A couple of women mentioned fear of developing lymphoedema, poor sleep patterns, weight gain and vaginal soreness. Clearly menopausal effects of therapy, specifically hot flushes, persist over time with little or no relief or improvement.

At the final time point, that is fifteen months after commencing routine follow-up, 70 responses were received, of which 14 omitted this question, leaving 56 comments in total. Proportionately even more women, nearly half, reported no problems or troubles. Similar numbers mentioned hot flushes or discomfort but of these many noted that, although still present, they were notably improved.

> *A few painful niggles, but nothing compared to what they were like six months ago* (participant 11) *N*

> *Some hot sweats still at night but they are actually much better than they were* (participant 47) *N*

Of note fear of recurrence existed for women at all ages, regardless of the time point. Similarly reports of tiredness and depleted energy were distributed evenly across all age ranges. However hot flushes were more predominant in women aged between 42 and 63 years. This might reflect that chemotherapy is more likely to induce menopause in women over forty years than in younger women and older women who are many years past a natural menopause are less likely to be given chemotherapy or to have symptoms recurring with the commencement of endocrine therapy.

The most frequently cited way that the above troubles were helped during the follow-up consultation related to receiving reassurance and being told that symptoms and feeling were normal. At all time points this was most commonly stated and accounted for about a quarter of all responses to this question.

> *The reassurance you get is worth its weight in gold* (participant 77) N

> *You worry about something you can feel and then they tell you it is completely normal, it's just scar tissue or something like that and you go away walking on air* (participant 55) D

Closely linked with reassurance is receiving clear explanations and practical advice and having all one's questions answered and, again across all time points, this was ranked the second most helpful intervention for addressing and resolving troubles or problems.

> *Understanding why something is happening means the world to me. If it makes sense, I don't worry!* (participant 66) D

> *I got some practical advice about my bra and prosthesis and it worked wonders* (participant 2) N

Being listened to and taken seriously, regardless of how trivial the question seemed was also consistently ranked highly at all time points.

> [Name of specialist nurse] *always listens carefully, no matter what I say. If it's something she has heard a million times before, she certainly doesn't show it* (participant 33) N

> *Knowing I can ask absolutely anything, no matter how stupid sounding is a great comfort blanket* (participant 50) N

Interestingly, being examined was not ranked that highly for resolving troubles. It was only mentioned at time points 3, 4 and 5 (months nine to fifteen), not early on and then only by three or four women. This raises the paradox of women wanting to attend for follow-up and rating reassurance so highly, versus finding the biomedical approach (the clinical examination is the main purpose of follow-up according to doctors) somewhat meaningless. One response found helpful was a friendly, relaxed approach by the health professional as this enables the woman to feel more relaxed herself and took some of the tension out of the consultation.

> [Name of specialist nurse] *is always so relaxed and friendly. She never looks worried so I stop worrying as well. Just seeing her smile when I walk in is a tonic in itself!* (participant 79) *N*

Other helpful interventions mentioned by one or two women were being referred to a specialist menopause clinic, having an in depth discussion about hormone replacement therapy and being offered extra physiotherapy sessions.

Other ways in which the health professional in the clinic responded to troubles mentioned included recommending the woman give the problem more time to resolve itself, suggesting she see her GP instead, and informing them that there was no solution or intervention to that problem.

> *He* [the doctor] *said he was sorry I was suffering but there was nothing he could really do to make it better, so I never mentioned it again* (participant 41) *D*

Of note substantial numbers (approximately one fifth) of women at all time points stated that they did not mention any of the problems or troubles they had. Reasons given for this were that it was not within the remit of the follow-up clinic, the health professional was not interested in hearing it, it had been mentioned before but no advice was given, or a reluctance to take up too much time.

> *I don't think they want things like weight gain reported. What could they say anyway?* (participant 39) *N*

> *I tend not to mention it, I don't think it is relevant to the examination* (participant 62) *D*

Approximately one quarter of the respondents omitted to write anything when asked about interventions employed in response to troubles mentioned. It is not clear if this is because they did not mention any problems in the first place or because no help or intervention was offered.

Frequency and Provision of follow-up visits

At all time points across all women at all ages the frequency of clinic visits, that is three monthly, was deemed about right by almost all of the participants. Only a couple of women suggested they would like to be seen more frequently but made no comment as to why. The few that preferred being seen less often also made little comment, except that they simply did not see a need for more frequent visits.

When asked about preference for the health professional providing the follow-up consultation (that is doctor or clinical nurse specialist) nearly all of the women randomised to see the nurse stated they would prefer only a nurse, with a few stating no preference or alternating the nurse with a doctor. No women in this group chose to be seen by a doctor only.

However, in the group randomised to see the doctor over half of all responses at all time points indicated a preference for a nurse specialist only (with back up from a doctor only when necessary) even though this group of women had never been exposed to nurse-led follow-up care. This corroborates with the differences in increasing and decreasing satisfaction over time between the two groups as shown in the statistical analysis. Of the remainder, the majority indicated no preference or wanted to see both professionals alternately. Less than ten percent of the women in this group preferred to see only a doctor, having been exposed to this model of care.

Positive and Negative aspects of breast cancer follow-up

The final free text questions asked the women to comment on aspects of their follow-up that had been particularly good and those ways in which follow-up could be improved. The women seen by the nurse detailed the positive aspects of follow-up as continuity, being seen regularly, being given adequate time, being taken seriously and feeling able to raise any issue, regardless of its nature.

> *I can raise absolutely anything and I know I will be listened to and not rushed. You don't feel as if you have been a bother* (participant 50) *N*

The majority of the women also made comments about the personal attributes of the specialist nurse conducting the clinic and commented that her friendliness and approachability were significant contributors to their satisfaction with the consultation.

> *She is wonderfully caring and attentive, just seeing her smiling face puts me at my ease* (participant 43) *N*

> *Her happy and optimistic demeanour and her personal touch is very special to me* (participant 9) *N*

In addition women rated their faith in the competence of the specialist nurse as a positive aspect of the clinic.

> *She* [specialist nurse] *is very thorough. I really feel I have been checked over* (participant 26) *N*

> *I feel assured that I am being carefully monitored and, probably most importantly, I trust her* (participant 43) *N*

The most commonly cited word overall that epitomised the women's views on the positive aspects of follow-up was *'reassurance'* which appeared on over three-quarters of the questionnaires completed by women in the nurse-led clinic.

Almost all of the women wrote nothing when asked about things that were not so good about follow-up. The few that did make a comment suggested they would have liked more information (preferably written) to warn them about the longer lasting affects of treatments such as hot flushes and more opportunity to join a patient support group at the hospital. The only negative aspects cited about the practicalities of the clinic were waiting around at the hospital at each visit and not enough flexibility in terms of the days and times they could attend for the visit, but these were only mentioned by very small numbers of women overall.

The most frequently stated positive aspect of follow-up, as reported by women seeing the doctor was being checked regularly.

> *Knowing you have been looked at, that you are OK there and then* (participant 51) *D*

Noticeably, far more women omitted to write anything for this question perhaps indicating a lack of strength of feeling about the positive aspects of doctor led follow-up. Reassurance was again a frequently cited word, although less so than with women receiving nurse-led follow-up. Generally the positive aspects listed pertained to the system in general, rather than the health professional, as was the case with the nurse-led clinic. These included meeting other patients in the waiting area and being able to swap stories and experiences, and being retained in the system, thus knowing access to care is there if one needs it. Only one or two women commented on the doctor's attitude as being 'friendly, caring and warm'.

The majority of comments pertaining to negative aspects made by women seen by doctors related to the lack of continuity with regards to whom they saw each time and this was mentioned by nearly all of the respondents.

> *I have never seen the same person twice* (participant 74) *D*

> *They just never know me or my case and you feel like a number on a conveyor belt* (participant 6) *D*

The second most commonly cited negative aspect related to the time allocated, particularly waiting a long time to be seen and then feeling rushed during the consultation.

> *I hate queuing to be seen, you wait hours sometimes and then the examination is so quick and not always very thorough* (participant 40) *D*

The lack of time resulted in many women feeling unable to address all of the issues that they wanted during the consultation.

> *They are just too busy to talk things through so I never mention everything that I had planned to say* (participant 15) *D*

> *I felt a bit palmed off. The surgeon was too remote and quite dismissive of my symptoms. I think he only wants to hear about new lumps* (participant 71) *D*

In contrast to the women in the nurse-led clinic, the third most frequently mentioned negative aspect of follow-up visits was that issues were not addressed or resolved.

Specifically some women mention that absence of discussion about cure and imply less reassurance achieved overall.

> *They never have any answers or solutions to the tiredness, so it seems a waste of time to even mention it anymore* (participant 4) D
>
> *The visit is patently physical, to examine the breast, so emotional fears don't get a look in* (participant 27) D
>
> *They never explain what my prospects are. I have never been given the all clear and actually I wouldn't know if I am cured or not* (participant 56) D

Finally, some women mentioned the lack of routine surveillance tests as a negative aspect and felt more frequent tests would indicate absence of disease more conclusively, therefore implying that the rationale for not conducting these tests had not been adequately explained.

10.5 Summary

Both questionnaires reveal greater satisfaction among women seen by a specialist nurse, compared to those seen by a doctor, in almost every category measured and at most time points. These differences reach statistical significance in the majority of cases, more so with the 'Your views of follow-up' questionnaire than with the FACT-B. In addition there was some suggestion of satisfaction among women receiving nurse-led follow-up increasing over time, whilst dissatisfaction with doctor-led follow-up was commonly seen to worsen over time. The qualitative data reveals potential sources of dissatisfaction which include poor continuity, hurried consultations, not being listened to, cursory or inadequate examinations and a failing to obtain much needed reassurance. These aspects are discussed in chapter eleven.

Chapter 11. DISCUSSION AND CONCLUSION

11.1 Introduction

This chapter considers the contribution to knowledge arising from this research and personal reflections on the experience. The contribution to new knowledge is set out by considering the project as a whole, revisiting the study aims and discussing the key findings. The strengths and weaknesses of the research are also appraised and suggestions for future studies are detailed, as well as recommendations about possible models for optimum provision of breast cancer follow-up.

The thesis began with a review of literature exploring the needs of women after treatment for breast cancer and the basis for the clinical practice of breast cancer follow-up, as well as issues surrounding evolution and role function of advanced nurse practitioners. This revealed ongoing individual need in this setting, not always taken in to account by health professionals when planning services, and limited efficacy of the traditional practice of medical follow-up for various reasons.

To address the research questions, namely the pros, cons and essential facets of breast cancer follow-up, and the advantages and disadvantages of nurse-led versus medical-led follow-up, three studies were conducted using a combination of qualitative and quantitative methods. Together these explored follow-up care, predominantly from the perspectives of those who attend it, but also in conjunction with those who provide it. The overall aim of the work was to evaluate nurse-led follow-up care. The results demonstrate corroboration with findings from previous research but also generate new knowledge in this important and politically relevant area. The work is discussed in light of the previously stated objectives of the three phases of the work.

11.2 Key Findings from Phase One: Exploration of current follow-up practices

11.2.1 Describing the emotional and physical impact of undergoing treatment for breast cancer

Data from the interviews with women and the focus group with doctors highlight the significance and magnitude of the impact of being treated for breast cancer. The resultant array of needs can be categorised as physical, emotional, informational and social. Physical symptoms attributable to breast cancer treatments experienced by women in this study concur with those reported by other researchers and include pain and discomfort, hot flushes secondary to treatment induced menopause, and fatigue. Emotional needs pertain mainly to fear of recurrent disease, and also concerns for passing on a breast cancer risk to family members. Interestingly the women in this study did not give great prominence to sexual attractiveness, as also reported by Luker et al (1995). Informational needs pertain to unanswered questions about breast cancer and treatments, such as the significance of features reported in the pathology on overall prognosis, and social needs relate to problems with incomes and insurance. As health care providers involved in the delivery of breast cancer follow-up we might commonly acknowledge that side effects of treatment occur but we rarely consider their impact and meaning for the individual, that is cancer is clearly an experience of both mind and body that continues long after the treatment is completed.

11.2.2 Identifying subsequent care needs after treatment is over for those that remain free of further disease

Feeling reassured is one aspect of the communication process that was monumentally valued by almost every woman and this was the most frequently used word in the qualitative analysis of the interview data. The perceived necessity of receiving reassurance probably derives from an uncertain outcome in terms of being cured from breast cancer. Women evidently have an enduring sense of vulnerability that is present regardless of the significance of the risk of cancer recurrence (Hassey-Dow 1990).

It is a well documented phenomenon that whilst women are often relieved to finish all of their treatment, they can also experience feelings of anti climax because their long period of contact with the hospital has come to an end. The women reiterated that the hospital is clearly associated as a safety net and they become fearful about losing the specialist contact when their treatment is over. One reason why most women demonstrate an explicit preference to continue hospital-based follow-up may derive from the generalised trust that they have in hospital doctors, because they are perceived as specialists in what they do.

The ability of women to communicate effectively relies partly on their having confidence to do this. It could be surmised that feeling vulnerable and uncomfortable at the time of the consultation is one way in which this confidence is reduced. The interviews highlight that having to wear gowns and/or being talked to in a state of undress contributes to feelings of vulnerability. Care needs to be taken to ensure women have adequate time to get dressed following a physical examination. The lack of privacy evidenced through hearing other women's conversations with the doctor may also make communication difficult. Ideally, an environment which allowed an examination in a cubicle, followed by a consultation in an office, thus separating the two events, would ensure women were not given medical facts or forced to ask important questions without even the dignity of clothing. However it is acknowledged that this may not be feasible in terms of existing outpatient department designs and the resources that may be needed to change their layout.

One could speculate that the gender of the doctor might contribute to the woman's perceptions of the consultation, in view of the essentially female client group and the obvious associations with the breast and fertility/ sexuality. Just over half the women in the interviews preferred to be seen by a female doctor. As currently the majority of breast care nurses and people with breast cancer are female and most surgeons are male, an investigation of the influence and possible threat of males on an essentially female situation would make an interesting further study.

11.2.3 Describing the strengths and weaknesses of the current system

Key strengths of conventional hospital based follow-up as stated by the women and the doctors were access to expertise and the rapid availability of diagnostic tests if needed, and specialist facilities. Interestingly, further analysis demonstrated that these features were particularly important during the early stages of follow-up as women felt more vulnerable at this time. A further advantage is that provision of follow-up implies caring, rather than being left alone to cope and thus relates to a desire for maximum optimum psychological benefit. Themes such as an ongoing desire for knowledge and support during uncertainty, as well as seeking control during unpredictability are apparent in this work.

Weaknesses of conventional medical follow-up apparent from both the interviews with women and the focus group with doctors include inadequate time devoted to the consultation that hindered all of the individual's problems being raised and fully discussed. Hurried consultations left doctors frustrated and women feel unable to raise emotional or psychological issues. Many of the women were of the opinion that the consultation was too focused on their physical needs and it is probable that the physical impact of cancer and its multiple treatments has the potential to absorb or hide the emotional impact (Carbone 1996). Sadly, there appears to be a perception among women and some health professionals that symptoms occurring as a result of treatment are less important because the disease has been eradicated.

Perpetuating this, the doctors were more amenable to addressing issues that could be responded to surgically or pharmacologically, and subsequently were more likely not to address emotional suffering. They admitted that they would be less likely to offer interventions for non-physical issues reported by the women, largely because they are unable to offer anything of substance that might lead to resolution of the problem. Similar attitudes were reported by Moore et al (1999) in which the doctors in lung cancer follow-up clinics placed an emphasis on recording physical symptoms in the medical notes, with very little reference to psychosocial problems. It was speculated that this was because they were reluctant to record problems for which they had little to offer in the way of interventions. Doctors are in a position to determine what kind of data they elicit in a consultation by adoption of a biomedical approach to their questioning that establishes clinical problems as the priorities (Rosser 1981). The focus group doctors explained that the repetitive nature of the breast cancer follow-up clinics often meant that they explained issues 'using the same patter', because they had explained it so many times before, irrespective of the needs of the person sitting in front of them. However, this approach clearly fails to recognise the individuality of women. For women who will differ greatly in their needs, resources and understanding, uniform disclosure is unlikely to be a constructive communication approach (Schain 1990).

Another weakness of conventional follow-up and a conceivable explanation for its apparent inability to resolve key problems is poor continuity. The lack of continuity provided by the doctors at the clinic was deemed unacceptable by the vast majority of participants in the interviews as well as by the doctors in the focus group. This promoted insecurities and dissatisfaction among the women who expressed grave concerns that the doctors were unfamiliar with their medical history and may, therefore, be less safe. Similar themes are apparent in the literature (for example Adewuyi-Dalton et al 1998, Moore et al 1999 & 2002). Continuity is relevant not only to safety but also success in resolving individual needs and as such can be considered more than a mere luxury desired by those attending.

11.2.4 Identifying ways in which organisation and delivery of conventional breast cancer follow-up care could be improved for women and health professionals

Taking into consideration the women's and doctors opinions of breast cancer follow-up, some refinement towards person-focused care is necessary. This work highlights the enormous value of successful communication during the follow-up consultation. Poor communication is likely to be exacerbated by both women and health professionals. For nearly all women the overwhelming concern was that further disease/recurrence would be discovered. Thus assessment of individual needs, especially those relating to the possibility of disease recurrence, may enable use of specific interventions aimed at alleviating such fears in the future. The adequacy of communication and support at one visit could directly influence the individual's perceptions of the next visit and appropriately targeted explanations and reassurance may serve to minimise key concerns and facilitate coping.

One option may be that the set appointment system could be more flexible within a given framework of frequency. That is, the doctor could discuss with a women when their next appointment should be. While a completely open access clinic is probably not indicated for most women, a combination of set appointments and open access may also be helpful in accommodating their needs, such as agreeing with an individual that they should return at some point within the next six months. This may enhance access to hospital staff and reduce the feeling of being 'tied' to set appointments for some women for whom this is problematic. Preserving access to an otherwise forbidding hospital system must be an important component of follow-up care (Brada 1995).

Strengths to be capitalised on through training and resource planning include behaviour that inspires confidence, such as the doctor knowing and understanding the clinical case; but interestingly doctors of various grades successfully inspired confidence if they had good interpersonal and communication skills, suggesting that rank or seniority alone are not enough to ensure women are satisfied, if the accompanying skills are lacking. One skill that women valued was the doctor not asking questions when the answers were already in the medical notes, as this inspired confidence that they knew the unique clinical details of the person in front of them. The current system for training doctors makes continuity of care harder to achieve, as consultants are mostly overseeing the care of newly referred and newly diagnosed patients, and junior doctors are rotating round in to different posts. However, provision of follow-up care by a Breast Care Nurse Specialist might enhance continuity, as these posts do not involve regular rotation or multiple levels of rank.

Other valuable interventions are ensuring the recipient of care knows what is expected of them, in terms of reporting symptoms, and also knowing what is normal. Taking the time to explain why something is experienced and emphasising that it is entirely expected and innocent is an effective way of alleviating worry as captured by a participant during the interviews.

> *On my fourth visit to the clinic a new doctor happened to explain that the shooting pains I had reported for the last nine months were normal and were due to nerve damage during the operation. He seemed surprised that I didn't know that they were nothing to do with new cancer and I sat there thinking if someone had told me this before I wouldn't have spent all these months worrying myself about them.* (participant W)

Similar processes are alluded to by Paterson et al (1999) who describe a strategy of normalisation that they term restructuring the illness experience. This involves the professional assisting the person to make a shift as to how they perceive their illness, for example from an insurmountable threat to something one can tackle head on. This is achieved by re-framing what is realistically possible, as well as the losses caused by the disease and treatment, and acknowledging the inevitable limitations they cause.

With many women deriving little or no reassurance from the clinical examination and the tests conducted at routine consultations, there is an indication that other means should be sought for reassuring women about possible disease recurrence such as teaching them and their partners breast awareness, especially as evidence suggests women are already more efficacious in recognising disease earlier on than routine surveillance. Evidently an approach that acknowledges the validity of women's knowledge and makes it possible for them to take an active role in the follow-up consultation is appropriate (Burkey et al 1997).

11.3 Key Findings from Phase Three: Evaluation of nurse-led follow-up

11.3.1 Identifying further subsequent care needs after treatment is over for those that remain free of further disease

The multi-dimensional ongoing needs of women have been discussed, however subsequent data arising from the FACT-B questionnaire indicate these physical concerns improve over a 12-month period, presumably because physical healing is ongoing over time. Whereas emotional, functional and social concerns remain largely stable over the first 12 months with some fluctuation but no significant improvement observed. It may be that recovery from breast cancer is in some way sequential in that women have to deal with some issues before others (Young-McCaughan 1996). For example pain may need to be resolved before attention turns to one's femininity, further highlighting the individual nature of recovery and that needs are not only ongoing but also changing over time. It would be interesting to extend this data collection to explore whether resolution of these concerns appears and how many years this takes. Women's perceptions of well-being in these areas may also be influenced by how they are coping with other aspects of their recovery. For example, pain or fatigue may be exacerbated if they are also emotionally distressed and highly anxious. It is perhaps unlikely that symptom measures apply to individuals in isolation.

The importance of obtaining reassurance was further substantiated in the randomised trial. When the women were asked in the randomised trial what intervention during the follow-up consultation they perceived would help most with their ongoing needs and problems, nearly all mentioned receiving reassurance and being told that symptoms experienced were normal. This exigency for reassurance is supported by other studies (for example Campbell et al 1997, Pelusi 1997 and Moore et al 1999) and thus raises the important question of what actually constitutes reassurance as perceived by those wanting it. A Thesaurus check on possible substitutes for the concept of reassurance revealed the descriptors of comfort, solace, optimism, encouragement and cheer. However, reassurance is more than being convinced that no new disease has been found and is derived as much from the attitude of the health provider. A professional who successfully inspires confidence, thus generating optimism and providing comfort, is perhaps more likely to reassure the women. A challenge lies in finding ways in which women can work though their fears of disease recurrence and death, and hence leave the clinic feeling reassured.

11.3.2 Comparing the outcomes of provision of breast cancer follow-up by doctors and a specialist nurse

In the randomised trial, the women's acceptance of nurse-led follow-up was very high and sustained throughout the study period. Once women had experienced follow-up from a nurse they were very satisfied with that care, none of the women in the nurse-led clinic would choose medically led follow-up and nearly all would choose this model again, compared to only less than 10% of those receiving conventional medical follow-up. In addition, only a handful of women seen by the nurse would choose to be seen by both a doctor and a nurse, suggesting the nurse alone was sufficient and not just an add on to medical care. This sentiment is supported in other studies, such as Faithfull et al (2001) and Moore et al (2002).

In comparison, over a third of women receiving medical follow-up obviously did not regard the doctor alone as sufficient for their care and wanted a specialist nurse involved as well. The implication is that these women identified that something was missing from their care when seen only by doctors. It is conceivable that nurses, by nature of their training and vocation, bring a different focus to the consultation and a willingness to discuss emotional and sensitive issues and to explore individual fears.

In attempting to elicit exactly what it was about the nurse-led care that resulted in greater satisfaction for the women, it would seem key elements were that I successfully took an interest in people, giving them the chance to speak and ask questions, listening to all of their worries, and taking their views in to account when exploring solutions to problems. Such actions are more likely to result in referral to other resources and professionals that will make a contribution to resolution of problems (Fredette and Beattie 1986). Hence women seen in the nurse-led follow-up clinic reported extremely high levels of satisfaction with the nature and amount of information received as well as with the standards of supportive care. Support is a broad and somewhat nebulous concept and in order to ensure the data is meaningful it is important elicit what precise aspects of the interaction the participants deemed supportive. One such component (found also by Pistrang and Barker 1992) was the opportunity to discuss concerns and feelings freely. Being able to talk about fear of recurrence and confide in people lessens the chances of such fears being blown out of proportion and reduces worries, allowing women to be more realistic about their circumstances (Northouse 1981). Another supportive component identified by the women was receiving appropriate and easy to understand information in response to questions raised so that any misconceptions held were clarified. Overall, the difference between the two groups in scores for rating of support received (on a visual analogue scale) was statistically significant at each time point, with women receiving nurse-led follow-up consistently reporting higher levels of satisfaction with support received.

Not all of the elements of satisfaction in the 'Your views of follow-up care' questionnaire consistently improved with nurse-led follow-up, nor were all improvements in satisfaction in either group sustained over time. Areas that remained stable over time, for example satisfaction with information and advice and confidence in the physical examination as reported by women seen in the nurse-led group, imply continuing care over time may merely sustain rather than improve satisfaction levels further. Areas that initially remained stable, but then gradually improved or deteriorated over time, for example feeling involved in the consultation, might indicate that women need time to assimilate their needs and assess how they are being met. Also the women will have got to know me better over the months and thus began to recognise the benefits I provided such as continuity and familiarity.

Whilst the questionnaire on 'Your views of follow-up care' related more to the process of follow-up, the FACT-B questionnaire revealed data relating more to the outcomes of follow-up, that is multi-dimensional well-being. The women differed between the 2 groups with their baseline scores of physical well-being and the section on additional concerns (including sexual attractiveness, weight changes and arm swelling), suggesting that those in the nurse-led care group may have been different in some way to begin with or had had less complicated disease or treatments. This leads me to exercise some caution as to whether these baseline differences occurred by chance alone or whether there are alternative explanations.

Slight differences in the treatments that each group had, for example conservation surgery versus mastectomy, may have influenced their physical and emotional baseline scores and thus their recovery and well-being throughout. Not all of the women were recruited to the trial from the same clinic lists and whilst they had all had the same consultant surgeon, they will have been exposed to different consultant oncologists for both chemotherapy and radiotherapy. This information was not collected so there may have been differences in the quality of care previously received by each group, for example with regards to explanations and information provision prior to commencing follow-up. Similarly I did not 'measure' each woman's previous exposure to a clinical nurse specialist in breast care, as conceivably women who had accessed their input more may also have been better informed and supported prior to commencing the trial.

In some areas, an improvement in satisfaction over time was seen in women followed up by a doctor or a nurse. Notably physical well-being, additional concerns and supplementary issues (such as hot flushes) improved over time in both groups and this was consistently more pronounced and statistically significant in the women who received doctor-led follow-up. This may be because doctors conventionally place a greater focus on physical and symptomatic (biomedical) aspects of care and may also be more equipped to practically manage these, in that they can, for example, prescribe analgesic medication or hormone replacement therapy. Indeed, scores for supplementary issues were higher in the nurse-led group at baseline and at 6 months but improved proportionately less over time suggesting areas in which I was less able to address need than the doctors. My inability to prescribe medication was frustrating and sometimes slowed down the progress of my clinic. For example I was unable to supply further tamoxifen or antibiotics for post operative wound infections. Recent advances in expansion of the authority of nurses to prescribe could ameliorate this in the future but only if the nurse was adequately prepared and trained.

Rating of functional well-being (such as enjoying hobbies) was also closely matched. There were no statistically significant differences in scores for functional well-being at any time points between the two groups and levels remained stable over time in both groups.

Baseline scores for emotional well-being were the same for each group, but women receiving nurse-led follow-up reported statistically significant higher levels at 6 and 9 months. Also, levels of emotional well-being appeared to remain stable over time in both groups of women. Thus, although I may have addressed emotional concerns more effectively than the doctors, this was consistently sustained and any interventions on my part did not result in improvements over time. Similarly the doctors did not make emotional well being worse over time.

Areas in which satisfaction remained stable over time with the nurse but declined over time with the doctor included social/family well-being, suggesting doctors are less able or willing to attend to concerns such as relationships with family/friends or financial matters during the follow-up consultation. Interestingly there was a dip in social well-being at nine months in both groups and this might be because women were returning to work after recovering from treatments and beginning to focus on financial and family issues that had previously taken less precedence.

11.3.3 Identifying alternative models of breast cancer follow-up care

Do we need breast cancer follow-up?

Certainly the evidence indicates that conventional follow-up is clinically flawed and fails to adequately meet individual needs or resolve the key issues for significant numbers of the women concerned and thus continuing with this model seems unreasonable. Solutions to this problem may be evasive in the current climate of large numbers of people being seen and increasing demands on staff. Completion of treatment brings with it changes in the relationship with the health care team, and women may have difficulty balancing the relief of knowing the treatment is over versus fear arising from the loss of close supervision (Fredette 1995). Professional support undoubtedly diminishes as the recovery period progresses, despite evidence that issues continue for months if not years after completion of therapy (Wong and Bramwell 1992, Smyth et al 1995).

The updated document on breast cancer service guidance, produced by the National Institute of Clinical Excellence (NICE 2002) since this work was conducted recommends that routine, long term follow-up should cease after two to three years, but this study indicates that merely ceasing to provide follow-up is unlikely to represent best care. Women attending for breast cancer follow-up were not consulted and the suggestion of indefinite open access to breast care nurse specialists in place of the follow-up clinic visits is somewhat flawed. Many of the participants in this study did not want to make appointments via an open access system and felt that they would prefer a set appointment system, and several studies demonstrate women want to continue to be seen by hospital based professionals (Loescher et al 1990, GIVIO 1994). In addition, breast care nurses were not consulted about the projected increase in workload arising from this reconfigured care, and no provision for extra posts has been forthcoming since the release of the guidelines. Another conundrum is that the basis for reducing follow-up care is its proven inefficacy in detecting recurrent disease more efficiently, yet advances in technology may rectify this situation. For example preliminary tests on small numbers of patients have indicated significant improvements in detection of recurrent and metastatic breast cancer with the use of positron emission tomography (PET) scans (Siggelkow et al 2003).

Women are undoubtedly an essential source of data about how breast cancer follow-up functions and they have a right to have their views taken into account when planning and evaluating new models of service (Avis et al 1995). Interestingly, it is not only women who crave reassurance from persisting with follow-up. Research suggests that doctors continue to fail to discharge women from follow-up and order tests even when evidence indicates this practice of surveillance can be reduced without compromising the clinical outcome for the woman (GIVIO 1994). A recent evaluation of breast cancer follow-up practices of over 200 American surgeons revealed that all of them maintain surveillance post completion of treatment and half continued performing blood chemistries and chest x-rays (Stark and Crowe 1996) . Of course the differences in health care systems and litigation processes within the UK and USA are acknowledged. The doctors in the focus group concurred with this and admitted that the main incentive for their actions was based around litigation. Nearly all of the participating doctors, regardless of seniority, shared the concern of not wanting to take the risk of missing something or making a mistake. Whilst understandable, this sentiment further supports the notion of follow-up practices designed with the system (or the providers), rather than the recipients, at the core. Such an approach cannot be regarded as person-centred, irrespective of government papers claiming otherwise. It is paradoxical to perpetuate a climate of dependence by frequently initiating clinically unnecessary or unproven tests and then expecting women to accept withdrawal of follow-up care or refusal to investigate symptoms that they perceive as frightening and very real.

However some sort of follow-up model is arguably needed. Widespread discharge of women early on will only serve to perpetuate their feelings of abandonment and anxiety and will do nothing to offer the reassurance that women in this study so obviously craved. Unfortunately, recognising survivorship needs exist and identifying expectations and doing something about them are not the same thing and there is little research that attempts to identify and evaluate ways that such problems and needs could be usefully addressed and resolved. Consideration should be given to the 'processing' of women through clinic and the consultation itself. Individual satisfaction appears to be multi-dimensional and significantly influenced by the provider of care as well as the setting in which it takes place. However it can be difficult to separate different dimensions or to evaluate the weighting of each since there will be differences in their relative importance among different individuals. Any future attempts to formulate policy and introduce new models of follow-up must recognise the diversity of individual need and preference as well as women's expectations (Beaver and Luker 2005). Obviously cost implications cannot be ignored and it may be difficult to justify vast expenditure in areas with limited clinical value because the women desire it. However it could also be argued that targeting resources at those who are newly diagnosed and undergoing treatment does not excuse the neglect or abandonment of survivors who may still have salient needs (Abbey 1997). Indeed, Clark (1990b) reminds us that it is indefensible to avoid measures of outcome whilst relying solely on measures of output. Of course, economics and human care are interrelated and ability to provide care will always be dependent on economic resources. If economic resources preclude optimum nursing care, then it is arguable that health professionals nurses have a responsibility to make the public aware of this, or at least to change the expectations of the people they serve so that they do not consistently continue to fall short in provision of care.

Who could provide breast cancer follow-up?

Previous research into individual preference for the source of information received suggests that it is usually the doctor whom people chose to receive information from and that doctors are viewed as more knowledgeable and more credible, especially concerning technical information (Oberst 1984, Karani and Wiltshaw 1986, Suominen et al 1994). However, just over half of the women in the interviews suggested that follow-up should be provided by a breast care nurse and the majority of participants supported the idea of some form of nurse-led follow-up care, as did the doctors in the focus group. Karani and Wiltshaw (1986) suggest that people with cancer need someone who is cognisant of their feelings to provide them with information and that a specialist nurse may meet this need because they are seen to be approachable, available and clinically credible.

The nurse-led follow-up provided in this research continued to operate according to a traditional model of care and as such, was fairly constrained in what it could achieve. Offering nurse-led care resulted in equal or greater satisfaction as perceived by women for most, but not all categories measured. However this model is not without flaws. It may not be feasible to train up sufficient numbers of specialist nurses to conduct breast cancer follow-up and many more nurses would be needed to accommodate this extra workload whilst also sustaining their existing activity. In addition, this model perpetuated the biomedical, that is clinical examination, approach to the consultation, which was identified in the literature review as having very poor efficacy. It seems inadequate to repeat the same model but with a different health professional, albeit a nurse who may provide superior care in areas such as emotional support and information provision.

In considering provision of follow-up by nurses, there is an explicit need to further identify components of care that are specifically attributable to nursing, because if nursing specifically can be shown to positively benefit women's outcomes its claim for greater dependence and professionalism will gain momentum (Bond and Thomas 1991). Outcomes are traditionally defined in the biomedical terms of the health status of the person, but an outcome could equally be the woman's knowledge following that episode of nursing care. Reasons for shifting the traditional boundaries of the clinical professions (and promoting nurse-led care) include increasing quality and satisfaction as perceived by the recipients, making greater use of the specific skills of nurses, enhancing the standing of nursing as a profession and reducing the burden on doctors (Normand and Stevens 1999).

What should follow-up consist of?

A minimum expectation is to consider a truly person-centred model of care. That individuals have differing needs regarding follow-up is not surprising as women will have differing coping abilities, social circumstances, treatment induced symptom profiles and prognoses. Yet, in spite of this, follow-up has traditionally remained routinised with everyone receiving the same schedule of care regardless of individual needs. Perhaps focusing efforts on providing more time during consultations, rather than further reducing acceptable waiting times, may be most appropriate, although it is acknowledged that the cost implications of this may render it impossible.

A truly person-centred approach might be more appropriate in order to obtain a balance between preventing women from feeling cast aside and isolated, and ensuring they are reassured by the need for less contact because they are well. As eloquently argued by Brada (1995), the perception of support engendered by attending clinic visits could be continued without necessarily perpetuating the convention of physician-centred follow-up. In the randomised trial a fifth of the women did not even bother to mention any of their key issues or needs. This may indicate that the attendees perceive that some areas associated with their disease and care might be appropriate to deal with in the consultation whilst others are not. It seems prudent to ensure women understand and agree on the purpose of follow-up if they are to utilise it effectively.

The concurrent use of a telephone follow-up system and/or weekend and evening clinics may also allow for greater flexibility and may assist with the relatively few women who expressed that their every day responsibilities made attendance more difficult, such as those caring for children or working full time. In addition, this may provide a facility for those women who do not feel able to access their GP. However, further professional and person-focused links with GP's and use of collaborative models could also be explored to enhance the availability and convenience of the service. One model of care could be to introduce a specialist nurse into a GP surgery for outreach clinics, but a drawback of this approach is that each GP surgery will probably see too few numbers of people for breast cancer follow-up to make it worthwhile. It would never be feasible to have such a system in all GP surgeries. Any alternatives to the conventional model of breast cancer follow-up that offer new avenues for improving care, whether they include nurse-led, telephone or GP input, are pointless if they merely shift the responsibility of this workload somewhere else, without actually addressing the nature of the needs of the users.

There is a need to balance convenience and cost savings with adequate support and reassurance. Previous studies have indicated that for some people follow-up is useful to gauge how well they are. If a longer interval is suggested before the next follow-up appointment, this is deemed to indicate all is well, thus the follow-up system may play a part in constructing expectations of health care and cancer in ways that have not been fully recognised (Moore et al 2002). The development and testing of a model of care designed to reduce individual dependency and increase their functional capacity would make a sound contribution to research in this field.

11.4 Discussion

During a follow-up consultation the individual's agenda is of paramount importance and to ignore it is to risk dysfunctional consultations with management being directed to issues not regarded as wholly relevant by the recipient (Middleton 1995). Yet doctors, by their own admission, may be poor at judging what is best to tell women and tend to overestimate the completeness of information given. If knowledge can be considered as empowering, than an honest approach, for example about the likelihood of disease recurrence, is essential as is correcting misperceptions that women may have. Of note, honesty may have been easier to achieve for both professionals in this trial because all of the participants had Stage 1 and 2 breast cancer and were therefore in a better prognostic group, with less likelihood of disease recurrence.

Young (1993) offers an explanation of the possible differences between the focus of the consultation between doctors and nurses that might reflect a distinction between the concepts of cure and healing. Doctors are perhaps more likely to focus on cure and therefore to adopt practices that are efficacious from the biomedical point of view, by either reversing, limiting or preventing new disease. Nurses, on the other hand, may place a greater focus on healing, and therefore adopt practices that are efficacious from the point of view of women, particularly in responding to the illness in the most optimum way. Of course in reality it is likely that these distinctions will not be as clear cut and that aspects of both approaches will determine optimum follow-up care.

McMahon and Pearson (1998) describe the potential of nursing as therapy arguing against nurses simply carrying out the instructions of doctors, and instead describing partnership, intimacy and reciprocity as the core elements of therapeutic nursing practice. Corner (1996) identifies some of the features of therapeutic cancer nursing as seeing an integrated view of the person (mind and body are inseparable), offering participative, collaborative and empowering care, and focusing care on the problem or the need rather than the symptom or treatment. All of this is in line with me as a nurse being more successful in listening to the women, informing them, involving them in what happened during the consultation and responding to their specific needs.

The type of emotional based care alluded to above can be termed as 'being there' for the woman, because mere presence (physical or psychological) can add a therapeutic dimension to the interaction taking place (Ersser 1998 p54). It can also be considered as relating to the individual, that is being available at an emotional level and actively tuning in to the needs of those being supported. Such skills are certainly more closely equated with the principles of nursing and are more likely to be capitalised on in nurse training than in medicine.

One can speculate that the nurse-led model adopted in the RCT was associated with high levels of satisfaction because it required the nurse to focus on the scientific and technical expertise of breast cancer development and examination, whilst also demonstrating an understanding of the nature of the individual lived experience of the disease (Faithfull 1994). Bond and Thomas (1991) also delineate the differences between clinical and therapeutic outcomes, the latter including broader concepts such as quality of life. Certainly health professionals and, more importantly, policy planners require a heightened awareness that follow-up needs comprise of more than a quick physical examination.

It is possible that satisfaction was influenced by the preconceptions held by women as to what nurses and doctors do. Women might already identify with nurses as someone that they can discuss emotional issues with, whilst they would not associate a surgeon, for example, with this function. This in itself could encourage broader communication, irrespective of the specific skills of the nurse seen at that time. In this way it is possible that beliefs and expectations are so relevant to perceptions of satisfaction that people may be likely to express satisfaction independently of the actual outcomes of the care provided (Linder-Pelz 1982). In the randomised study the nurse and the doctor were effectively providing the same 'package' of care, as dictated by the unit protocol for follow-up. Yet in areas where the outcomes were similar as revealed in the FACT-B questionnaire, such as functional wellbeing, satisfaction remained higher with nurse-led care, even though actual functional scores were not improved. This further supports the notion that satisfaction relates to how care is perceived as well as what it achieves. Differences on the perceptions of care provided are likely to be influenced by the unique nature of nursing input (the interpersonal and communication skills exhibited by that professional group).

Conceivably, my communication style within the follow-up consultation significantly influenced the satisfaction of the recipient. Hammond et al (1995) attempted to elicit specific differences between a nurse practitioner and a doctor in a hospital based breast clinic. The consultations were tape recorded and transcribed. The contents were then analysed using the Roter System of Interactional Analysis (Roter 1977), whereby every utterance made by either health provider is placed into categories that determine whether the communication was person-centred or doctor-centred. Similarly to my work, the results indicated that the nurse gave more detailed information and more frequently checked the women's understanding and whether they had any further questions. However doctors may be more reluctant to discuss psychosocial concerns or sensitive issues and this in itself can sometimes provoke more fear.

Salvage and Smith (2000) wisely recommend greater dialogue on how the talents of both doctors and nurses can be harnessed to improve services for women overall because this would refocus the debate on what both professionals actually do. They suggest that instead of becoming engrossed in boundary disputes, efforts could be directed on capitalising on the wealth of skills that all health professionals bring to improving health and well being. Perhaps what characterises collaboration is recognition not only of what professional groups have in common, but also their differences because both doctors and nurses have equally valid knowledge and expertise (Davies 2002).

11.5 Contribution to knowledge

This thesis has contributed the following new knowledge to what was already known about this topic:

i. Moving beyond awareness that physical, emotional and social needs exist after treatment for breast cancer, this work shows how such needs fluctuate over time and are not consistent in their resolution. Hence the work adds information to the patterns of recovery, not just their presence.

ii. This work shows the absolute and almost unanimous significance of receiving reassurance from care after treatment is over and factors that contribute to achieving this (or not)

iii. Previous studies have explored the clinical value of breast cancer follow-up but pay scant attention to what the consultation actually consists of. This work elicits which specific components of the follow-up consultation (for example being reassured, receiving clear explanations, being listened to, the clinical examination) are deemed most important to women over time

iv. In depth exploration of doctors views of providing follow-up is revealed in this work, this has not been previously addressed and yet is crucial to marrying up care provided with the needs of those receiving it

v. This work provides greater detail on precise differences between care offered by doctors and a specialist nurse, eliciting what was done well and not so well by each in the context of breast cancer follow-up and whether satisfaction by women was successfully sustained over time with each health professional

vi. This work reveals glaring flaws with a health care system that claims to be informed by the needs of users. It is disturbing to expose obvious discrepancies between actual care provided and the stated intentions of health service planners. Claims of ensuring the focus is on the woman, that they are consulted in any planning of care and that their satisfaction is paramount appear deceptive in breast cancer follow-up care.

11.6 My reflections

When considering the findings of this work with my own previous clinical experience and preconceptions there are many similarities but also findings that were not anticipated. I anticipated that the women would feel vulnerable after completion of treatment. Questions pertaining to how an individual knows if they are cured and if the treatment has worked are very commonly posed to me as a specialist nurse. However I think I still underestimated this in terms of the ongoing and overwhelming need for reassurance that women demonstrated throughout. I also underestimated the ongoing duration of multidimensional need. Whilst I have witnessed unresolved emotional needs over time, I was more surprised by the stable, and thus unresolving, social needs. I was also surprised that physical needs resolved as quickly as they did.

I wonder if recommendations to reduce the input and duration of breast cancer follow-up (NICE 2002) can ever be realistically implemented in practice if women continue to want it and doctors continue to always seek, whenever uncertain, the support of information from diagnostic tests. As well as the desire to avoid any litigation, it is conceivable that the biomedical underpinnings of medical practice necessitate in doctors an urge to be seen to be doing something. This approach is embroiled within issues of power in the consultation and with not wanting to appear impotent with regards to making the individual well again. Even in studies where GP's have demonstrated willingness to take on greater responsibility for breast cancer follow-up, hospital specialists remain reluctant (Grunfeld et al 1995c). Although this may be partly due to a lack of awareness and limited knowledge about the levels of care available to the woman after discharge to their GP (Burkey et al 1997).

If I was doing it all again I might have designed an alternative intervention for the nurse rather than providing follow-up within the medical model. I did not appreciate how the world was going to change around me with regards to calls to shorten or cease follow-up and had initially wanted to begin by exploring the nature of the problem and finding out whether a nurse was suited to this care. Nurse-led care can be reconfigured to make follow-up more responsive to individual need and increase satisfaction and as such I regret not designing an alternative model earlier on.

With regards to my chosen theoretical underpinnings (feminist and post positivist), on reflection, I believe they were both suitable conceptual templates to the overall study and enriched my research experience. I have learnt valuable lessons from each. The main advantages of using a feminist theoretical framework to inform my study was its obvious affinity to considering how women are treated in health care systems. This approach was very suited to exploring the ramifications behind the women's needs for reassurance and their ongoing vulnerability and how I, as a nurse, could influence this by the way I conducted the follow-up consultation. Arguably, by increasing the women's satisfaction with nurse-led follow-up, I began to empower them in their recovery from breast cancer. The close contact I maintained with the women over a couple of years and the difficulties ending that contact, meant that I inevitably invested myself closely in the process and thus epitomised the lack of researcher detachment, so integral to a feminist framework.

Whilst the feminist underpinning maximised my ability to explore the experiences of the women, the doctors and myself in breast cancer follow-up, it was complemented by the post positivist theory that underpinned the randomised controlled trial. I identified with the quantitative elements but was able to also incorporate qualitative meaning and capture individual points of view. This is evident in the rich and meaningful quotations presented. By selecting two philosophical underpinnings, I could balance the weaknesses inherent in each. Avoiding exclusive use of either, enabled me to research the women as people and their crucial needs whilst on follow-up, whilst also retaining a scientific approach. In this way it could be said that feminist and post positivist underpinnings characterise nursing and medicine respectively, and this seems highly suited to a study that evaluates a nurse undertaking traditionally medical activity.

11.7 Recommendations for improving the experience and practice of breast cancer follow-up

The research has highlighted the advantages and disadvantages of conventional follow-up care perceived by women who are using the service and doctors and a specialist nurse providing it. In consideration of conventional follow-up initially, the following recommendations are made.

i. The current appointment system should be explored with a view to consideration of the possibility of

- a flexible appointment system;
- a combination of set appointment and open access system;
- weekend and evening clinics

ii. Efforts should be made to provide more time during consultations and/or improve health care professional communication *[time invested early on will benefit and hasten later consultations]*

- a re-engineering of the 'processing' of people through clinic and the consultation, for example with specific attention to achieving better continuity, would enhance satisfaction with care

However, conventional follow-up using a biomedical model can be construed as sub optimal care. Thus more meaningful recommendations for practice must consider more radical change.

i. Follow-up care need not rely only on traditional attendance at an outpatients department

- a combination of set appointment and/or open access and/or telephone system might enable a more flexible approach to suit different people's needs;
- further professional and clinical links with GP's could be used to strengthen the possibility and success of follow-up provision in primary care settings;

- women could be targeted in groups, for example workshops, classes and residential courses to learn about living after breast cancer, managing their physical symptoms and emotional coping strategies.

ii. Follow-up care need not include the clinical examination and detection of disease as the main focus

- adoption of a more personalised, de-routinised approach to follow-up care that acknowledges the meaning of the experience for the individual as well as their unique needs at different time points. The development of understanding and meaning in relation to the cancer is as much a critical component of the healing process as the physical recovery is (Siegel 1986).

- utilising strategies that maximise reassurance and minimise anxiety for those attending including training in relaxation skills

- improved holistic care, such as providing interventions for menopausal symptoms, advice on changing diet, running exercise classes and support groups dedicated to women who have completed their treatment.

11.8 Suggestions for further research

- Design and evaluate a model of training for specialist nurses who are extending their roles in clinical areas such as breast cancer follow-up, for example accreditation of examination skills, and build on recommendations for support and supervision of nurses undertaking these extended roles

- There is little research that attempts to implement and evaluate ways that the problems and needs experienced by women after completion of treatment for breast cancer could be usefully addressed and resolved. Whilst research on follow-up may give some recognition that women require support and encouragement they rarely elaborate further or suggest interventions to improve care

- Research should be conducted into the communication process within clinics to ascertain 'best' person-focused practice in order to facilitate communication exchange (perhaps using conversation analysis)

11.9 Limitations of study design

Overall, this study was designed to evaluate nurse-led follow-up care and the sample size was large enough to detect any significant changes. There were some limitations, which will be addressed. These results can not be generalised to all women with breast cancer but could be representative of women with early stage (I and II) breast cancer. The hospital used in the study is a recognised specialist centre and this might have affected the quality of care women received prior to commencing follow-up. Greater attention to information and emotional needs earlier on might have affected perceptions of needs on follow-up, so I cannot be certain the results are generalisable to all hospital settings. Replication at other centres in the UK, with a range of nurse specialists and outside the context of a research study would be essential to confirm the absolute generalisability of the findings. Perceptions held could also have influenced recruitment to the trial as conceivably those women who believed their prognosis was worse might have felt more vulnerable and thus safer having surveillance from a doctor rather than trusting in a nurse for 'medical' aspects of their care. I did not ask women their preference for the intervention, so that even those agreeing to be randomised might have been influenced by getting or not getting the professional of their choice. Certainly some women looked relieved when told they were seeing a doctor, whilst one woman cried when she heard she would not be seeing the nurse. Preferences for an intervention could undoubtedly influence subsequent ratings of the intervention received.

Whilst attempts were made to ensure representative sampling of the women in the randomised controlled trial, factors that may have influenced their behaviour in the consultation, such as educational attainment, were not addressed in this study. It is feasible, for example, that those women who are less educated and articulate may be less able to ask questions and get adequate answers in a consultation with a health professional. In addition the majority of women in this study were white and drawn from a population of middle class women in the south of the UK because of the location of the research in West London. It may be important to reproduce the work in other socio-economic and cultural groups. However randomised allocation to each group should have ensured that any factors that may influence the perception of follow-up would have been distributed evenly in women in both groups.

Generally it can be argued that participants agreeing to take part in a research study do so because they have strong views (good or bad) about the subject area and as such a vested interest in taking part. This might mean that the women in this study were not representative of the whole population of women attending breast cancer follow-up. However, whilst this could be so for the first study of the views of women already exposed to the practice of follow-up, it is unlikely to be so for the randomised controlled trial. The participants here had never yet experienced follow-up and as such were unlikely to have developed strong views on its delivery. It should be noted that nearly one quarter of those approached refused to participate in the study and this was predominantly because they wanted to see a doctor for their follow-up care. Therefore it is possible that those agreeing to be randomised may not have had strong views about who provided follow-up care and this may have influenced the findings.

The fact that I was also a clinical nurse specialist (CNS) within the breast unit under study may have biased the findings in that the women may have been reluctant to criticise care in front of a key care provider. However within Phase One (the interviews with women), only a small proportion of the participants were previously known to me in my CNS capacity. This was because the study took place over two sites of the NHS Trust, whilst I only worked clinically in one, and because the CNS team comprised of 5 nurses meaning that many of the women had met the other team members in the past. I knew more women in the randomised trial as this was performed only on one site. The randomisation meant that those women I did know and those I had not met had equal chances of being randomised to nurse-led or doctor-led care. Interestingly, analysis of those refusing to take part revealed slightly more knew me in my specialist role, suggesting that previous contact with me did not result in women accepting the possibility of being randomised to nurse-led care. It is possible that this was because the women could not make the connection between traditional and extended nursing roles and thus could not envisage a specialist nurse providing a safe and thorough clinical examination.

> *I feel bad saying no to this. I think* [name of researcher] *is wonderful, but examining me, looking for lumps and all that. Well, that is the job of the surgeons isn't it?* [name of researcher] *is there for me to talk to.*

Thus the novelty of a nurse providing this area of clinical care probably resulted in me being especially conscious of the necessity to establish trust with the women because they may have held doubts about my ability to perform tasks previously only undertaken by doctors. It is conceivable that this initially led to greater efforts to communicate well and remove any sense of vulnerability in the women I saw because of having something to prove. This is even more likely given that I knew I would be evaluating my own performance as an integral part of the study. However the satisfaction and reassurance resulting in women seen by me continued throughout the entire duration of the randomised study, suggesting that these skills were naturally inherent in my practice.

It is hypothetically possible that me being a nurse may have affected participation in the studies because women could conceivably place more importance on doctor led studies as opposed to studies led by nurses or other health care professionals. This may be due to the authority vested in doctors or there may be an element of wanting to please the doctor in order to ensure they receive the best care. Overall recruitment levels to the randomised trial were 53%. The design of the trial required a substantial commitment from the women in that questionnaires would need to be completed regularly for over a year. It was possible that this may have been another underlying reason for other refusals and withdrawals, however reasons for withdrawal were actually predominantly due to new disease occurring and so could not really have been improved upon by amending the trial design.

Clearly there was only one nurse conducting follow-up but several different doctors. I would have theoretically been consistent in my approach, but different doctors may have had different approaches and also differing levels of clinical and communications skills and knowledge. Homogeneity cannot be guaranteed in complex interventions such as nursing because each nurse has unique characteristics that may impact on the effectiveness of care delivery in some way (Lindsay 2004). I cannot, therefore, be certain if the women were evaluating nursing per say or me. Follow-up provided by different specialist nurses may well have resulted in different findings. I am an experienced nurse specialist, and have attained master's level academic and numerous relevant professional qualifications. Not all nurse specialists are equal in terms of knowledge and experience. My age, gender and ethnic background might also have been relevant characteristics. Finally I also received special training in order to become proficient in clinical examination, in real world situations outside of clinical trials, nurses may receive substantially less preparation and support (Lindsay 2004). Similarly, because I was the only nurse conducting follow-up and also the only researcher, I was placed in the position of evaluating my own practice. Ideally, practice should be evaluated by an impartial observer and not by those with a vested interest in the quality of their own performance. By self-evaluating, it is feasible I lost some objectivity with regards to identifying key issues arising from the analysis. I have tried to balance this by owning my preconceptions about possible findings, asking an independent statistician to verify the statistical findings and transparently acknowledging the negative as well as the positive aspects of nurse-led (my own) care.

Of note, an efficiency and cost comparison between the two health professionals was not done. Efficiency relates to the relationship between what resources are used to provide the nurse-led service (that is the costs) and the outcomes arising from this expenditure (the benefits) for the service, which is crucial as cheaper may not always equate with better (Phillips et al 1994 p82). Humphris (1999) reminds us that economic judgements should be concerned with assessment of *value*, not just costs. However consideration of costs should perhaps have taken more precedence, as it will inevitably be a major influence in the development of similar nurse-led follow-up initiatives in the future (McCaffrey Boyle 1995). Cost efficiency may, of course, not be relevant to the women in terms of their ability to recognise its importance, but providers of nurse-led clinics are accountable to more than just their users. It is conceivable that nurse-led follow-up will not prove more cost effective because post holders will be in senior clinical positions with salaries comparable to junior doctors who normally perform this care. Inevitably the NHS is devoid of infinite resources and the cost implications of alternative models of care delivery will always be a predominant concern. However, a more meaningful approach may be evaluating how appropriately targeted input and productive attention to need early on will help to reduce costs over time. Attention paid to issues such as those cited in the recommendations could ensure investment results in optimum and effective care and thus greater *value* for money. This is preferable than opting for care that may prove) ent with adjuvant therapy.

cheaper but also perpetuates the delivery of long term, repetitive, inefficacious care that neither doctors nor women are satisfied with.

11.10 Summary and Conclusion

In this study breast cancer follow-up was provided by a specialist nurse as an alternative to traditional doctor-led care. This is in line with government directives for nurses to make a strong contribution to the care of patients with cancer and to extend their traditional roles (Department of Health 2000c). Involvement of specialist nurses in the follow-up of people with breast cancer leads to positive outcomes. Recipients of nurse-led care in this study deemed it effective, acceptable and highly satisfactory in numerous domains of care, albeit that they were only exposed to nurse-led care by me. It is important to stress that such work is aimed not at proving supremacy in quality of care between one professional and another, but at evidence based discovery of the subtle differences between what doctors and nurses offer and identification of the best professional to enhance care within this setting. In this way services and resources could be targeted more effectively with diminished frequency of less helpful, more costly investigations (Loomer et al 1991) and attention paid to the provider and the recipient's agenda, that is the issues that both parties believe hinder rehabilitation following treatment for breast cancer. Only by understanding the experiences and expectations of people who survive breast cancer, can we prepare successive individuals for entering the follow-up era and health professionals for caring for them (Carter 1989). This is crucial because, without doubt, clinical cure of the disease is not the only measure of a successful outcome of cancer therapy (Faithfull 1994).

REFERENCES

Abbey L (1997) Surviving cancer: a review of the impact and consequences. *Nursing Standard*, 12 (4), 44-47

Adewuyi-Dalton R, Ziebland S, Grunfeld E, Hall A (1998) Patients' views of routine hospital follow-up: a qualitative study of women with breast cancer in remission. *Psycho-Oncology*, 7 (5), 436-439

Allen A (2002) The meaning of the breast cancer follow-up experience for the women who attend. *European Journal of Nursing*, 6 (3), 155-161

Altman D (1996) Better reporting of randomised controlled trials: the CONSORT statement (editorial). *British Medical Journal*, 313, 570-571

Armstrong S, Tolson D, West B (2002) Role Development in Acute Nursing in Scotland. *Nursing Standard*, 16 (17), 33-38

Ashkanani F, Sarkar T, Needham G, Coldwells A, Ah-See A, Gilbert F, Hutcheon A, Eremin O, Heys S (2001), What is achieved by mammographic surveillance after breast conservation treatment for breast cancer. *American Journal of Surgery*, 182 (3), 207-210

Ashworth P, Gerrish K, McManus M (2001) Whither nursing? Discourses underlying the attribution of master's level performance in nursing. *Journal of Advanced Nursing*, 34 (5), 621-628

Autar R (1996) The scope of professional practice in specialist practice. *British Journal of Nursing*, 5 (16), 984-990

Avis M, Bond M, Arthur A (1995) Satisfying solutions? A review of some unresolved issues in the measurement of patient satisfaction. *Journal of Advanced Nursing*, 22, 316-322

Baildam A, Keeling F, Noblet M, Thomson L, Bundred N, Hopwood P (2002) Nurse-led follow-up clinics for women treated for primary breast cancer: a randomised controlled trial, *European Journal of Cancer* [abstract], 38 (suppl.3), 136

Ball S (1990) Self doubt and soft data: social and technical trajectories in ethnographic fieldwork. *Qualitative Studies in Education*, 3, 157- 171

Ball C (1997) Planning for the future: advanced nursing practice in intensive care. *Intensive and Critical Care Nursing*, 13, (1), 17-26

Barker P (1991) Questionnaire in Cormack D (editors) The Research Process in Nursing. Blackwell Science Publications, Oxford, p 215-227

Baum M (1994) Clinical Trials – a brave new partnership: a response to Mrs Thornton. *Journal of Medical Ethics*, 20, 23-25

Beaver K, Luker K (2005) Follow-up in breast cancer clinics: reassuring for patients rather than detecting recurrence. *Psychooncology*, 14 (2), 94-101

Beck C (1993) Caring relationships between nursing students and their patients. *Nurse Educator*, 18 (5), 28-32

Benard F, Bujold R, Nabid A (1994) Para clinical tests and follow-up of breast cancer: how do Quebec oncologists use them? *Union Medical Canada*, 123 (3), 163-171

Benner P (1984) From novice to expert: Excellence and power in clinical nursing practice, Addison Wesley, California

Ben-Sira Z (1982) Stress potential and esotericity of health problems: the significance of the physician's affective behaviour. *Medical Care*, 20, 414-424

Bianchi J, Todd M (2000) The management of a patient with lymphoedema of the legs. *Nursing Standard*, 14 (40), 51-56

Biglia N, Cozzarella F, Cacciari R, Ponzone R, Roagno F, Maggiorotto D, Sismondi p (2003) Menopause after breast cancer: a survey on breast cancer survivors. *Maturitas* 45, 29-38

Bilodeau B, Degner L (1996) Information needs, sources of information and decisional roles in women with breast cancer. *Oncology Nursing Forum*, 23 (4), 691-696

Black N (1996) Why we need observational studies to evaluate the effectiveness of health care. *British Medical Journal,*312, 1215-1218

Blesch K, Paice J, Wickham R (1991) Correlates of fatigue in people with breast or lung cancer. *Oncology Nursing Forum*, 18, 81-87

Blomfield R, Hardy S (2000) Evidence-based nursing practice. In Trinder L, Reynolds S (Editors), Evidence-Based Practice: A Critical Appraisal, Blackwell Science, London (p111-137)

Boccardo F, Bruzzi P, Cionini L, Confalonieri C, Fossati R et al (1995) Appropriateness of the use of clinical and radiological examinations and laboratory tests in the follow-up of surgically treated breast cancer patients. *Annals of Oncology*, 6, supplement 2, 57-59

Bond S, Thomas L (1991) Issues in measuring outcomes of nursing. *Journal of Advanced Nursing*, 16, 1492-1502

Borgers R, Mullen P, Meertens R, Rijken M, Eussen G, Plagge I, Visser A, Blijham G (1993) The information seeking behaviour of cancer outpatients: a description of the situation. *Patient Education and Counselling*, 22, 35-46

Bousfield C (1997) A phenomenological investigation into the role of the Clinical Nurse Specialist. *Journal of Advanced Nursing*, 25 (2), 245-256

Bowling A (1992) Assessing health needs and measuring patient satisfaction. *Nursing Times*, 88 (31), 31-34

Bowling A (2005) Measuring Health: a review of quality of life measuring scales. Open University Press, Maidenhead

Brada M (1995) Is there a need to follow-up cancer patients? *European Journal of Cancer*, 31a (5), 655-667

Brady M, Cella D, Fei M, Bonomi A, Tulsky D, Lloyd S, Deasy S et al (1997) Reliability and Validity of the Functional Assessment of Cancer Therapy-Breast Quality of Life Instrument. *Journal of Clinical Oncology*, 15 (3), 974-986

Breier-Mackie S (2001) Patient autonomy and medical paternity: can nurses help doctors to listen to patients? *Nursing Ethics*, 8 (6), 510-521

Briggs A (1972) Report of the Committee on Nursing, HMSO, London

Brink P, Wood M (1998) Advanced Design in Nursing Research. Thousand Oaks: Sage Publications, New York

Briscoe M (1985) Perceived quality of life: problems in the assessment of health and social functioning. *Midwife, Health Visitor and Community Nurse*, 21, 98-102

Bristol T, Fern E (1996) Exploring the atmosphere created by focus group interviews: comparing consumer's feelings across qualitative techniques. *Journal of the Market Research Society*, 38, 185-195

British Association of Surgical Oncology (BASO) Breast Specialty Group (1998), Guidelines for Surgeons in the Management of Symptomatic Breast Disease in the United Kingdom, W.B. Saunders, London

British Association of Surgical Oncology (BASO) Breast Specialty Group (2005), Guidelines for the Management of Symptomatic Breast Disease, W.B. Saunders, London

Brown L, Payne S, Royle G (2002) Patient initiated follow-up of breast cancer. *Psychooncology*, 11, 346-355

Bryman A (1984) The debate about quantitative and qualitative research: a question of method or epistomology. *British Journal of Sociology,* 35 (1), 75-92

Burden N (1992) Telephone follow-up of ambulatory surgery patients following discharge is a nursing responsibility. *Journal of Post Anaesthesia Nursing*, 7, 256-261

Burkey Y, Black M, Reeve H (1997) Patients' views on their discharge from follow-up outpatient clinics: qualitative study. *British Medical Journal*, 315, 1138-1141

Burnard P, Morrison P (1990) Nursing research in action: developing basic skills, Macmillan Press, London

Burnet K, Chapman D, Wishart G, Purushotham A (2004) Nurse specialists in breast care: a developing role. *Nursing Standard*, 18 (4), 38-42

Burstein H, Winer E (2000) Primary care of survivors of breast cancer. *New England Journal of Medicine*, 343 (15), 1086-1094

Bury M (1991) The sociology of chronic illness: a review of research and prospects. *Sociology of Health and Illness*, 13 (4), 451-466

Caffo O, Amichetti M, Ferro A, Lucenti A, Valduga F, Galligioni E (2003) Pain and Quality of Life after surgery for breast cancer. *Breast Cancer Research and Treatment*, 80, 39-48

Calman K, Hine, R (1995) A Policy Framework for Commissioning Cancer Services. A report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales, NHS Executive Publication, Department of Health, London

Campbell J, German L, Dodwell D, Lance C (1997) Nurse-led clinics in radiotherapy outpatient care. *Oncology Newsletter*, 20-23

Cancer Research UK (2004) About Cancer [Breast]: Statistics - Incidence and Mortality. http://www.cancerresearchuk.org/

Canter R (2001) Patients and medical power. *British Medical Journal*, 323, 7310, 414

Carbone P (1996) Hodgkinsons's disease in adolescence: a psychoanalytic approach. *Journal of Child Psychiatry*, 22 (1), 121-126

Carpenter J, Andrykowski M, Cordova M (1997) Hot flashes in postmenopausal women treated for breast carcinoma: prevalence, severity, correlates, management and relation to quality of life. *Cancer*, 82, 1682-1691

Carpenter J, Andrykowski M (1999) Menopausal Symptoms in Breast Cancer Survivors. *Oncology Nursing Forum,* 26, 1311-1317

Carter B (1989) Cancer Survivorship: a topic for nursing research. *Oncology Nursing Forum*, 16, 435-437

Carter D (1991) Quantitative Research in Cormack D (editors) The Research Process in Nursing. Blackwell Science Publications, Oxford, p 139-145

Carter B (1993) Long term survivors of breast cancer: a qualitative descriptive study. *Cancer Nursing*, 16, 354-361

Carter B (1994) Surviving breast cancer: a problematic work re-entry. *Cancer Practice*, 2, 135-139

Castledine G (1996) The role and criteria of an advanced nurse practitioner. *British Journal of Nursing*, Volume 5, Number 5, 288-289

Castledine G (1999) Clinical Governance and self-regulation in nursing. *British Journal of Nursing*, 8 (7), 474

Cella D (1987) Cancer survival: psychosocial and public issues. *Cancer Investigation*, 5 (1), 59-67

Chait I, Glynne-Jones R, Thomas S (1998) A pilot study exploring the effect of discharging cancer survivors from hospital follow-up on the workload of general practitioners. *British Journal of General Practitioners*, 48, 1241-1243

Chalmers K, Thomson K, Degner l (1996) Information, support, and communication needs of women with a family history of breast cancer. *Cancer Nursing*, 19 (3), 204-213

Chekryn J (1984) Cancer recurrence: personal meaning, communication, and marital adjustment. *Cancer Nursing*, December, 491-498

Ciatto S, Pacini P, Andreoli C, Cecchini S, Iossa A, Grazzini G, Buranelli F, Campa T, Costa A, Magni A, Pizzichetta M (1989) Chest X-ray survey in the follow-up of breast cancer patients. *British Journal of Cancer*, 60, 102-103

Clark D (1990a) Nursing: a problem solving or a needs meeting activity. *Senior Nurse*, 10 (2), 13-14

Clark A (1990b) Some conclusions. In Hopkins A and Costain D (Editors) Measuring the Outcomes of Medical Care. *Royal College of Physicians*, London

Clark A (1998) The qualitative-quantitative debate: moving from positivism and confrontation to post-positivism and reconciliation. *Journal of Advanced Nursing*, 27, 1242-1249

Clark A (1999) Focus group interviews in health care research. *Professional Nurse*, 14, 395-397

Clinical Outcomes Group (1996) Guidance for Purchasers on Improving Outcomes in Breast Cancer: The Manual. *NHS Executive*, Crown Copyright, London

Cochrane Library (2001) A systematic review of follow-up strategies for women treated for early breast cancer, Update Software Limited, Oxford

Collins R, Bekker H, Dodwell D (2004) Follow-up care of patients treated for breast cancer: a structured review. *Cancer Treatment Reviews,* 30, 19-35

Concise Oxford Dictionary (1996) 9th Edition, Oxford University Press, Oxford

Cook J and Fonow M (1990) Knowledge and Women's interests: issues of epistemology and methodology in feminist social research, in Nielsen J (Editors) Feminist research Methods: exemplary readings in the social sciences. Westview Press, Boulder, San Francisco, p 69-93

Cook D, Campbell T (2004a) Popper and falsificationism. In Seale C (Editor) Social research methods. Routledge, London (chapter 5, p43-47)

Cook D, Campbell T (2004b) Validity. In Seale C (Editor) Social research methods. Routledge, London (chapter 6, p48-53)

Corner J (1991) In search of more complete answers to research questions. Quantitative versus qualitative research method: is there a way forward? Journal of Advanced Nursing, 16, 718-727

Corner J (1996) Beyond Survival rates and side effects: cancer nursing as therapy, Plenary Paper delivered at 9th International Conference on Cancer Nursing, Brighton, England

Corner J (2001) Between You and Me: closing the gap between people and health care, The Nuffield Trust Publications Committee, London

Corner J (2003) The role of nurse-led care in cancer management. *Lancet Oncology*, 4 (10), 631-637

Corri C (2003) Medical Humanities in nurse education. *Nursing Standard*, 17 (33), 38-40

Cote-Arsenault D, Morrison- Beedy D (1999) Practical advice for planning and conducting focus groups. *Nursing Research*, 48 (5), 280-283

Coulthard A, Beveridge C, Potterton A (1999) MRI in routine breast cancer follow-up: correlation with clinical outcome. *Clinical Radiology*, 54 (7), 459-461

Cox K, Wilson E (2003) Follow-up for people with cancer: nurse-led services and telephone interventions. *Journal of Advanced Nursing,* 43 (1), 51-61

Cranston M (2002) Clinical effectiveness and evidence-based practice. *Nursing Standard*, 16 (24), 39-43

Crinson I (1999) Clinical Governance: the new NHS, new responsibilities*? British Journal of Nursing*, 8 (7), 449-453

Crowe M (2000) The nurse patient relationship: a consideration of its discursive context. *Journal of Advanced Nursing*, 31 (4), 962-967

Curtin L (1983) The nurse as advocate: a cantankerous critique. *Nursing Management,* 14 (5), 9-10

Cutcliffe J, McKenna H (1999) Establishing the credibility of qualitative research findings: the plot thickens. *Journal of Advanced Nursing*, 30 (2), 374-380

Davies C (2002) Getting health professions working together (editorial). *British Medical Journal*, 320, 1021-1022

Davies K (2003) The body and doing gender: the relations between doctors and nurses in hospital work. *Sociology of Health and Illness*, 25 (7), 720-742

Day P, Klein R (2001) Commission for Health Improvement invents itself (editorial) *British Medical Journal*, 322, 1502-1503

De Bock G, Bonnema J, Zwaan R, van de Velde C, Kievit J, Stiggelbout A (2004) Patient's needs and preferences in routine follow-up after treatment for breast cancer. *British Journal of Cancer*, 90 (6), 1144-1150

De Lena M, Ferguson J, Liberati A (1995) Consensus Conference on Follow-up in Breast Cancer, Selected Papers. *Annals of Oncology*, 6, suppl 2, 1-70

Degner L, Kristjanon L, Bowman L et al (1997) Information needs and decisional preferences in women with breast cancer. *Journal of American Medical Society*, 233, 1485-1491

Degner L, Hack T, O'Neil J, Kristjanson L (2003) A new approach to eliciting meaning in the context of breast cancer. *Cancer Nursing*, 26 (3), 169-178

Del Giudice M, Leszez M, Pritchard K, Vincent L, Goodwin P (1997) Attitudes of Canadian oncology practitioners toward psychosocial interventions in clinical and research settings in women with breast cancer. *Psycho-Oncology*, 6, 178-189

Del Turco M, Palli D, Cariddi A, Ciatto S, Pacini P, Distante V (1994) Intensive Diagnostic Follow-up after treatment for Primary Breast Cancer, *Journal of American Medical Society*, 271 (20), 1593-1597

Denmark-Wahnefried W, Winer E, Rimer B (1993) Why women gain weight with adjuvant chemotherapy for breast cancer. *Journal of Clinical Oncology*, 11, 1418

Denzin N, Lincoln Y (1998) Introduction: Entering the Field of Qualitative Research in Denzin N and Lincoln Y (editors) Strategies of Qualitative Inquiry. Sage Publications, London, p 1-34

Department of Health (1997) The New NHS: Modern, Dependable. HMSO, London

Department of Health (1998) A First Class Service: Quality in the New NHS. HMSO, London

Department of Health (1999) (a) Patient and Public Involvement in the *new* NHS, Crown Copyright, Leeds

Department of Health (1999) (b) Making a Difference: Strengthening the Nursing, Midwifery and Health Visiting Contribution to Health and Health Care, Crown Copyright, London

Department of Health (2000) (a) The NHS Cancer Plan, Crown Copyright, London

Department of Health (2000) (b) The Nursing Contribution to Cancer Care, Crown Copyright, London

Department of Health (2000) (c) A health service of all the talents: developing the NHS workforce, HMSO, London

Department of Health (2001) (a) The Expert Patient: a new approach to chronic disease management for the 21st century, Crown Copyright, Leeds

Department of Health (2001) (b) Your Guide to the NHS, Crown Copyright, London

Department of Health (2001) (c) Workforce development confederations guidance: functions of a mature confederation, Crown Copyright, London

Department of Health (2001) (d) Investment and Reform for NHS Staff – taking forward the NHS plan, Crown Copyright, London

Department of Health (2001) (e) Shifting the Balance of Power in the NHS, Crown Copyright, London

Derdiarian A (1986) Informational needs of recently diagnosed cancer patients, Nursing Research, 35,276-280

Detmar S, Muller M, Wever L, Schornagel J, Aaronson N (2001) The patient-physician relationship. Patient-physician communication during outpatient palliative treatment visits: an observational study. *Journal of American Medical Association*, 285 (10), 1351-1357

Devane D, Begley C, Clarke M (2004) How many do I need? Basic principles of sample size estimation. *Journal of Advanced Nursing*, 47(3), 297-302

Dewar J, Kerr G (1985) Value of routine follow-up of women treated for early breast cancer. *British Medical Journal*, 291 (6507), 1464- 1468

Dewar J (1995) Follow-up in Breast Cancer. *British Medical Journal*, 310, 685- 686

Dewar A, Morse J (1995) Unbearable incidents: failure to endure the experience of illness. *Journal of Advanced Nursing*, 22, 957-964

DiGiacomo S (1987) Biomedicine as a cultural system: an anthropologist in the kingdom of the sick. In Baer H (editor) Encounters and Biomedicine, Gordon and Breach, New York, 315-346

Dingwall R, Murphy E, Watson P, Greatbatch D, Parker S (1998) Catching goldfish: quality in qualitative research. *Journal of Health Services Research and Policy*, 3 (3), 167-172

Dingwall R, Allen D (2001) The implications of healthcare reforms for the profession of nursing. *Nursing Inquiry*, 8 (2), 64-74

Donne J (1987) John Donne: selected prose, Penguin Books, London

Donnelly J, Mack P, Donalson L (2001) Follow-up of breast cancer: time for a new approach? *International Journal of Clinical Practice*, 55 (7), 431-433

Dow K (1992) On the nature and meaning of locally recurrent breast cancer. *Quality Life Nurse Challenge*, 1, 27-34

Dowling S, Barrett S, West R (1995) With nurse practitioners, who needs house officers? *British Medical Journal*, 311, 309-313

Doyal L, Cameron A (2000) Reshaping the NHS Workforce. *British Medical Journal*, 320, 1023-1024

Earnshaw J, Stephenson Y (1997) First two years of a follow-up breast clinic led by a nurse practitioner. *Journal of the Royal Society of Medicine*, 90, 258- 259

Easton D, Peto J (1990) The contribution of inherited predisposition to cancer incidence. *Cancer Surg*, 9, 395-416

Eby M (1993) Validation: choosing a test to fit the design. *Nurse Researcher,* 1 (2), 26-32

Eddington C, Piper J, Tanna B, Hodkinson H, Salmon P (1990) Relationships between happiness, behavioural status and dependency on others in elderly patients. *British Journal of Clinical Psychology*, 29, 43-50

Edwards K (1995) What are nurses' views on expanding practice? *Nursing Standard*, 9 (41), 38-40

Elder R, Bullough B (1990) Nurse Practitioners and Clinical Nurse Specialists: Are the Roles Merging? *Clinical Nurse Specialist*, 4 (2), 78-84

Epstein R (1995) A randomised study of symptom-driven versus routine outpatient follow-up in asymptomatic breast cancer patients receiving regular mammography – The Hotline Study Research Proposal (unpublished)

Ersser S (1998) The presentation of the nurse: a neglected dimension of therapeutic nurse-patient interaction? In McMahon R, Pearson A (editors) Nursing as Therapy. Stanley Thornes Limited, Cheltenham, p37-63

European Council (1993) Council Directive No 93/104/EC of 23 November 1993 concerning certain aspects of the organisation of working time. The Council Of The European Union, Brussels

Expert Advisory Group on Cancer (1994), A Policy Framework for Commissioning Cancer Services. *Department of Health*, London

Evans D, Burnell L, Hopwood P (1993) Perception of risk in women with a family history of breast cancer. *British Journal of Cancer*, 67, 612-614

Faithfull S (1994) The concept of cure in cancer care. *European Journal of Cancer* Care, 3, 12-17

Faithfull S (1999) Randomised trial, a method of comparisons: a study of supportive care in radiotherapy nursing. *European Journal of Oncology Nursing*, 3 (3), 176-184

Faithfull S, Corner J, Meyer L et al (2001) Evaluation of nurse-led follow-up for patients undergoing pelvic radiotherapy. *British Medical Journal*, 85, 1853-1864

Fallowfield L, Ford S, Lewis S (1995) No news is not good news: information preferences of patients with cancer. *Psycho-Oncology*, 4, 197-202

Farrell G (1991) How accurately do nurses perceive patients' needs? A comparison of general and psychiatric settings. *Journal of Advanced Nursing*, 16, 1062-1070

Feher Waltz C, Strickland O and Lenz E (1991) Measurement in Nursing Research, FA Davis Company: Philadelphia

Fenton M (1985) Identifying competencies of clinical nurse specialists. *Journal of Nursing Administration*, 15 (12), 31-37

Ferrans C (1994) Quality of life through the eyes of survivors of breast cancer. *Oncology Nursing Forum*, 21 (10), 1645-1651

Ferrell B, Dow K, Leigh S, Ly J, Gulasekaram P (1995) Quality of life in long term cancer survivors. *Oncology Nursing Forum*, 22 (6), 915-922

Ferrell B, Grant M, Funk B, Otis-Green S, Garcia N (1997) Quality of Life in breast cancer. Part 1: Physical and Social well-being. *Cancer Nursing*, 20 (6), 398-408

Field P and Morse J (1992) Nursing Research: The Application of Qualitative Approaches, Chapman and Hall: London

Finlay T (2000) The scope of professional practice: a literature review to determine the document's impact on nurses' role. *Nursing Times Research*, 5 (2), 115-125

Fisher B, Jeong J, Dignam J, Anderson S, Mamounas E, Wickerham D, Wolmark N (2001) Findings from recent national surgical adjuvant breast and bowel project adjuvant studies in stage I breast cancer. *Journal National Cancer Institute Monographs* 30, 62-6

Flanagan M (1998) The impact of change on the tissue viability nurse specialist: part 1. *British Journal of Nursing*, 7 (11), 648-657

Fontana A and Frey J (2000) The interview: from structured questions to negotiated text. In Denzin N and Lincoln Y (Editors) Handbook of Qualitative Research. Sage Publications, London (chapter 24, p645-672)

Ford-Gilboe M, Campbell J, Berman H (1995) Stories and numbers: coexistence without compromise. *Advances in Nursing Science*, 18 (1), 14-26

Forward L, Hobby L (2002) A practical guide to conducting a systematic review. *Nursing Times*, 98 (2), 36-37

Fosket J (2000) Problematizing Biomedicine: women's constructions of breast cancer knowledge in Potts L (editor) Ideologies of Breast Cancer: feminist perspectives. Macmillan Press Limited, London, p15-36

Fredette S, Beattie H (1986) Living with cancer: a patient education programme. *Cancer Nursing*, 9 (6), 308-316

Fredette S (1995) Breast cancer survivors: concerns and coping. *Cancer Nursing*, 18 (1), 35-46

Froggatt K (2001) The analysis of qualitative data: processes and pitfalls. *Palliative Medicine*, 15, 433-438

Gamarnikow E (1978) Sexual division of labour: the case of nursing. In Kuhn A and Wolpe A (editors) Feminism and Materialism. Women and modes of production. Routledge and Kegan Paul, London, chapter 5, p96-123

Ganz P, Coscarelli-Schag A, Lee J, Polinsky M, Tan S-J (1991) Breast Conservation versus Mastectomy. *Cancer*, 69 (7), 1729-1738

Garvican l, Grimsey E, Littlejohns P, Lowndes, S, Sacks N (1998) Satisfaction with clinical nurse specialists in a breast care clinic: questionnaire survey. *British Medical Journal*, 316, 976-977

Gaudine A, Sturge-Jacobs M, Kennedy M (2003) The experience of waiting and life during breast cancer follow-up. *Research and Theory for Nursing Practice*, 17 (2), 153-168

Gergen and Gergen (1991) Toward reflexive methodologies. In Steirer F (Editor) Research and Reflexivity. Sage, London (chapter 5, p76-95)

Ginsburg J, Prelevic G (2000) Lack of significant hormonal effects and controlled trails of phyto-oestrogens. *Lancet*, 355 (9199), 163-164

Girouard S (1996), Evaluating Advanced Nursing Practice. In Hamric A, Spross J, Hanson C (Editors) Advanced Nursing Practice: An Integrative Approach. WB Saunders, Philadelphia (p569-600)

GIVIO Investigators [Gruppos Interdisciplinaire Volutazione Oncologier] (1986) What doctors tell patients with breast cancer about diagnosis and treatment: findings from a study in general hospitals. *British Journal of Cancer*, 54, 319-326

GIVIO Investigators [Gruppos Interdisciplinaire Volutazione Oncologier] (1994) Impact of Follow-up testing on Survival and Health Related Quality of Life in Breast Cancer Patients. *Journal of the American Medical Association*, 271 (20), 1587-1592

Goodwin, P. J., M. Ennis, K. I. Pritchard, M. Trudeau, and N. Hood. 1999 "Risk of menopause during the first year after breast cancer diagnosis." *Journal of Clinical Oncology* 17:2365-70.

Gray J (1997) Evidence-based healthcare. Churchill Livingstone, Edinburgh

Graydon J (1994) Women with breast cancer: their quality of life following a course of radiotherapy. *Journal of Advanced Nursing*, 19 (4), 617-622

Greenhalgh T (1997) How to read a paper: papers that summarize other papers (systematic reviews and meta-analyses). *British Medical Journal*, 315, 672-675

Grunfield E, Yudkin P, Adewuyl-Dalton R, Vessey M, Mant D (1995) (a) Quality of Life Unaffected by General Practice Follow-up. *British Medical Journal*, 311, 54

Grunfield E, Mant D, Vessey M, Yudkin P (1995) (b) Evaluating primary care follow-up of breast cancer: methods and preliminary results of three studies. *Annals of Oncology*, 6 (suppl 2), S47-S52

Grunfield E, Mant D, Vessey M, Fitzpatrick R (1995) (c) Specialist and general practice views on routine follow-up of breast cancer patients in general practice. *Family Practitioner*, 12 (1), 60-65

Grunfield E, Mant D, Yudkin P, Adewuyi-Dalton R, Cole D, Stewart J, Fitzpatrick R, Vessey M (1996) Routine follow-up of breast cancer in primary care: randomised trial. *British Medical Journal*, 313, 665-669

Guba E, Lincoln Y (1989) Fourth Generation Evaluation. Sage Publications, California

Gulliford T, Opomu M, Wilson E, Hanham I, Epstein R (1997) Popularity of less frequent follow-up for breast cancer in randomised study: initial findings from the hotline study. *British Medical Journal*, 314, 174-177

Haghighat S, Akbari M, Holakouei K, Rahimi A, Montazeri A (2003) Factors predicting fatigue in breast cancer patients. *Support Care Cancer*, 11 (8), 533-538

Hakim C (1987) Research Design Strategies and Choices in the Design of Social Research, Unwin Hyman: London

Hammerlsey M (1991) Some reflections on ethnography and validity. *Qualitative Studies in Education*, 5 (3), 195-203

Hammerlsey M (1992) The paradigm wars: reports from the front. *British Journal of Sociology of Education*, 13 (1), 131-143

Hammerlsey M (1996) The relationship between qualitative and quantitative research: paradigm loyalty versus methodological eclecticism. In Richardson J (Editor) Handbook of qualitative research methods for psychology and the social sciences. British Psychosocial Society, Leicester (chapter 12, p159-174)

Hammond C, Chase J, Hogbin B (1995) A unique service? *Nursing Times*, 91 (30), 28-29

Hamric A & Spross J (1989) (Editors) The Clinical Nurse Specialist in Theory and Practice (2nd Edition). WB Saunders, Philadelphia

Harding S (2004) Is there a feminist method? In Seale C (Editor) Social research methods. Routledge, London (chapter 71 p456-464)

Hardy S, Garbett R, Tichen A, Manley k (2002) Exploring nursing expertise: nurses talk nursing. *Nursing Inquiry*, 9 (3), 196-202

Hassey-Dow K (1990) The enduring seasons in survival. *Oncology Nursing Forum*, 17 (4), 511-516

Hassey-Dow K, Harris, J, Roy C (1994) Pregnancy after breast conserving surgery and radiation therapy for breast cancer. *Journal of the National Cancer Institute*, 16, 131-137

Hassey-Dow K (1995) A review of the late effects of cancer in women. *Seminars in Oncology Nursing*, 11 (2), 128-136

Hassey-Dow K, Ferrell B, Leigh S (1996) An evaluation of the quality of life among long-term survivors of breast cancer. *Breast Cancer Research and Treatment*, 39, 261-273

Hedges B (2004) Sampling. In Seale C (Editor) Social research methods. Routledge, London (chapter 8 p63-72)

Henwood K (1996) Qualitative inquiry: perspectives, methods and psychology. In Richardson J (Editor) Handbook of qualitative research methods for psychology and the social sciences. British Psychosocial Society, Leicester (chapter 3, p25-40)

Hewitt-Taylor J (2001) Use of constant comparative analysis in qualitative research. *Nursing Standard*, 15 (42), 39-42

Hewitt-Taylor J (2004) Challenging the balance of power: patient empowerment. *Nursing Standard*, 18 (22), 33-37

Heys S, Chaturvedi S, Hutcheon A, Sarkar T (2005) Guidelines, guidelines and more guidelines: and we still do not know how to follow-up patients with breast cancer, *World Journal of Surgical Oncology*, 3 (54), 1477-1478

Hilton B (1988) The relationship of uncertainty, control, commitment and threat of recurrence to coping strategies used by women diagnosed with breast cancer. *Journal of Behavioural Medicine*, 12 (1), 39-54

Hiramanek N (2004) Breast cancer recurrence: follow-up after treatment for primary breast cancer. *Postgraduate Medical Journal,* 80 (941), 172-176

Holli K, Saaristo R, Isola J, Hyoti M, Hakama M (1998) Effect of radiotherapy on the interpretation of routine follow-up mammography after conservative breast surgery: a randomised study. *British Journal of Cancer*, 78 (4), 542-545

Holmes P (1991) The patient's friend. *Nursing Times*, 87 (19), 16-17

Horrocks S, Anderson E, Salisbury C (2002), Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. *British Medical Journal*, 324, 819-823

Horton J (1984) Follow-up of Breast Cancer Patients. *Cancer*, 53, 790-797

Humphris D (1999) A framework to evaluate the role of nurse specialists. *Professional Nurse*, 14 (6), 377-379

Hunt M (1991) Qualitative Research in Cormack D (editors) The Research Process in Nursing. Blackwell Science Publications, Oxford, p 117-128

Iliffe S (2000) Nursing and the future of primary care. *British Medical Journal*, 320, 1020-1021

Imoto S, Jitsuiki Y (1998) Detection of the first recurrence during intensive follow-up of breast cancer patients. *Japan Journal of Clinical Oncology*, 28 (10), 597-600

Ingleton C, Seymour J (2001) Analysing Qualitative Data: examples from two studies of end-of-life care. *International Journal of Palliative Nursing*, 7 (5), 227-233

Irvine D, Brown, B, Crooks, Roberts J, Browne, G (1991) Psychosocial adjustment in women with breast cancer. *Cancer*, 67, 1097-1117

James N, Guerrero D, Brada M (1994) Who should follow-up cancer patients? Nurse Specialist based outpatient care and the introduction of a phone clinic system. *Clinical Oncology*, 6, 283-287

Jary J, Franklin L (1996) The role of the specialist nurse in breast cancer. *Professional Nurse*, 11 (10), 664-665

Johnson J (1982) The effects of a patient education course on persons with a chronic illness. *Cancer Nursing*, April, 117-123

Johnston M (1982) Recognition of patients' worries by nurses and by other patients. *British Journal of Clinical Psychology*, 21, 255-261

Jones S (2004) Depth Interviewing. In Seale C (Editor) Social research methods. Routledge, London (chapter 37 p257-260)

Joseph E, Hyacinthe M, Lyman G, Busch C, Demps L, Reintgen D, Cox C (1998) Evaluation of an intensive strategy for follow-up and surveillance of primary breast cancer. *Annals of Surgical Oncology*, 5 (6), 522-528

Karani D, Wiltshaw E (1986) How well informed? *Nursing Times*, 9 (5), 238-242

Karim K (2001) Assessing the strengths and weaknesses of action research. *Nursing Standard*, 15 (26), 33-35

Katlove H, Liberati A, Keeler E, Brook R (1995) Benefits and Costs of Screening and Treatment for Early Breast Cancer. *Journal of the American Medical Association*, 273 (2), 142- 148

Kemeny M, Wellisch D, Schain W (1988) Psychosocial outcome in a randomized surgical trial for treatment of primary breast cancer. *Cancer*, 62, 1231-1237

Kennedy I (2003) Patients are experts in their own field. *British Medical Journal*, 326, 7402, 1276-1277

King E (1996) The use of the self in qualitative research. In Richardson J (Editor) Handbook of qualitative research methods for psychology and the social sciences. British Psychosocial Society, Leicester (chapter 13, p175-188)

Kinnersley P, Anderson E, Parry K, Clement J, Archard L, Turton P, Stainthorpe A, Fraser A, Butler C, Rogers C (2000) Randomised controlled trial of nurse practitioner versus general practitioner care for patients requesting 'same day' consultations in primary care. *British Medical Journal,* 320, 1043-1048

Kitzinger J (1996) Introducing Focus Groups in Mays N and Pope C (editors) Qualitative Research in Health Care. *BMJ Publishing Group*, London, p 36-45

Koch T (1992) A review of nursing quality assurance. *Journal of Advanced Nursing*, 17, 785-794

Koch T (1995) Interpretive approaches in nursing research: the influence of Husserl and Heidegger. *Journal of Advanced Nursing,* 21, 827-836

Koinberg I, Fridlund B, Engholm G, Holberg L (2004) Nurse-led follow-up on demand or by a physician after breast cancer surgery: a randomised study. *European Journal of Oncology Nursing,* 8 (2), 109-117

Kollias J, Evans A, Wilson A, Ellis I, Elston C, Blamey R (2000) Value of contralateral surveillance mammography for primary breast cancer follow-up. *World Journal of Surgery*, 24 (8), 988-989

Komorita n, Doehring K, Hirchert P (1991) Perceptions of caring by nurse educators. *Journal of Nurse Education*, 30 (1), 23-29

Korsch B, Gozzi E, Francis-Negrete V (1982) Doctor-patient communication. *Scientific American*, 227, 66-74

Kunz R, Oxman D (1998) The unpredictability paradox: review of empirical comparisons of randomised and non-randomised clinical trials. *British Medical Journal;*, 317, 1185-1190

Larson P (1986) Cancer nurses' perceptions of caring. *Cancer Nursing*, 9 (2), 86-91

Lash T, Silliman R (2001) Medical Surveillance after breast cancer diagnosis. *Medical Care*, 39 (9), 945-955

Lawson P, Emmerson P (1995) Nurse Practitioners: agents of change. *Health Visitor*, 68 (6), 244-245

Lazarus R, Folkman S (1984) Stress, Appraisal and Coping, Springer, New York

Lees G, Richman J, Salauroo M, Warden S (1987) Quality Assurance: is it professional insurance? *Journal of Advanced Nursing*, 12, 719-727

Leigh S (1992) Myths, monsters and magic: personal perspectives and professional challenges of survival. *Oncology Nursing Forum*, 19, 1475-1480

Leigh S (1994) Cancer survivorship: a consumer movement. *Seminars in Oncology*, 21 (6), 783-786

Leininger M (1985) The nature, rational and importance of qualitative research methods in nursing. In Leininger M (editor) Qualitative Research Methods in Nursing. Grune and Stratton, Oxford

Leydon G, Boulton M, Moynihan C, Jones A, Mossman J, Boudioni, McPherson K (2000) Cancer patients' information needs and information seeking behaviour: in depth interview study. *British Medical Journal*, 320, 909-913

Lewis F, Ellison E, Woods N (1985) The impact of breast cancer on the family. *Seminars in Oncology Nursing*, 1, 206-213

LincolnY, Guba E (1985) Naturalistic inquiry. Sage Publications, California

LincolnY, Guba E (2000) Paradigmatic controversies, contradictions and emerging confluences, in Denzin N & Lincoln Y (Editors) Handbook of Qualitative Research 2nd edition. Sage Publications, California, chapter 6, p163-188

Linder-Pelz (1982) Social psychological determinants of patient satisfaction: a test of five hypotheses. *Social Science and Medicine*, 16, 583-589

Loescher L, Clark L, Atwood J, Leigh S, Lamb G (1990) The impact of the cancer experience on long-term survivors. *Oncology Nursing Forum*, 17 (2), 223-229

Lofland J (1971) Analysing social settings: a guide to qualitative observation, cited in In Seale C (Editor) Social research methods. Routledge, London (chapter 33, p232-235)

Loomer L, Brockschmidt J, Muss H, Saylor G (1991) Post operative follow-up of patients with early breast cancer. *Cancer*, 67, 55-60

Loong S, Wilkins M, Bliss J, Davidson J, Ebbs S, Regan J, Yarnold J (1998) The effectiveness of the routine clinic visit in the follow-up of breast cancer patients: analysis of a defined patient cohort. *Clinical Oncology*, 10 (2), 103-106

Loprinzi L, Barton B, Sloan J, Zahasky K, Smith de S, Pruthi S, Novotny P, Perez E, Christensen B (2002) Pilot evaluation of gabapentin for treating hot flashes. *Mayo Clinic Proceedings* 77:1159-63.

Love R, Cameron L, Connell B, Leventhal H, (1991) Symptoms associated with tamoxifen treatment in postmenopausal women. *Arch Intern Med,* 151, 1842-1847

Luker K, Beaver K, Leinster S, Glynn Owens R, Degner L, Sloan J (1995) Information Needs and Sources of Information for women with Breast Cancer. *Journal of Advanced Nursing*, 23, 1-9

Mackillop W, Stewart W, Ginsburg A, Stewart S (1988) Cancer patients perceptions of their disease and its treatment. *British Journal of Cancer*, 58, 355-358

Maclean U (1974) Nursing in contemporary society. Routledge and Kegan Paul, London

Macleod-Clark J, Maben J, Jones K (1996) The use of focus group interviews in nursing research: issues and challenges. *Nursing Times Research,* 1 (2), 143-153

Madriz E (2000) Focus groups in feminist research. In Denzin N and Lincoln Y (Editors) Handbook of Qualitative Research. Sage Publications, London (chapter 32 p835-850)

Maguire P (1994) Psychological Aspects, in Dixon J (Editor), ABC of Breast Diseases. *BMJ Publishing Group*: London

Maher J (1995) Non surgical management of breast cancer in the United Kingdom: follow-up. *Clinical Oncology*, 7, 227-231

Maher J, Bradbury J, Adewuyl-Dalton R (1995) Patients prefer specialist follow-up. *British Medical Journal*, 311, 54

Mallett J (1997) Nurse-Patient Haemodialysis Sessions: Orchestrated Institutional Communication and Mundane Conversations PhD Thesis: Open University

Malterud K (1993) Strategies for empowering women's voices in the medical culture. *Health Care for Women International*, 14 (4), 365-373

Manley K (1997) A conceptual framework for advanced practice: an action research project operationalizing an advanced practitioner consultant nurse role. *Journal of Clinical Nursing*, 15, 118-135

Manley K (2000a) Organisational culture and consultant nurse outcomes: part 1 organisational culture. *Nursing Standard,* 14 (36), 34-38

Manley K (2000b) Organisational culture and consultant nurse outcomes: part 2 nurse outcomes. *Nursing Standard*, 14 (37), 34-39

Manley K, Garbett (2000) Paying Peter and Paul: reconciling concepts of expertise with competency for career structure. *Journal of Clinical Nursing*, 9 (3), 347-359

Mansi J, Earl H, Powles T, Coombes R (1988) Tests for detecting recurrent disease in the follow-up of patients with breast cancer. *Breast Cancer Research and Treatment*, 11, 249-254

Marsden J (1995) Setting up nurse practitioner roles: issues in practice. *British Journal of Nursing*, 4 (16), 948-952

Marshall Z, Luffingham N (1998) Does the specialist nurse enhance or de-skill the general nurse. *British Journal of Nursing*, 7 (11), 658-662

Maslin-Prothero S (2003) Developing user involvement in research. *Journal of Clinical Nursing*, 12, 412-421

May C (1992) Nursing work, nurses' knowledge, and the subjectification of the patient. *Sociology of Health and Illness*, 6, 132-151

Maynard M (1994) Methods, practice and epistemology: the debate about feminism and research, in Maynard M & Purvis J (Editors) Researching women's lives from a feminist perspective. Taylor and Francis, London, p 10-26

McArdle J, George W, McArdle C, Smith D, Moodie A, Hughson A, Murray G (1996) Psychological support for patients undergoing breast cancer surgery: a randomised study. *British Medical Journal*, 312, 813-816

McCaffrey D (1991) The unspoken subroles of the clinical nurse specialist. *Clinical Nurse Specialist*, 5 (2), 71-72

McCaffrey Boyle D (1995) Documentation and Outcomes of Advanced Nursing Practice. *Oncology Nursing Forum*, 22 (8), 11- 17

McCorkle R, Benoliel J, Donaldson L et al (1989) A randomised clinical trail of home nursing care for lung cancer patients. *Cancer,* 64, 1375-1382

McGee P, Castledine G, Brown R (1996) A Survey of Specialist and Advanced Nursing Practice in England. *British Journal of Nursing*, 5 (11), 682-686

McGee P (1998) Specialist and Advanced Practice: issues for research. In Castledine G and McGee P (Editors) Advanced and Specialist Nursing Practice. Blackwell Science, London, (p87-92)

McKee M, Britton A, Black N, McPherson K, Sanderson C, Bain C (1999) Interpreting the evidence: choosing between randomised and non-randomised studies. *British Medical Journal,* 319, 312-315

McMahon R, Pearson A (1998) Nursing as Therapy. Stanley Thornes Limited, Cheltenham

McPherson K, Steel C, Dixon J (2000) Breast Cancer – epidemiology, risk factors and genetics. *British Medical Journal*, 321, 624-628

McSharry M (1995) The evolving role of the clinical nurse specialist. *British Journal of Nursing*, 4 (11), 641-646

McSherry R, Haddock J (1999) Evidence-based healthcare: its use within clinical governance. *British Journal of Nursing*, 8 (2), 113-117

McSweeney P (1990) Accountability in nursing practice. *Nursing Standard*, 4 (18), 30-31

Mead G (1934) Mind, self and society. University of Chicago press, Chicago

Mellink W, Holland R, Hendriks J, Peeters P, Rutgers E, Van Ddaal W (1991) The contribution of routine follow-up mammography to an early detection of asynchronous contralateral breast cancer. *Cancer*, 67, 1844-1848

Meininger, J (1998) Epidemiologic Designs in Brink P and Wood M (editors) Advanced Design in Nursing Research, Thousand Oaks: Sage Publications, New York

Miaskowski C, Dibble S (1995) Prevalence and morbidity of pain in women with breast cancer. *Innovations in Breast Cancer Care*, 1, 6-8

Middleton J (1995) Asking patients to write lists: feasibility study. *British Medical Journal*, 311, 34

Miers M (1999) Involving clients in decision making: breast care nursing in Wilkinson G and Miers M (editors) Power and Nursing Practice. Macmillan Press Limited, London, p 187-203

Miller W, Crabtree B (1998) Clinical Research in Denzin N and Lincoln Y (Editors) Strategies of Qualitative Inquiry. Sage Publications, London, p 292-314

Mimnagh A (2002) Customer satisfaction is all important? (electronic letter) www.bmj.com/cgi/eletters/324/7341/819 6-7

Mitchell E (1986) Multiple triangulation: a methodology for nursing science. *Advances in Nursing Science,* 8 (3), 18-26

Moher D, Schulz K, Altman D (2001) The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet,* 357, 1191-1194

Molleman E, Krabbendam P, Annyas A, Koops H, Sleijfer D, Vermey A (1984) The significance of the doctor-patient relationship in coping with cancer. *Social Science and Medicine*, 18 (6), 475-480

Moore S, Corner J, Fuller F (1999) Development of nurse-led follow-up in the management of patients with lung cancer. *Nursing Times Research*, 4 (6), 432-445

Moore S, Corner J, Haviland J, Wells M, Salmon E, Normand C, Brada M, O'Brien M, Smith I (2002) Nurse led follow up and conventional medical follow up in management of patients with lung cancer: randomised trial. *British Medical Journal*, 325, 1145-1147

Morgan D (1993) Qualitative content analysis: a guide to paths not taken. *Qualitative Health Research*, 3,1, 112-121

Morgan D (1997) Focus Groups as Qualitative Research. Sage Publications, London

Morris T, Greer S, White P (1977) Psychological and social adjustment to mastectomy: a two-year follow-up study. *Cancer*, 40, 2381-2387

Morris S, Corder A, Taylor, I (1992) What are the benefits of routine breast cancer follow-up. *Postgraduate Medical Journal*, 68 (805), 904-907

Morrison-Beedy D, Cote-Arsenault D, Fischbeck-Feinstein N (2001) Maximizing results with focus groups: moderator and analysis issues. *Applied Nursing Research*, 14 (1), 48-53

Morse J, Bottorff J, Hutchinson S (1995) The paradox of comfort. *Nursing Research*, 44 (1), 14-19

Morse J (1996) Comforting: enabling enduring and facilitating suffering, Proceedings of Mebius Kramer Lecture, Utrecht, Campion Press, Edinburgh

Morse J (1998) Designing Funded Qualitative Research in Denzin N and Lincoln Y (Editors) Strategies of Qualitative Inquiry. Sage Publications, London, p56-85

Mortimer J, Boucher I, Baty J, Knapp D, Ryan E, Rowland J (1999) Effect of tamoxifen on sexual functioning in patients with breast cancer. *Journal of Clinical Oncology*, 17, 1488-1492

Mosconi P, Bruno G, Aloe F (1995) Working group on socio-psychological implications of follow-up. The patients' point of view. *Annals of Oncology*, 2 (supplement), 65-68

Moser C, Kalton G (2004) Questionnaires. In Seale C (Editor) Social research methods. Routledge, London (chapter 9 p73-87)

Mundinger M, Kane R, Lenz E, Totten A, Tsai W-Y, Cleary P (2000) Primary care outcomes in patients treated by nurse practitioners or physicians: a randomised trial. *Journal of the American Medical Association*, 283, 59-68

Murray S, Tapson J, Turnbill L, McCallum J, Little L (1994) Listening to local voices: adapting rapid appraisal to assess health and social needs in general practice. *British Medical Journal*, 308, 698-700

Muss H, McNamara M, Connelly R (1988) Follow-up after stage II breast cancer: a comparative study of relapsed versus non relapsed patients. *American Journal of Clinical Oncology*, 11, 451-455

Nagamani M, Kelver M, Smith E (1987) Treatment of menopausal hot flashes with transdermal administration of clonidine. *American Journal of Obstetrics and Gynaecology*, 156, 561

National Cancer Alliance (1996) Patient-centred services? What patients say. Oxford National Cancer Alliance

National Health Service (1999) Our Healthier Nation, Crown Copyright, London

National Health Service Executive (NHSE) (1996a) Promoting Clinical Effectiveness: A Framework for Action in and Through the NHS, *Department of Health*, Crown Copyright, London

National Health Service Executive (NHSE) (1996b) Patient partnership building a collaborative strategy, *Department of Health*, Crown Copyright, Leeds

National Health Service Executive (NHSE) (1999) Health Service Circular: Nurses, Midwives and Health Visitor Consultants: establishing posts and making appointments, *Department of Health*, Crown Copyright, London

National Health Service Management Executive (NHSME) (1991) Junior doctors: The new deal, *National Health Service Management Executive*, London

National Institute of Clinical Effectiveness (NICE) (2002), Guidance on Cancer Services: Improving Outcomes in Breast Cancer - Manual Update, *National Institute of Clinical Effectiveness*, London

Nesbitt I (2002) Different interpretations (electronic letter) www.bmj.com/cgi/eletters/324/7341/819 15-16

Neuling S, Winefield H (1988) Social support and recovery after breast cancer: frequency and correlates of supportive behaviours by family, friends and surgeon. *Social Science and Medicine*, 27, 385-392

Newbold D (1996) An evaluation of the role of the nurse practitioner. *Nursing Times*, 29 (22), 45-46

Nielsen J (1990) Feminist research Methods: exemplary readings in the social sciences. Westview Press, Boulder, San Francisco

Nolan M, Behi R (1995) Measurement in Research. *British Journal of Nursing,* 4 (7), 402-405

Norman I, Redfern S, Tomalin D, Oliver S (1992) Applying triangulation to the assessment of quality of nursing. *Nursing Times,* 88 (8), 43-46

Normand C, Stevens W (1999) Commentary: nurse-led care must benefit both patients and the public purse. *Nursing Times Research*, 4 (6), 446

Northouse L (1981) Mastectomy patients and the fear of cancer recurrence. *Cancer Nursing*, 4, 213-230

Northouse L, Swain M (1987) Adjustment of patients and husbands to the initial impact of breast cancer. *Nursing Research*, 36, 221-225

Northouse L (1989) The impact of breast cancer on patients and husbands. *Cancer Nursing*, 12, 276-284

Nyberg J (1990) The effects of care and economics on nursing practice. *Journal of Nursing Administration*, 20 (5), 13-18

Oakley A (1981) Interviewing women: a contradiction in terms. In Roberts H (editor) Doing feminist research. Routledge: London

Oberst M (1984) Patients' Perceptions of Care: Measurement of Quality and Satisfaction. *Cancer*, 15, 2366-2373

Oda D, Fine J, Heilbron D (1986) Impact and cost of public health nurse telephone follow-up of school dentist referrals. *American Journal of Public Health*, 76, 1348-1349

Olesen V (2000) Feminisms and qualitative research at and into the millennium. In Denzin N and Lincoln Y (Editors) Handbook of Qualitative Research. Sage Publications, London (chapter 8, p215-255)

Oppenheim A (1992) Questionnaire Design, Interviewing and Attitude, Pinter: London

Oppenheim A (2004) Attitude scaling methods. In Seale C (Editor) Social research methods. Routledge, London (chapter 11 p96-104)

Opie A (1992) Qualitative research, appropriation of the 'other' and empowerment. *Feminist Review*, 40, 52-69

Owen S (2001) The practical, methodological and ethical dilemmas of conducting focus groups with vulnerable clients. *Journal of Advanced Nursing*, 36 (5), 652-658

Pace B, Tinker M (1994) Follow-up of patients with breast cancer. *Clinical Obstetrics and Gynaecology*, 37 (4), 998-1002

Pal B (1998) Following up outpatients by telephone: pilot study. *British Medical Journal*, 316, 1647-1650

Palsson M-B, Norberg A (1995) Breast cancer patients' experiences of nursing care with the focus on emotional support: the implementation of a nursing intervention. *Journal of Advanced Nursing*, 21, 277-285

Palviainen P et al (2003) Do nurses exercise power in basic care situations? *Nursing Ethics*, 10 (3), 269-280

Pandya K, McFadden E, Kaalish L, Carbone P (1985) Frequency and patterns of early disease recurrence and method of detection in operable breast cancer with pathologically positive axillary lymph nodes on Eastern Co-operative Oncology Group adjuvant studies: a preliminary report. *Cancer Treatment and Symptoms*, 2, 117-122

Paterson B, Thorne S, Crawford J, Tarko M (1999) Living with diabetes as a transformational experience. *Qualitative Health Research*, 9 (6), 786-802

Patton M (1990) Qualitative Evaluation and research methods. Sage publications: California. 2nd edition

Pawson R, Tilley N (2004) Go forth and experiment. In Seale C (Editor) Social research methods. Routledge, London (chapter 7, p54-58)

Pelusi J, (1997) The lived experience of surviving breast cancer. *Oncology Nursing Forum,* 24, 1343-53

Pennery E (2003) The differing roles of specialist nurses, in Harmer V (Editor) Breast Cancer Nursing Care and Management. Whurr Publishers Ltd, London (chapter 16, p334-351)

Pennery E, Mallett J (2000) A preliminary study of patients' perceptions of routine follow-up consultations and examinations of patients after treatment for breast cancer after treatment for breast cancer. *European Journal of Oncology Nursing*, 4 (3), 138-145

Perez D, Milan J, Ford H, MacDonald J, Powles T, Gazet J, McCready R, Coombes C (1983) Detection of breast carcinoma metastases in bone: relative merits of x-rays and skeletal scintigraphy. *The Lancet*, 613-616

Perone M, Musolino A, Michiara M Di Blasio B, Bella M, Franciosi V, Cocconi G, Camisa R, Todeschini R, Cascinu S (2004) Early detection of recurrences in the follow-up of primary breast cancer in an asymptomatic or symptomatic phase, *Tumori,* 90 (3), 276-279

Perry M (2000) Reflections on intuition and expertise. *Journal of Clinical Nursing*, 9 (1), 137-145

Physician Insurers Association of America (PIAA) (1995) Breast Cancer Study, PIAA, Washington

Pistrang N, Barker C (1992) Disclosure of concerns in breast cancer. *Psycho-Oncology*, 1, 183-192

Pivot X, Asmar L, Hortobagyi G, Theriault R, Patorini F, Buzdar P (2000) A retrospective study of first indicators of breast cancer recurrence. *Oncology*, 58 (3), 185-190

Playle J (1995) Humanism and positivism in nursing: contradictions and conflicts *Journal of Advanced Nursing*, 22, 979-984

Polinsky M (1994) Functional Status of long-term breast cancer survivors: demonstrating chronicity. *Health Social Work*, 19 (3), 165-173

Polit DF, Beck C and Hungler B (2003) Essentials of Nursing Research. Methods, Appraisal and Utilization JP Lippincott Company: Philadelphia. 5TH Edition

Poole K (1996) The evolving role of the clinical nurse specialist within the comprehensive breast cancer centre. *Journal of Clinical Nursing*, 5, 341-349

Pope C and Mays N (1996) Qualitative methods in health and health services research in Mays N and Pope C (editors) Qualitative Research in Health Care. BMJ Publishing Group, London, p 1-9

Potts L (2000) Introduction in Potts L (editor) Ideologies of Breast Cancer: feminist perspectives. Macmillan Press Limited, London, p1-14

Rafferty A (1996) The politics of nursing knowledge, Routledge, London

Raftery J, Addington-Hall J, MacDonald L et al (1996) A randomised controlled trial of the cost-effectiveness of a district co-ordinating service for terminally ill cancer patients. *Palliative Medicine*, 2, 151-161

Rainsbury D (1996) Routine Follow-up of breast cancer in primary care. *British Medical Journal*, 313, 1547 (letter to the editor)]

Read S, Lloyd Jones M, Collins K, McDonnell A, Jones R, Doyal L, Cameron A, Masterson A, Dowling S, Vaughan B, Furlong S, Scholes J, Levenson R (1999) Exploring New Roles in Practice: Implications of developments within the clinical team (ENRIP), ScHARR, *University of Sheffield*, Sheffield

Redfern S, Norman I (1990) Measuring the quality of nursing care: a consideration of different approaches., *Journal of Advanced Nursing*, 15, 1260-1271

Reichardt C, Cook T (1979) Beyond qualitative versus quantitative methods. In Cook T and Reichardt C (editors) Qualitative and Quantitative Methods in Evaluation Research. Sage Publications, Beverly Hills, p 7-32

Renton J, Twleves C, Yuille F (2002) Follow-up in women with breast cancer: the patient's perspective. *The Breast,* 11, 257-261

Richard R (1992) Follow-up study by telephone, six weeks after the final communication with the clinical geneticist. *Birth Defects*, 28, 37-40

Richards M, Baum M, Dowse H et al, (1994) Provision of Breast Services in the UK: The advantages of specialist breast units. Report of a Working Party of the British Breast Group, Guys Hospital, London

Richardson L (2000) Writing: a method of inquiry. In Denzin N and Lincoln Y (Editors) Handbook of Qualitative Research. Sage Publications, London (chapter 36, p923-948)

Richert-Boe K (1995) Heterogeneity of cancer surveillance practices among medical oncologists in Washington and Oregon. *Cancer*, 75 (10), 2605-2612

Ritchie J, Spencer L (1994) Qualitative data analysis for applied policy research. In Bryman A, Burgess R (editors) Analysing Qualitative Data. Routledge, London. 173-194

Ritz L, Nissen M, Swenson K, Farrell J, Sperduto P, Sladek M, Lally R, Schroeder L (2000) Effects of advanced nursing care on quality of life and cost outcomes of women diagnosed with breast cancer., *Oncology Nursing Forum*, 27 (6), 923-932

Robson C (2001) Real World Research: A Resource for Social Scientists and Practitioner-researchers, 3rd Edition. Blackwell Science, Oxford

Rodger A (1997) Routine follow-up of breast cancer in primary care. *British Medical Journal,* 314, 1129 (letter to the editor)]

Rogers M, Todd C (2002) Information exchange in oncology outpatient clinics: Source, valence and uncertainty. *Psychooncology*, 11, 336-345

Rojas M, Telaro E, Russo A, Fossati R, Palli D, Rosselli Del Turco M, Confalonieri C, Liberati A (2001) Follow-up strategies for women treated for early breast cancer (Cochrane Review). In Cochrane Library, Issue 2, Update Software, Oxford

Rosser J (1981) The interpretation of women's experience: a critical appraisal of the literature on breast cancer. *Social, Science and Medicine*, 15e, 257-265

Roter D (1977) Patient participation in the patient-provider interaction. *Health Education Monographs*, 5, 281-315

Royal College of Nursing (1975) New Horizons in Clinical Nursing, RCN London

Royal College of Nursing (1988) A Report of the Working Party Investigating the Development of Specialties within the Nursing Profession, RCN London

Royal College of Nursing (1997) Nurse Practitioners: your questions answered, RCN, London

Royal College of Nursing (1998) RCN Recognised Expert Practitioner: discussion paper, RCN, London

Royal College of Nursing (1999) Developing Roles: nurses working in breast care, RCN, London

Royal College of Nursing (2002) Advanced Nursing Practice in Breast Cancer Care, RCN Direct, London

Ruff Dirksen R (1995) Search for meaning in long term cancer survivors. *Journal of Advanced Nursing*, 21, 628-633

Ryan G, Bernard R (2000) Data management and analysis methods. In Denzin N and Lincoln Y (Editors) Handbook of Qualitative Research. Sage Publications, London (chapter 29, p769-802)

Rycroft-Malone J, Harvey G, Kitson A, McCormack B, Seers K, Titchen A (2002) Getting evidence in to practice: ingredients for change. *Nursing Standard*, 16 (37), 38-43

Sakr M, Angus J, Perrin J, Nixon C, Nicholl J, Wardrope J (1999) Care of minor injuries by emergency nurse practitioners or junior doctors: a randomised controlled trial. *Lancet*, 354, 1321-1326

Salvage J (1998) Whose side are you on? *Senior Nurse*, 6 (2), 20-21

Salvage J (1998) Evidence-based practice: a mixture of motives? *Nursing Times Research*, 3, 406-418

Salvage J, Smith R (2000) Doctors and nurses: doing it differently (editorial). *British Medical Journal*, 320, 1019-1020

Sandelowski M (1986) The problem of rigor in qualitative research. *Advances in Nursing Science*, 8 (3), 27-37

Sardell S, Sharpe G, Ashley S, Guerrero D, Brada M (2000) Evaluation of a nurse-led telephone clinic in the follow-up of patients with malignant glioma. *Clinical Oncology*, 12 (1), 36-41

Scanlon E, Oviedo M, Cunningham M et al (1980) Preoperative and Follow-up procedures on patients with breast cancer. *Cancer*, 46, 977-979

Schafer A (1982) The ethics of the randomised controlled trial. *New England Journal of Medicine*, 307 (12), 719-724

Schain W (1990) Physician-patient communication about breast cancer. *Surgical Clinics of North America*, 70 (4), 917-937

Schapira D (1991) A Minimalist policy for Breast Cancer Surveillance. *Journal of the American Medical Association*, 265 (3), 380-382

Schapira D (1993) Breast cancer surveillance – a cost effective strategy. *Breast Cancer Research and Treatment*, 25 (1), 107-111

Schapiro D, Boggs S, Melamed B, Graham-Pole J (1992) The effect of varied physician affect on recall, anxiety and perceptions of women at risk for breast cancer: an analogue study. *Health Psychology*, 11 (1), 61-66

Schapiro C, Manola J, Leboff M (2001) Ovarian failure after adjuvant chemotherapy is associated with rapid bone loss in women with early-stage breast cancer. *Journal of Clinical Oncology* 19 (14), 3306-3311

Scheper-Hughes N (1983) The problem of bias in androcentric and feminist anthropology. *Women's Studies,* 19, 109-116

Scotland J (2002) NP's do not want to replace (electronic letter) www.bmj.com/cgi/eletters/324/7341/819 22-24

Scott J (1991) The evidence of experience. *Critical Inquiry*, 17, 773-779

Seale C 1999 The Quality of Qualitative Research, Sage Publications, London

Shum C, Humphreys A, Wheeler D, Cochrane M, Skoda S, Clement S (2000) Nurse management of patients with minor illnesses in general practice: multicentre, randomised controlled trial. *British Medical Journal*, 320, 1038-1043

Siegel B (1986) Love, Medicine and Miracles, Harper Row, New York

Siegel S (1992) Telephone follow-up programs as creative nursing interventions. *Paediatric Nursing*, 18, 86-89

Siggelkow W, Zimny M, Faridi A, Petzold K, Buell U, Rath W (2003) The value of positron emission tomography in the follow-up for breast cancer. *Anticancer Research*, 23 (2c), 1859-1867

Silverman D (1993) Interpreting qualitative data: strategies for analysing talk, text and interaction, Sage, London

Sim J (1998) Collecting and analysing qualitative data: issues raised by the focus group. *Journal of Advanced Nursing*, 28 (2), 345-352

Smith I, de Boer R (2000) Role of systemic treatment for primary operable breast cancer. In Dixon M (Editors) ABC of Breast Diseases, 2nd edition. BMJ Publishing Group, London, chapter 10

Smith J, Heshusius L (1986) Closing down the conversation: the end of the quantitative-qualitative debate among educational inquirers. *Educational Research*, 15, 4-12

Smith J (1996) Evolving issues for qualitative psychology. In Richardson J (Editor) Handbook of qualitative research methods for psychology and the social sciences. British Psychosocial Society, Leicester (chapter 14, p189-201)

Smith T, Davidson N, Schapira D, Grunfeld E, Muss H, Vogel J, Somerfield M (1999) American Society of Clinical Oncology 1998 update of recommended breast cancer surveillance guidelines. *Journal of Clinical Oncology*, 17 (3), 1080-1082

Smythe M, McCaughan E, Harrison S (1995) Women's perceptions of their experiences with breast cancer: are their needs being addressed. *European Journal of Cancer Care*, 4, 86-92

Snee M (1994) Routine follow-up of breast cancer patients. *Clinical Oncology*, 6, 154-156

Snee M (1996) Follow-up of women treated for breast cancer. *Clinical Oncology*, 8, 85-89

Sowden A, Sheldon T, Alberti G (1995) Shared care in diabetes (editorial). *British Medical Journal,* 310, 142-143

Stark M, Crowe J (1996) Breast cancer evaluation and follow-up: a survey of the Ohio Chapter of the American College of Surgeons. *American Journal of Surgery*, 62 (6), 458-460

Steinberg M, Juliano M, Wise L (1985) Psychological outcome of lumpectomy versus mastectomy in the treatment of breast cancer. *American Journal of Psychiatry*, 142, 32-39

Stewart D, Shamdasani P (1990) Focus Groups: Theory and Practice. Sage Publications, California

Stierer M, Rosen H (1989) Influence of Early Diagnosis on Prognosis of Recurrence Breast Cancer. *Cancer*, 64, 1128-1131

St Leger A, Schnieden H, Walsworth-Bell J (1993) Evaluating Health Services, Open University Press, Milton Keynes

Suominen T, Leino-Kilpi H, Laippala P (1994) Nurses' role in informing breast cancer patients: a comparison between patients' and nurses opinions. *Journal of Advanced Nursing*, 19, 6-11

Suominen T, Leino-Kilpi H, Laippala P (1995) Who provides support an how? *Cancer Nursing*, 18 (4), 278-285

Thomas L, McColl E, Priest J (1996) The Newcastle Satisfaction with Nursing scales: an instrument for quality assessments of nursing care. *Quality in Health Care,* 5, 67-74

Tilden V, Weinert C (1987) Social support and the chronically ill individual. *Nursing Clinics of North America*, 22 (3), 613-620

Trinder L (2000) Introduction: the context of evidence-based practice. In Trinder L, Reynolds S (Editors), Evidence-Based Practice: A Critical Appraisal, Blackwell Science, London (p1-16)

Tobin M, Lacey H, Meyer L, Mortimer P (1993) The psychological morbidity of breast cancer related arm swelling. *Cancer* 72 (11), 3248-3252

Tomiak E, Piccart P (1993) Routine follow-up of patients after primary *therapy for early cancer: changing concepts and challenges for the future. Annals* of Oncology, 4 (3), 199-204

UKCC [United Kingdom Central Council for Nursing, Midwifery and Health Visiting] (1992) The Scope of Professional Practice, *UKCC*, London

UKCC [United Kingdom Central Council for Nursing, Midwifery and Health Visiting] (1994) The future of professional practice - the Council's standards for education and practice following registration. Position statement on policy and implementation. *UKCC*, London

UKCC [United Kingdom Central Council for Nursing, Midwifery and Health Visiting] (1999) A higher Level of Practice – draft descriptor and standard. *UKCC*, London

UKCC [United Kingdom Central Council for Nursing, Midwifery and Health Visiting] (2001) Standards for Specialist Education and Practice. *UKCC*, London

US Office of Technology (1986) Assessment: Nurse Practitioners, Physicians Assistants and Certified Nurse Midwives, *Government Printing Office*, Washington DC

Utian W (1999) The International Menopause Society menopause related terminology definitions. *Climacteric*, 2, 284-286

Vassilopoulou-Sellin R, Zolinski C (1992) Estrogen replacement therapy in women with breast cancer: a survey of patient attitudes. *American Journal of Medical Science,* 304, 145-149

Venning P, Durie A, Roland M, Roberts C, Leese B (2000) Randomised controlled trial comparing cost effectiveness of general practitioners and nurse practitioners in primary care. *British Medical Journal*, 320, 1048-1053

Waitzkin H (1984) Doctor-patient communication: clinical implications of social scientific research. *Journal of the American Medical Association* [JAMA], 252, 2441-2446

Wallace W (2004) The logic of science in sociology. In Seale C (Editor) Social research methods. Routledge, London (chapter 4, p35-42)

Wasson J, Gaudette C, Whaley F, Sauvigne A, Baribeau P, Welch G (1992) Telephone Care as a Substitute for Routine Clinic Follow-up, *Journal of the American Medical Association* [JAMA], 267 (13), 1788-1793

Wetherall (2003) Core Competency Framework. *Cancer Nursing Practice*, 2 (10), 16-17

Webb C (1991) Action Research in Cormack D (editors) The Research Process in Nursing. Blackwell Science Publications, Oxford, p 155-165

Webb C (1993) Feminist research: definitions, methodology, methods and evaluation. *Journal of Advanced Nursing*, 18, 416-423

Weber R (2004) Content analysis. In Seale C (Editor) Social research methods. Routledge, London (chapter 14 p117-124)

Weintrob F, Hagopian G (1990) The effects of nursing consultation on anxiety, side effects and self care of patients receiving radiation therapy. *Oncology Nursing Forum*, 17 (suppl), 31-38

Welch-McCaffery D, Hoffman B, Leigh S, Loescher L, Meyskens F (1989) Surviving adult cancers. Part 2: psychosocial implications. *Annals Internal Medicine*, 111, 517-524

Weston J (1975) Whither the 'nurse' in nurse practitioner? *Nursing Outlook*, 23, 148-152

Wheeler T, Stenning S, Negus S, Picken S, Metcalfe S (1999) Evidence to support a change in follow-up policy for patients with breast cancer: time to first relapse and hazard ration analysis *Clinical Oncology*, 11 (3), 169-173

Wickerham L, Fisher B, Cronin W (1984) The efficacy of bone scanning in the follow-up of patients with operable breast cancer. *Breast Cancer Research and Treatment*, 4 (4), 303-307

Williams S (1999) Is there anybody there? Critical realism, chronic illness and the disability debate. *Sociology of Health and Illness*, 21 (6), 806

Wilson-Barnett J (1988) Patient teaching or patient counselling? *Journal of Advanced Nursing*, 13, 215-222

Wilson-Barnett J (1995) Specialism in nursing: effectiveness and maximization of benefit. *Journal of Advanced Nursing*, 21 (1), 1-2

Wilson K, Williams A (2000) Visualism in community nursing: implications for telephone work with service users. *Qualitative Health Research*, 10 (4), 507-520

Wolberg W, Romsaas E, Tanner M, Malec J (1989) Psychosexual Adaptation to Breast Cancer Surgery. *Cancer*, 63, 1645-1655

Wolf M, Putnam S, James S et al (1978) The medical interview satisfaction scale: development of a scale to measure patient perceptions of physical behaviour. *Journal of Behavioural Medicine,* 1 (4), 391-401

Wong C, Bramwell L (1992) Uncertainty and anxiety after mastectomy for breast cancer. *Cancer Nursing*, 15, 363-371

Woods M (2003) Lymphoedema and breast cancer in Harmer V (Editor) Breast Cancer Nursing Care & Management, Whurr Publishers, London, Chapter 11, 214-232

Woods M (2004) Causes and treatment of early lymphoedema. *Cancer Nursing Practice*, 3 (5), 25-30

Woolgar S (1996) Psychology, qualitative methods and the ideas of science. In Richardson J (Editor) Handbook of qualitative research methods for psychology and the social sciences. British Psychosocial Society, Leicester (chapter 2, p11-24)

World Health Organisation (1989) Quality assurance in health care, Volume 1, Number 2/3, WHO, Geneva

Worster A, Bass M, Wood M (1996) Willingness to follow breast cancer. Survey of Family Physicians., *Cancer Family Physician*, 42, 263-268

Wyatt G, Kurtz M, Liken M (1993) Breast cancer survivors: an exploration of quality of life issues. *Cancer Nursing*, 16 (6), 440-448

Young A (1993) The relevance of traditional medical cultures to modern primary health care. *Social Science and Medicine*, 17, 1205-1212

Young-McCaughan S (1996) Sexual functioning in women with breast cancer after treatment with adjuvant therapy. *Cancer Nursing*, 19 (4), 308-319

Appendix A

Research of the experience of life after treatment for breast cancer

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
1.	**Adewuyi-Dalton et al** (1998) Oxford, UK	Purposive sample of 109 women attending for hospital based breast cancer follow-up	To investigate the experience of specialist hospital based, medical, breast cancer follow-up	Descriptive	Interviews	Continuity of care and an unrushed consultation were highly desirable. Access to expertise, diagnostic tests and specialist facilities were valued features of follow-up.
2.	**Caffo** et al (2003) Trento, Italy	Consecutive sample of 529 breast cancer patients who had undergone surgery	To evaluate pain and quality of life after surgery for breast cancer	Survey	In house pain questionnaire Quality of life questionnaire (physical, psychological, relational, autonomy subscales) Sexual activity questionnaire	Pain reported by 39.7% of the women, higher in incidence in those undergoing breast conservation than mastectomy Pain occurred earlier in those women undergoing breast conservation surgery Women with pain had significantly worse quality of life scores on all subscales than those without pain
3.	**Carpenter and Andrykowski** (1999) Nashville, USA	114 postmenopausal breast cancer survivors	To examine the prevalence and severity of menopausal symptoms among breast cancer survivors and the relationship between menopausal symptoms and quality of life	Cross-sectional, descriptive	Telephone interviews. Blatt menopausal index and QOL (SF-12 health survey)	The most commonly reported menopausal symptoms (joint pain 77%, feeling tired 75%, trouble sleeping (68%) and hot flashes 65%) were also the most severe. The total number and severity of symptoms reported was not significantly related to time post diagnosis.
4.	**Degner** et al (2003) Winnipeg, Canada	1012 Canadian women after diagnosis and 3 years later in follow-up	To elicit the meaning of surviving breast cancer using 8 preset categories	Cross-sectional survey	List of pre set categories HADS	At follow-up after 3 years 78.9% who chose challenge & value to describe the meaning of breast cancer on diagnosis did so again Those choosing negative meaning descriptors such as enemy, loss or punishment had significantly higher levels of depression and anxiety that those who chose positive descriptors
5.	**Ferrans** (1994) Chicago, USA	Convenience sample of 61 women who had completed treatment for breast cancer	To examine the quality of life of long term survivors of breast cancer in order to identify their needs	Survey	Questionnaire containing 2 open ended questions	95% thought that the treatment experienced had 'been worth it', stating they were happy to be alive Domains of quality of life mentioned were health and functioning, psychological/spiritual, family and social/economic Positive experiences of the above domains contributed to a higher quality of life and negative aspects resulted in a lower quality of life
6.	**Ferrell** et al (1997) California, USA	21 breast cancer survivors	To identify the individual aspects and domains of quality of life and the impact of breast cancer and treatment on quality of life	Descriptive Study	QOL-BC In-House Semi-structured interview guide	Pain was the predominant aspect affecting physical well being. Fatigue, weight gain, menopausal symptoms and fertility were also mentioned Impact on the family (including fear for daughters at risk) was the predominant aspect affecting social well being. Ability to work and maintain employment, financial concerns, sexuality and cultural belonging were also mentioned

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
7.	**Fredette** (1995) Massachusetts, USA	14 women who had lived at least 5 years after diagnosis of breast cancer	To delineate concerns and coping after breast cancer as perceived by women	Descriptive Study	Semi-structured interview devised by the researcher and consisting of 14 open-ended questions	Coping strategies included working (normalcy), spirituality, information seeking, support groups, family and friends and a hopeful attitude. Impact was described in terms of attitudes to surviving (belief in cure or not) and the meaning of having cancer (positive and negative changes to life)
8.	**Ganz** et al (1992) California, USA	109 women being followed up for primary breast cancer and participating in an existing randomised trial testing rehabilitation interventions	To evaluate quality of life, performance status and psychological adjustment in women who have breast conservation versus those having mastectomy one year after treatment	Prospective cohort study	FLIC CARES KPS POMS GAIS	No statistically significant differences between quality of life, mood disturbance, performance status or global adjustment between women having mastectomy (n=57) versus women having breast conservation surgery (n=52) Women had greater difficulties with clothing and body image after mastectomy but this did not affect assessment of mood or quality of life Women having breast conservation did not experience improved quality of life
9.	**Haghighat** et al (2003) Tehran, Iran	Consecutive sample of 112 patients attending for follow-up in a breast centre in Iran	To investigate the factors predicting fatigue in patients who have been treated for breast cancer	Survey	HADS CFS In house questionnaire on physical symptoms	49% reported experiencing fatigue severe anxiety and depression was reported in 16% and 32% respectively fatigue was predicted by depression, pain, current tamoxifen use, undergoing mastectomy and anxiety
10.	**Kemeny** et al (1988) California, USA	Consecutive sample of 52 women who were already randomised in to a study comparing the clinical efficacy of mastectomy versus wide local excision as treatment for primary breast cancer	To explore the differences in the psychosocial effects of mastectomy versus wide local excision	Survey	Psychological reactions to different types of breast cancer surgeries questionnaire BSI	Women who had undergone wide local excision had a statistically significant more positive perception of sexual and body image than those undergoing mastectomy. Concerns about cancer recurrence were less in those women who had undergone wide local excision but were prevalent in both groups.
11.	**Loprinzi** et al. (2000) Rochester, USA	Fifty women taking adjuvant tamoxifen for locally treated breast cancer.	To evaluate the nature of hot flashes experienced during tamoxifen therapy and to describe the natural history of these hot flashes.	Prospective evaluative study	Hot flash diary	Half reported no substantial hot flashes while the other half reported flashes of variable intensity. Flashes gradually inc. over 3 months and then reached a plateau. 16% reported the desire for therapy for their hot flashes.

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
12.	**Love** et al (1991) Madison, USA	140 postmenopausal women with axillary node negative breast cancer in remission	To evaluate the symptoms associated with tamoxifen therapy	Placebo-controlled, randomised toxicity study	Physician evaluation	Tamoxifen recipients reported moderated or severe vasomotor symptoms up to 17% and gynaecologic symptoms up to 4% more frequently than placebo subjects did. Persistent vasomotor, gynaecologic, or other major side effects were reported by 48% of tamoxifen recipients, and by 21% of placebo subjects.
13.	**Luker** et al (1995) Liverpool, UK	105 women being followed up for primary breast cancer in one consultant's practice	To examine the specific information needs and sources of information for women with breast cancer at a mean of 21 months from diagnosis (follow-on from earlier study on the women when newly diagnosed)	Survey	List of 9 information needs presented in subset of two using a paired comparison approach List of sources of information	Most important information needs at follow-up were likelihood of survival and risk to family of developing breast cancer. Information about sexual attractiveness was ranked least important. No significant differences were found in responses between women at different ages. Key sources of information at follow-up were magazines, the consultant and television/radio, with the breast care nurse, other nurses, medical books and support groups being ranked last.
14.	**Morris** et al (1992) London, England	285 women attending follow-up for primary breast cancer. 223 replies	To investigate the attitudes of patients to breast cancer follow-up	Survey		Regular follow-up was preferred to attendance only when symptomatic by 190 women (85%) and to GP follow –up by 169 (76%). 81% (n=174) felt reassured and less anxious as a result of attending routine follow-up.
15.	**Northouse** (1981) Michegan, USA	Non probability sample of 30 women who had undergone mastectomy within the past 1-4 years	To determine the relationship between significant others and fear of disease recurrence	Survey	Fear of Recurrence Questionnaire (22 items on Likert type scale) Significant Other Interview Instrument (4 questions)	There was a strong relationship between significant others and fear of recurrence. Those with fewer significant others had higher fear of recurrence. Those with more significant others had a lower fear of recurrence. A strong negative relationship was found between the number of significant others whom the subject identified as understanding her health concerns and fear of recurrence Age, marital status, extent of disease, type of treatment and time since treatment were not significantly related to fear of recurrence
16.	**Rijken** et al (1995) Utrecht, Netherlands	Purposive sample of 112 women who had been treated for Stage I or II breast cancer	To detect differences in depressive symptomatology in post menopausal breast cancer patients who had recently undergone mastectomy or breast conserving surgery	Survey	CES-D (rate frequency of 20 items)	No significant differences in mean scores between the two treatment groups Women undergoing mastectomy (n=63) or breast conserving surgery (n=49) have comparable levels of depressive symptoms

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
17.	**Suominen** et al (1995) Turku, Finland	109 patients with breast cancer and 125 nurses	To investigate the support provided for breast cancer patients and the evaluation of this support by patients and nurses	Survey	2 in-house questionnaires with multiple choice, open ended questions	Patients perceived postoperative support came from relatives rather than friends. 69% of nurses felt patients were not well supported. 58% of patients felt they could have received better support including being listened to, more positive attitudes and social support.
18.	**Vassilopoulou-Sellin and Klein** (2002) Texas, USA	73 patients and 22 physicians	To understand the opinion of breast cancer survivors and their physicians about long-term health, especially menopause.	Survey	Questionnaire	One third of specialists preferred follow-up of 5 years or less, while 59% preferred 10 years or longer; 46% of patients preferred follow-up for 10 years or longer. Physicians preferred that primary care physicians supervise menopausal health (55%), but patients disagreed (30%).
19.	**Wolberg** et al (1989) Wisconsin, USA	Consecutive sample of women waiting to be seen in a breast diagnostic clinic (n=191)	To compare changes in psychological assessments in women who had undergone a benign breast biopsy with those that had undergone surgery for breast cancer	Prospective Survey	Administered pre diagnosis, after seeing physician, post chemotherapy and radiotherapy (for patients with cancer) POMS, HLC PAIS, DSFI MAT, MCMI	72 women had a benign biopsy, 41 had breast cancer treated with breast conservation, 78 had breast cancer treated with mastectomy. Disturbance among cancer patients was higher at all times, than in patients with benign disease. More distress, depression and fatigue were noted in the patients with cancer post operatively. Patients having breast conservation surgery reported higher (more positive) scores for sexuality and appearance than those who had undergone mastectomy.
20.	**Wyatt** et al (1993) Michegan, USA	Convenience sample of 38 long term breast cancer survivors, 21 recruits	To explore long term survivorship with women who have been treated for breast cancer	Focus Groups	Discussion prompted around four domains of physical, social, psychological and spiritual well being	Key survivorship themes were: integration of disease process into current life change in relationships with others restructuring of life perspective unresolved issues
21.	**Young-McCaughan** (1996) Washington, USA	67 women diagnosed with stage I, II, or III breast cancer	To describe menopausal symptoms and sexual functioning in women with breast cancer comparing chemotherapy and endocrine therapy	Survey	mailed questionnaire Derogatis Sexual Functioning Inventory (DSFI)	Controlling for endocrine therapy, the 25 women treated with chemotherapy were significantly more likely than women not treated with chemotherapy to report weight changes, hot flashes, mood swings, vaginal dryness and decreased libido. There was a significant negative effect of chemotherapy on body image, psychological symptoms and overall sexual functioning. Controlling for chemotherapy, the 20 women treated with endocrine therapy did not experience either menopausal or sexual dysfunction symptoms significantly differently from women not treated with endocrine therapy.

Key:

HADS = Hospital Anxiety and Depression Scale
QOL SF-12 = 12 item health survey
QOL-BC = Quality of Life Breast Cancer Version
FLIC = Functional Living Index - Cancer
CARES = Cancer Rehabilitation Evaluation System
KPS = Karnofsky Perfomance Status
POMS = Profile of Mood States
GAIS = Global Adjustment to Illness Scale
CFS = Cancer Fatigue Scale
BSI = Brief Symptom Inventory psychological test
CES-D = Centre for Epidemiological Studies – Depression scale
HLC = Health Locus of Control scale
PAIS = Psychosocial Adjustment to Illness Scale
DSFI = Derogatis Sexual Functioning Inventory
MAT = Marital Adjustment Scale
MCMI = Millon Clinical Multiaxial Inventory

Appendix B

Research of the value of routine breast cancer follow-up in detection of recurrent disease and improving survival

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
1.	**Ashkanani** et al (2001) Aberdeen, UK	Purposive sample of 695 patients who had undergone breast conservation surgery within a selected 5 year time frame	To evaluate what is achieved by mammographic surveillance after breast conservation treatment for breast cancer	Prospective analysis	Local recurrence rates in the conserved breast Method of detection of local recurrence (clinical examination versus mammography)	A total of 2181 mammograms were performed. Local recurrence occurred in 21 patients out of 695 (3%). Method of detection of recurrence was clinical examination in 11 patients (52%) and mammogram in 10 patients (48%). False positive rate with mammography was 2.3%
2.	**Ciatto** et al (1989) Florence, Italy	Purposive sample of 182 cases of intrathoracic metastases out of 1225 first recurrences in women with breast cancer	To assess the diagnostic and prognostic significance of chest x-ray in the routine* follow-up surveillance of breast cancer patients	Retrospective analysis	Disease free survival Overall survival	80 patients were symptomatic at diagnosis of intrathoracic metastases found at interval visits 102 were aysmptomatic and were detected at routine visits DFS** was shorter in patients diagnosed at interval visits – chest x-ray facilitated earlier detection No differences in OS*** between the two
3.	**Coulthard** et al (1999) Newcastle, UK	Purposive sample of 26 breast cancer follow-up patients with equivocal mammographic findings and 33 control patients receiving breast cancer follow-up	To examine the utility of Magnetic resonance imaging (MRI)**** as a routine test in the follow-up of breast cancer patients	Retrospective analysis	Clinical outcome post MRI	All abnormal MRI scans were subsequently shown to be benign disease. None of the patients with equivocal results developed local recurrence. None of the control group who developed local recurrence had an abnormal MRI. Use of MRI is a poor predictor of breast cancer local recurrence in the routine follow-up setting.
4.	**Del Turco** et al (1994) Florence, Italy	1243 women under 70 years with confirmed invasive breast cancer with no evidence of metastases	To evaluate the effectiveness of early detection of intrathoracic and bone metastases in reducing mortality in breast cancer patients	Multi centre randomised controlled trial	Incidence of recurrence Detection of recurrence by chest x-ray and bone scan Disease free survival Overall survival	393 recurrences observed in total Intensive+ group (n=622): chest x-ray and bone scans resulted in earlier detection of lung and bone metastases (reduced disease free survival) Control group (n=621) No differences in overall survival between the 2 groups
5.	**Dewar & Kerr** (1985) London, UK	Consecutive sample of women attending routine follow-up clinics after treatment for breast cancer	To assess the value of routine follow-up for women treated for early breast cancer	Retrospective analysis	Incidence of recurrence at interval versus routine clinic visits	546 patients made 6863 clinic visits 192 episodes of recurrent disease, 93 of which detected at routine visits and 99 at interval visits No adverse effect on prognosis for those with distant recurrence detected at interval visits

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
6.	**Donnelly** et al (2001) Grimsby, UK	Purposive sample of 108 female patients treated for primary operable breast cancer, with subsequent recurrent disease	To explore the presentation patterns of women with breast cancer recurrence	Retrospective review	Time taken to presenting with recurrent disease detected my different methods	74% of patients presented at earlier (interval)++ appointments. 17% drew attention to symptoms themselves at routine visits. 2% of recurrences were found by annual screening imaging 7% during the doctor's clinical examination. The median time to presentation was 19 months.
7.	**GIVIO Investigators** [Gruppos Interdisciplinaire Volutazione Oncologier] (1994) Milan, Italy	1320 women under 70 years with confirmed invasive primary breast cancer	To assess prospectively the impact on survival and health-related quality of life of two follow-up protocols , intensive and control+	Multi-centre Randomised Controlled Trial	Overall survival Time to detection of recurrence Health-related quality of life	Intensive group (n=655): 132 deaths (20%), mean of 53.39 months to detection of metastatic disease Control group (n=655): 122 deaths (18%), mean of 54.07 months to detection of metastatic disease Health related quality of life was not affected by follow-up in either group
8.	**Gulliford** et al (1997) London, UK	196 women with primary breast cancer and no symptoms suggestive of recurrence	To compare the experiences of patients receiving conventional breast cancer follow-up with those on limited follow-up of mammogram only	Randomised controlled trial	Patient acceptability and satisfaction of randomised allocation via in-house quality of life questionnaire. Use of telephone and GP.	More patients were satisfied with conventional follow-up, deeming it more reassuring (94% versus 88%) More patients wished to remain with conventional follow-up (94% versus 89%). No increased use of GP or telephone triage seen in women receiving mammogram-only follow-up.
9.	**Imoto** and **Jitsuiki** (1998) Chiba, Japan	Consecutive sample of 65 patients treated for primary breast cancer within a four year time frame	To explore the efficacy of different methods of detection of first site of recurrent breast cancer during intensive+ follow-up	Retrospective analysis	Time taken to presenting with recurrent disease detected my different methods	45% (n=29) of recurrences were found as a result of the patient reporting symptoms, 22% (n=14) were detected by clinical examination, the remainder by imaging and blood tests. No significant differences in OS** between methods of detection of recurrence and symptomatic versus asymptomatic cases
10.	**Joseph** et al (1998) Florida, USA	Consecutive sample of 126 patients with recurrent disease identified from a database of all breast cancer patients (1898) receiving follow-up	To evaluate the role of intensive follow-up in detection of breast cancer recurrence and overall survival	Retrospective analysis	Overall survival Time to detection of recurrence Method of detection of recurrence	26 (21%) had recurrence detected by intensive investigations (such as blood chemistries, chest x-ray, CT scan and bone scan) 79% had recurrence detected by reporting symptoms No significant differences in time to detection of recurrence between two groups No significant differences in overall survival between two groups

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
11.	**Kollias** et al (2000) Nottingham, UK	2511 women under 70 years of age who had been treated for primary operable breast cancer	To determine the value of contralateral mammograms in detecting contralateral new primary breast cancer during routine follow-up surveillance	Retrospective analysis	Detection of asymptomatic contralalteral breast cancer by mammogram	5102 contralateral mammograms performed overall. 65 metachronous contralateral breast cancers were identified, 32% (n=21) at routine* clinic examination, 37% (n=24) at mammography and 31% (n=20) by patients in between visits. In women with a good prognosis the contralateral cancer detection rate was 6.5 per 1000 women.
12.	**Loong** et al (1998) Sutton, UK	Consecutive sampling of 490 women with breast cancer entered in to a radiotherapy fractionation trial after breast conserving surgery for primary breast cancer	To identify the proportion with relapse that was detected at a routine follow-up clinic visit	Retrospective analysis	Detection of relapse in women seen for routine follow-up 3 monthly for one year, then 6 monthly up to five year, then annually thereafter	48 patients developed local recurrence, of which 44% (n=21) were asymptomatic with 17 detected by routine clinical examination & 4 by routine mammography. 67 patients developed distant metastases of which 3 were asymptomatic.
13.	**Pandya** et al (1985) Rochester, USA	Consecutive sample of patients with operable breast cancer attending routine follow-up	To evaluate the efficacy of screening investigations for detecting metastatic breast cancer	Retrospective analysis	Frequency and patterns of early disease recurrence and method of detection	Detection rates of recurrence (n=208): five percent for six monthly chest X-rays, eight percent for annual bone scans and 12 percent for blood tests. Routine asymptomatic investigations demonstrate poor efficacy in detecting systemic disease
14.	**Pivot** et al (2000) Nice, France	Consecutive sample of patients treated for primary breast cancer within a seven year time frame (n=1125)	To evaluate the first indicators of breast cancer recurrence including the first metastatic site and the means of detection (symptoms, clinical examination, blood tests and imaging)	Retrospective analysis	Symptoms	Symptoms were the primary indication of relapse in 58% (n=648) 32% were detected by clinical examination Bone scans, liver scans, chest x-rays and blood tests revealed asymptomatic disease in 10% (n=116). 22% of all recurrences were detected at routine visits, the remainder were at interval++ visits No statistically significant differences in DFS** or OS*** between patients with recurrent disease detected asymptomatically or symptomatically

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
15.	**Scanlon** et al (1980) Chicago, USA	Consecutive sample of patients with stage II or III breast cancer who had had surgery and chemotherapy and were attending routine follow-up	To compare use of routine investigations with no investigations in the success of routine follow-up in detecting recurrence breast cancer	Retrospective audit of two groups	Frequency and patterns of early disease recurrence and method of detection	194 in group 1 receiving 6 monthly follow-up with clinical examination and chest x-ray 60 in group 2 receiving 4 or 6 monthly follow-up with no routine investigations 79% (n=31) of recurrences were symptomatic in group 1 compared to 71% (n=43) in group 2 In group 1 routine investigation detected 13% (n=5) of all recurrences
16.	**Siggelkow** et al (2003) Aachen, Germany	Purposive sample of 57 patients receiving routine follow-up for primary breast cancer	To investigate the diagnostic value of positron emission tomography (PET) in the follow-up of breast cancer patients	Prospective analysis	Incidence of and absence of recurrent disease correctly detected by PET	The absence of disease was correctly detected by PET~ in 25 out of 38 scans in 24 patients receiving follow-up. Sensitivity was 80.6%, specificity was 97.6%
17.	**Snee** (1994) Merseyside, UK	Patients with a history of operable breast cancer attending routine follow-up clinics (n=33)	To determine the clinical outcome of routine follow-up for breast cancer patients	Retrospective audit	Relapse diagnosed Relapse denied Incidence of recurrent disease detected at routine and interval appointments Treatment related morbidity	Total of 325 clinic visits over a period of 3 – 132 months of follow-up Recurrent disease detected at routine visit: NAD# = 281 Relapse = 8 compared to 7 at interval visits 2 of 315 visits were of clinical benefit (<1%)
18.	**Stierer & Rosen** (1989) Vienna, Austria	Consecutive sample of patients treated for primary breast cancer (n = 676) who then developed recurrence (n = 133) to evaluate the impact of intensive routine follow-up	To evaluate the impact of routine technical and laboratory follow-up on the detection rate of subclinical distant metastases and improvement of prognosis	Retrospective analysis	Disease free survival Overall survival	93 patients developed symptomatic metastatic recurrence detected at interval visits 56 patients developed asymptomatic metastases detected with routine investigations No statistical differences in OS or DFS between the 2 groups

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
19.	**Wagman** et al (1991) California, USA	Consecutive sample of 208 female breast cancer patients receiving routine follow-up for breast cancer	To assess the value of commonly available, regularly performed diagnostic tests for recurrent breast cancer	Retrospective analysis	Time to detection of recurrence Method of detection (interval visit versus routine investigations) Overall survival	51 patients developed metastatic disease (16 to bone, 13 to lung, 11 to chest wall, 3 to liver and 8 with multiple sites) Time to detection of recurrence 29 months for interval visiting patients, 28 months for patients having routine investigations Overall survival did not differ between the two groups
20.	**Wheeler et al** (1999) Cambridge, UK	Consecutive sample of all breast cancer patients (n=416) attending one general oncology follow-up clinic in a given time frame	An examination of conventional follow-up practices to determine if a more cost effective approach could be employed while maintaining equivalent patient care	Retrospective analysis	The time to relapse at any site The prognostic significance in terms of subsequent relapse of nodal status, menopausal status and T stage at diagnosis	The annual rate of relapse increased progressively over 4 years. Nodal disease was the most important single variable as predictor for relapse. The annual rate of relapse increased progressively over four years from 5% in year one, to 10% in year two, then 14% in years three and four in patients with node positive disease Intensive early follow-up provided no gain in terms of disease free survival or overall survival
21.	**Wickerham** et al (1984) Pittsburgh, USA	Consecutive sample of all patients treated for node positive, primary, operable breast cancer within a three year time frame under another trial protocol for chemotherapy	To evaluate the efficacy of routine bone scanning in the follow-up of patients with breast cancer	Retrospective Analysis	Detection of bone metastases by routine bone scans performed 6 monthly for 3 years then annually thereafter (n = 7984)	Bone scans detected bone metastases as the first site of recurrence in 163 patients 76% (n=111) were symptomatic 24% (n=35) were asymptomatic 2% (n=163) of 7984 routine scans were +ve for bone metastases 35 (0.4%) were asymptomatic No differences in overall survival

Key:

* routine visits are those that have been pre booked at a previous attendance

** DFS - Disease Free Survival, length of time patients lives with no evidence or symptoms of disease recurrence

*** OS - Overall Survival

**** MRI - Magnetic resonance imaging scan

+ intensive follow-up involves regular clinical examinations (every 3 or 6 months) plus yearly mammogram, blood chemistry, chest x-ray, liver scan & bone scan. In this context control follow- up involves clinical examination and yearly mammogram, with no other investigations unless indicated by the presence of symptoms

++ interval visits are those that were previously unscheduled and are made at the specific request of the patient, the GP or another health professional

~ PET - positron emission tomography

NAD – no abnormality detected

Appendix C

Research of alternative models of follow-up surveillance

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
1	**Adewuyi-Dalton et al** (1998) Oxford, UK	Purposive sample of 109 women attending for hospital based breast cancer follow-up	To investigate the experience of specialist hospital based, medical, breast cancer follow-up	Descriptive	Interviews	Continuity of care and an unrushed consultation were highly desirable. Access to expertise, diagnostic tests and specialist facilities were valued features of follow-up.
2	**Chait et al** (1998) London, UK	Consecutive sample of 65 patients who had attended oncology follow-up for more than 5 years	To determine the consequences for GP's of discharging cancer patients from hospital outpatient follow-up clinics	Pilot Study	HADS Scales at discharge and at 4 months. Self administered questionnaire completed by the GP's	No significant increase in consultation rates. No significant change in patients' anxiety or depression scores 4 months after discharge. GP's reported concerns over lack of available specialist oncology community nurses.
3	**Grunfeld et al** (1995a) Oxford, UK	296 women attending breast cancer follow-up clinics who had completed primary treatment at least 3 months earlier	To assess the effect on patient satisfaction of transferring primary responsibility for follow-up from hospital clinics to general practitioners	Randomised controlled trial	Self administered questionnaires: HADS Scale SF 36 EORTC QLQ-C30 administered three times in 18 months	The change from baseline in the mean depression score was higher in the GP group. There was no significant differences in anxiety or EORTC scores between the groups There was no significant differences in health or social functioning scores between the groups Greater satisfaction was reported in patients receiving follow-up from GPs, which increased from baseline over the course of the study.
4	**Grunfeld et al** (1996) Oxford, UK	296 women attending breast cancer follow-up clinics who had completed primary treatment at least 3 months earlier	To assess the effect on time to diagnosis of recurrence of transferring primary responsibility for follow-up from hospital clinics to general practitioners	Randomised controlled trial	Time between first presentation of symptoms to confirmation of recurrence	Conventional* schedule of hospital follow-up (n=148) versus Follow-up in Primary Care (the same schedule but examination performed by the GP) 69% of recurrences presented as interval** events. 44% of people with recurrence in the hospital follow-up group presented first to general practice. The median time to hospital confirmation of recurrence was 21 days compared to 22 days in the GP group.
5	**James et al** (1994) London, UK	Consecutive sample of patients receiving radiotherapy for central nervous system tumours	To pilot and evaluate a nurse-led follow-up system for neuro-oncology patients, including a telephone assessment at 2 weeks post radiotherapy treatment	Retrospective audit	Numbers of patients seen in the medical neuro-oncology outpatient clinic. Estimated savings in consultation times. Problems identified in nurse-led clinics.	A reduction in clinic numbers seen after introduction of nurse-led clinics (18 versus 30). Estimated gain of 30% of medical time per clinic. The range of problems patients encountered was identified effectively by the specialist nurse.

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
6	**Moore et al** (2002) London, UK	203 patients with lung cancer who had completed their primary treatment	To compare post treatment nurse-led follow-up versus traditional doctor-led follow-up clinic including monthly telephone follow-up	Randomised controlled trial	Quality of life Patient satisfaction GP satisfaction Survival Use of resources	Nurse-led clinic demonstrated higher patient acceptability, less severe dyspnoea at 3 mths; higher patient satisfaction; higher proportion of home deaths no differences in GP satisfaction, survival, disease progression rates, or quality of life
7	**Pal** (1998) Manchester, UK	Purposive sample of 170 patients attending routine follow-up in a rheumatology outpatient clinic	To evaluate a pilot study offering telephone follow-up to patients attending routine follow-up in a rheumatology outpatient clinic	Descriptive	In house questionnaire on patient satisfaction Recorded success in reaching patient by telephone Changes in condition or treatment	Telephone consultations lasted an average of 3.5 minutes per patient Patients reported being clear about information provided with no misunderstandings arising from telephone care 20 patients could not be contacted on the agreed date Patients stated advantages of telephone follow-up saved time & money, was more relaxed & less stressful & obviated problems with transport & long waits in clinic. Disadvantages were the impersonal approach, hearing and language problems
8	**Sardell** (2000) Sutton, UK	Consecutive sample of 43 patients completing primary therapy for high grade gloom	To evaluate nurse-led telephone follow-up of patients with high grade glioma as an alternative to conventional clinic follow-up		Semi structured questionnaire Barthel Activities of Daily Living Index	Median survival from diagnosis was 16 months Median time of telephone follow-up was 6 months 254 calls were made (234 routine and 20 non routine, initiated by patients or carers) Patient satisfaction was high, with a median score of 9 on a scale of 1-10.
9	**Wasson et al** (1992) Hanover, Canada	434 elderly, ambulatory people with chronic diseases	To explore whether substituting telephone care with clinic visits would be resource effective without affecting health	Randomised controlled trial	Use of prescribed medication & investigations. No's of clinic visits. Hospital inpatient stays. Satisfaction via open-ended questionnaires.	Participants receiving telephone care had fewer clinic visits, less prescribed medication, fewer admissions and shorter hospital stays. Satisfaction scores with quality of care, provider continuity and access were the same for telephone care and conventional clinic visit patients.
10	**Wilson & Williams** (2000) Manchester, UK	15 community nurses	To explore the potential effects of visualism (a prejudice in favour of the seen) on the perceived legitimacy of telephone follow-up in community nursing	Multi-method descriptive study	National postal study of community nurses 14 guided interviews with a subset of respondents a survey of service users	Nurses referred to being able to see the patient as enhancing self-awareness, knowledge and assessment of people and health problems. The telephone was associated with impersonality and requires more creative ways of communication

Key:

GP = General Practitioner
HADS = Hospital Anxiety and Depression Scale
* = Conventional clinic schedule involved visits every 3 months for the first year, every 4 months the second year, every 6 months from years 3 to 5 and annually thereafter
** = interval visits are those that were previously unscheduled and are made at the specific request of the patient, the GP or another health professional
SF 36 = 36 item health survey
EORTC QLQC30 = European Organisation for Research and Treatment of Cancer core quality of life questionnaire

Appendix D

Research of advanced nursing practice and nurse-led care

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
1.	**Armstrong et al** (2002) Glasgow, Scotland	Purposive sample of 7 nursing and midwifery roles chosen because of adherence to preset criteria and geographical spread	To explore the nature and experience of role development in nursing and midwifery in Scotland	Descriptive Case Studies	Semi-structured interviews with the nurse's direct line manager, the nurse and another health professional in direct contact with the nurse	Major themes included: The nature of the work (elements of specialist and advanced practice) Professional merit (knowledge and high standards of care) Benefits to patients (continuity, co-ordination, expertise) Evaluation of the role (poorly done)
2.	**Ashworth et al** (2001) Sheffield, UK	Purposive sample of 18 nurse lecturers in the UK responsible for master's level programmes in nursing	To explore the characteristics which nurse educators attributed to the practice of master's level nursing graduates	Descriptive	In-depth interviews	Characteristics attributed to master's level nurses were: Cognitive competencies (critical analysis, synthesis, problem solving) Practice-related competencies (analysis, problem solving, autonomous decision making) Research orientation Personal dynamism (personal change, confidence , assertiveness)
3.	**Bousfield** (1997) Nottingham, UK	Purposive sample of 7 clinical nurse specialists (CNS)	To investigate how a group of clinical nurse specialists think and experience their role	Phenomenological approach	Semi-structured interviews	8 key elements of the CNS* role: enthusiasm for leadership knowledge, lack of support isolation, poor time management inter/intra role conflict, disempowerment burn out
4.	**Campbell et al** (1997) Leeds, UK	Purposive sample of one consultant's radiotherapy patient caseload (n=71)	To evaluate the effectiveness of a nurse-led service for patients receiving radiotherapy compared to a conventional radiotherapy clinic	Descriptive Evaluative	No. of visits to nurse-led clinic Semi structured interview of patient's perceptions of nurse and doctor led clinics Doctors and radiographers perceptions of both clinics	Nurse-led clinic initiated greater numbers of reported interventions on management of side effect (30%), psychosocial assessment (41%), information giving (19.5%), checking treatment site (8.5%), but decreases in investigations (3%) and prescriptions given (3%). Nurse-led clinic resulted in more referrals to other health professionals. Patients expressed confidence and satisfaction with nurse-led clinic. Doctors and radiographers found the nurse-led clinic reduced waiting times, paid greater attention to individuals and their feelings, provided continuity of care
5.	**Earnshaw and Stephenson** (1997) Gloucester, UK	Purposive sample of female patients with breast disease attending 382 clinic visits	To determine clinical efficacy of follow-up clinics for women with breast disease being run by a specially trained nurse practitioner	Prospective, descriptive study	Clinical evaluation by consultant at alternate review and when required	Of 191 clinic visits for benign disease, 9% required consultant review. Of 191 clinic visits for malignant disease, 13% were reviewed by the consultant outside of the planned alternate reviews. No breast lesion was missed by the nurse practitioner demonstrating clinical efficacy.

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
6.	**Elder & Bullough** (1990) New York, USA	Consecutive sample of 132 CNS's and NP's** from another study group of from an MSc. Programme within one American university	To conduct a comparison of CNS and NP roles and the views of the post holders	Survey	Questionnaires – lists of role components; views on professional issues;	Significant difference emerged between the CNS and NP roles in only 8 out of 25 activities; NPs were more likely to conduct physical examination, order laboratory tests, prescribe medications and treatments and make referrals. CNS's were more likely to conduct support groups. Both were involved in teaching and psychosocial assessment.
7.	**Faithfull et al** (2001) London, UK	115 men undergoing pelvic radiotherapy for prostate cancer	To compare nurse-led follow-up with open access clinics and telephone follow-up with standard doctor-led care during and after completion of radiotherapy	Randomised controlled trial	Quality of life Symptoms of radiotherapy toxicity Satisfaction with care Comparison of costs	Greater satisfaction with nurse–led care. Costs were lower with nurse-led care. No differences in quality of life or symptom profiles.
8.	**Garvican et al** (1998) London, UK	Consecutive sample of 119 new referrals to a breast assessment clinic cancer	To explore patient satisfaction with clinical nurse specialist-led care of women referred to a hospital breast clinic and to compare clinical efficacy in sample taking	Retrospective descriptive study	In-house patient satisfaction questionnaire Audit of fine needle aspiration samples by clinician	75% were satisfied with the speed of diagnosis or reassurance. 70% were very satisfied with the standard of care provided. Women were more satisfied with the nurse than with any other aspect of their care. Specialist nurses compared with medical team members aspirated a lower percentage of inadequate samples.
9.	**Hammond et al** (1995) Sussex, UK	Consecutive sample of patients seen by the nurse practitioner over a 5 month time frame	To assess the effectiveness of the post of the breast care nurse practitioner	Retrospective survey	Medical Interview Satisfaction Scale State-Trait Anxiety Inventory Tape recorded consultations	Patients seeing the NP expressed greater satisfaction and less anxiety than those seeing a doctor. The NP gave more patient- centred information and checked patients' understanding more frequently. Clinical efficacy and accuracy was the same in both groups
10.	**James et al** (1994) London, UK	Consecutive sample of patients receiving radiotherapy for central nervous system tumours	To pilot and evaluate a nurse-led follow-up system for neuro-oncology patients, including a telephone assessment at 2 weeks post radiotherapy treatment	Retrospective audit	Numbers of patients seen in the medical neuro-oncology outpatient clinic. Estimated savings in consultation times. Problems identified in nurse-led clinics.	A reduction in clinic numbers seen after introduction of nurse-led clinics (18 versus 30). Estimated gain of 30% of medical time per clinic, however no reduction in the workload of the whole unit (but a shift from doctor to a nurse based system). The range of problems patients encountered was identified effectively by the specialist nurse.

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
11.	**Kinnersley et al** (2000) Cardiff, Wales	1368 patients requesting same day consultations from 10 general practices in Wales and England	To ascertain any differences between care from NP's and GP's*** for patients seeking same day consultations in primary care	Randomised controlled trial	Patient satisfaction Resolution of symptoms Care provided Information provided Patients future intentions for care	No notable differences in resolution of symptoms between patients seen by NP's or GP's Satisfaction scores were skewed negatively for GP consultations, and were statistically higher for NP consultations in some practices and for consultations with children. No notable differences in prescriptions ordered or referrals made. NP consultations were significantly longer. Patients seen by NP's reported receiving more information. More patients in both groups stated they would consult a GP in the future.
12.	**Manley** (1997) London, UK	One advanced practice post holder	To analyse an advanced practice post and develop a conceptual framework for operationalising advanced nursing practice roles	Action Research	Diary and field notes analysis Questionnaire to key staff (itemised check list) Focus groups with nursing teams	Nine themes resulted from multiple in-depth analyses: Role modeller, Catalyst, Facilitator, Staff development, Practice development, Change agent, Change manager, Infrastructure development, Strategist. Sub roles were: Expert practitioner, Educator, Researcher, Consultant
13.	**McCorkle et al** (1989) Philadelphia, USA	166 patients with lung cancer	To compare nurse specialist led home care versus standard home care versus doctor-led outpatient based care	Randomised controlled trial	Symptom distress Mood Current concerns Social dependency	Doctor-led care patients deteriorated more quickly and showed greater social dependency Nurse specialist led care had fewer hospital admissions
14.	**McCreaddie** (2001) Glasgow, Scotland	Purposive sample of 20 clinical nurse specialists from two sites and different clinical specialties	To investigate the current work and role of the clinical nurse specialist	Grounded theory	Semi-structured interviews with 3 main foci: How had they become a CNS Description of day to day work Consideration of how they had changed over time	Key themes: Communicator-carer – specific, recognisable contact, valued helping relationship Other roles included educator; less than half were involved in research. Factors affecting the role: Increasing workload, - professional and personal impact Relationship with others, specifically doctors Proving the role – evaluation Support for the role

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
15.	**McGee et al** (1996) Birmingham, UK	Purposive sample of 371 NHS trusts, 230 responses	To explore the expectations of senior personnel in NHS trusts in England with regard to specialist and advanced nursing roles and develop baseline data on these roles	Survey	Questionnaire with two sections on definitions of specialist (SN) and advanced (ANP) nursing	No.s of SN**** posts greatly exceeded numbers of ANP posts (236 v 66) 320 fields of practice were identified among SN postholders and 93 among ANP's*****. ANP fields of practice reflected more technical areas and areas where impact on doctors working hours was more likely (e.g. A&E). SN's adopted a more multifaceted role (clinical practice, education, consultancy, research and management) Advantages of roles included continuity, more time with patients and increased patient satisfaction. Disadvantages included deskilling of other staff, too narrow a focus, loss of generic skills
16.	**Moore et al** (2002) London, UK	203 patients with lung cancer who had completed their primary treatment and were expected to survive for more than 3 months	To compare post treatment nurse-led follow-up versus traditional doctor-led follow-up clinic in patients with lung cancer	Randomised controlled trial	Quality of life Patient satisfaction GP satisfaction Survival Progression free survival Use of resources Comparison of costs	Nurse-led clinic demonstrated higher patient acceptability, less severe dyspnoea at 3 mths; higher patient satisfaction; higher proportion of home deaths no differences in GP satisfaction, survival, disease progression rates, or quality of life
17.	**Raftery et al** (1996) London, UK	554 patients terminally ill with cancer	To compare outcomes of care individually co-ordinated by a specialist nurse versus standard care	Randomised controlled trial	Physical symptom Psychiatric problems Satisfaction with services and carers	Little differences in all outcomes noted for patients. Costs of care lower when co-ordinated by specialist nurse
18.	**Ritz et al** (2000) Minneapolis, USA	210 women newly diagnosed with breast cancer	To evaluate the input of an advanced practice nurse in co-ordinating care and supporting women newly diagnosed with breast cancer in addition to standard medical care and compared to medical care alone	Randomised controlled trial	Quality of life Psychological well-being (including uncertainty, mood states, well-being) Costs	Uncertainty decreased significantly from baseline in patients seen by the nurse at 1, 3 and 6 months after diagnosis No significant cost differences between the two groups

	Reference	Sample	Aims of study	Study design	Outcome measures	Main study findings
19.	**Shum et al** (2000) Manchester, UK	Purposive sample of 5 general practices in South East London and Kent involving 1815 patients	To assess the acceptability and safety of a minor illness service led by practice nurses in general practice compared to GP's	Multicentre, randomised controlled trial	Satisfaction with consultation questionnaire Length of consultation Number of prescriptions Rates of referral to GPs by practice nurses Patient's reported health status Patient's anticipated future health seeking behaviour Number of return visits Number of out of hours calls	Patients were statistically significantly more satisfied with nurses than with GPs Consultations with nurses took an average of 10 minutes compared to 8 minutes with GPs Numbers of prescriptions were comparable between nurses and GPs Nurses referred on 27% of patients to GPs 91% of patients seen by the GP and 94% of those seen by the nurse stated they would seek input for future health problems No differences found in patient's rating of their health status, 20% returned for repeat visits in each group 7 out of hour calls were made to patients seen by nurse, compared to 10 in patients seen by GP
20.	**Venning et al** (2000) Manchester, UK	Purposive sample of 20 general practices in England and Wales seeing 1303 patients who had requested appointments same day	To compare cost effectiveness of General Practitioners (GPs) and nurse practitioners (NPs) as first point of contact in primary care	Multicentre, randomised controlled trial	Consultation process Patient satisfaction Patient health status Return clinic visits Cost	NP consultations were longer than those with GPs (11.57 minutes versus 7.28 minutes) NPs carried out more tests than GPs (8.7% versus 5.6%) NPs asked patients to return more commonly than GPs (37.2% versus 24.8%) No significant differences in prescribing or health status outcomes between the 2 groups Patients were more satisfied with NP consultations No significant differences in health care costs between the two groups
21.	**Weintrob et al** (1990) North Carolina, USA	56 patients receiving radiotherapy	To compare nurse-led consultations versus doctor-led care with additional general health information versus doctor-led care alone	Randomised controlled trial	Side effects Anxiety	Lower anxiety in patients receiving nurse-led care

Key:

* CNS = clinical nurse specialist

** NP = nurse practitioner

*** GP = general practitioner

**** SN = specialist nurse

***** ANP = advanced nursing practice

Appendix E

Domains of the ENB Specialist Practice Award

(UKCC 2001)

Standards for Specialist Education and Practice

1) Specialist Clinical Practice

- Assess health, health related and nursing needs of patients or clients, their families and other carers by identifying and initiating appropriate steps for effective care for individuals and groups
- Set, assess and manage critical and clinical events to ensure safe and effective care
- Support and empower patients and clients, their families and other carers to influence and participate in decisions concerning their care by providing information on a range of specialist nursing care and services
- Facilitate learning in relation to identified health need for patients, clients and carers
- Provide counselling and psychological support for individuals and their carers

2) Care and Programme Management

- Supervise and manage clinical practice to ensure safe and effective holistic research-based care
- Initiate and contribute to strategies designed to promote and improve health and prevent disease in individuals and groups by identifying and selecting from a range of health and social agencies, those that will assist and improve care
- Recognise ethical and legal issues which have implications for nursing practice and take appropriate action

3) Clinical Practice Leadership

- Lead and clinically direct the professional team to ensure the implementation and monitoring of quality assured standards of care by effective and efficient management of finite resources
- Identify individual potential in registered nurses and specialist practitioners, through effective appraisal systems. As a clinical expert advise on educational opportunities that will facilitate the development and support of their specialist knowledge and skills to ensure they develop their clinical practice
- Ensure effective learning experiences and opportunity to achieve learning outcomes for students through preceptorship, mentorship, counselling, clinical supervision and provision of an educational environment

4) Clinical Practice Development

- Create an environment in which clinical practice development is fostered, evaluated and disseminated
- Identify specialist learning activities in a clinical setting that contribute to clinical teaching and assessment of learning in a multi-disciplinary environment within scope of expertise and knowledge base
- Initiate and lead practice developments to enhance the nursing contribution and quality of care
- Identify, apply and disseminate research findings relating to specialist nursing practice

Appendix F

Explanatory Invitation Letter & Consent Form

(Phase One)

Phase One

dd/mm/yy

Dear

We would like to invite you to take part in a research study that aims to find out patient's feelings about their Outpatient visits, after finishing all treatment for breast cancer. It is hoped that the results of this study will lead to an improvement in the quality of follow-up care provided for patients with breast cancer.

The study will involve you being interviewed by a breast care nurse for approximately one hour. This can take place either during one of your hospital visits or at your home. The interview will be taped, however, the tape can be turned off or the interview stopped at any time if you wished.

The tapes will be anonymous and will be stored securely and destroyed after the study in order to protect your confidentiality. In addition some data will be collected from your clinical notes.

Please be assured participation in the study is entirely voluntary and if you do not wish to take part, or chose to withdraw at any time, this will in no way affect your future care or the attitudes of your carers towards you. If you do consent to take part in the study your legal rights will not be affected in any way.

If you agree to take part in this study or you have any further questions please contact Emma Pennery, breast care nurse, via the xxxxxxx switchboard, on xxxx xxx xxxx, and ask for extension xxxx or bleep xxx.

Yours sincerely
The Breast Care Team

Phase One

Patient casenote number:

XXXX NHS TRUST

WRITTEN PATIENT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: **A Preliminary Study of Patients' Perceptions of Routine Follow-up After Completion of Treatment for Breast Cancer**

Ethics Committee Protocol No: **1278**

SECTION 1 - To be signed by the patient

I, ... consent to participate (to the participation of ....) in the above research study.
The purpose and nature of this study has been fully explained to me by ....**Emma Pennery**..

I understand that my participation in this study is entirely voluntary and that I may withdraw from it at any time without giving a reason and without giving jeopardy to my further care.

I also understand that if I decide to withdraw from the study, I will continue to receive the best conventional treatment that is available. If I have any further questions regarding the study at any time, I should contact ....**Emma Pennery**..

Signature of Patient .... Date ....
(or Parent/Guardian)

SECTION II - To be signed by the Clinical Nurse Specialist

I, ...**Emma Pennery**... declare that the purpose and nature of the above research study has been explained to the above person in writing and verbally. This explanation included a description of the procedures involved, possible benefits to the patient, potential risks or side effects and the expected duration of the patient's participation.

Signature of Clinical Nurse Specialist .... Date ....

SECTION III - To be signed by a witness

I, ... declare that in my opinion the patient (or parent/guardian) has understood the purpose and nature of the above study. He/she was given the opportunity to ask relevant questions and his/her consent was given freely.

Signature of Witness .... Date ....

Designation ....

*SECTION IV - To be signed by the Patient **after** the taped interview*

I, ... consent to the transcript and use of the tape recording for the purpose of the above research study.

Signature of Patient .... Date ....

Appendix G

Semi-Structured Interview Schedule (Phase One)

Ground rules:

Introduction and reaffirmation of confidentiality and termination of interview or taping if the person request it

Access to Clinic Visits:

1. How much time approximately does each visit take you from when you leave home to when you return?
2. How do you travel to the clinic and how much does it cost you?
3. Do you ever have any difficulties coming to the clinic? [prompts: travel arrangements or costs, time off work, child care]

Clinic Consultation:

4. What normally happens during your follow-up clinic visit?
5. How do you feel about the staff you see in terms of their manner and standards of care?
6. Do you find your clinic visits worthwhile and why?
7. To what extent do you feel the clinic visits meet you needs in term of
    - providing information required and answering your questions
    - providing emotional (psychological) support
    - providing optimal health care
8. Who would you prefer to meet your follow-up needs and why?
9. What are the advantages of coming to the breast cancer follow-up clinic?
10. What are the disadvantages of coming to the breast cancer follow-up clinic?
11. Would you prefer to come back to the clinic more or less often and why?

Any other comments, thoughts, ideas?

Appendix H

Focus Group Guide (Phase One)

Each participant arrives, sits comfortably and has refreshments before facilitator begins

Introductory remarks and welcome
Thank everyone for his or her participation and for staying late
Explain my role as facilitator
Explain the aims of the study and this focus group
Explain the reason for choosing a focus group and for their selection as invited participants
Set ground rules
    Everyone has the equal right to participate
    Try to speak one at a time for the tape and transcription
    Agree to confidentiality – for verbal information shared in the room and the tape and transcription
    There are no right or wrong answers, positive and negative viewpoints are equally welcome and valuable
    The facilitator's role is to remain objective and manage the flow of the discussion, not to participate or give answers
Start by checking tape and perform a sound check by asking the participants to state their first names and their job titles

General brainstorm of ideas and opinions about how breast cancer follow-up runs within the current model
Prompts: what generally happens, how do they work, what is the current model, how does it fit in to the rest of their duties?

Why might the system operate as it does, for example with use of clinical examination and investigations?
Prompts: to find recurrent disease?

What are the perceived logistical problems with the breast cancer follow-up?
Prompts: availability of resources and equipment?

What works well within the current system?
Prompts: seeing patients after surgery, providing surveillance, addressing problems, your own learning?

What does not work well within the current system?

Prompts: too greater numbers of patients, rushed consultations?

How does follow-up impact on the emotional needs of people with breast cancer?

How does follow-up impact on the information needs of people with breast cancer?

How does follow-up impact on the physical needs of people with breast cancer?

What contribution do specialist nurses make to the breast cancer follow-up clinics?

Could breast cancer follow-up be led by specialist nurses?

Have I missed anything that you would like to comment on?
Any final comments?
Thank participants for their valuable contribution
Remind about confidentiality and re-check verbal consent from each participant to refer to the content in the thesis and future publications

Appendix J

Role Development Profile: Breast Cancer Follow-up

ROLE DEVELOPMENT PROFILE

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER

PLEASE NOTE
BEFORE UNDERTAKING THIS AREA OF DEVELOPMENT SUPPORT MUST HAVE BEEN SECURED FROM YOUR CLINICAL MANAGER

Name : ……………………………………………………

Clinical Area : ……………………………………………………………………

Date : ……………………………………………………

Document Control :

Version Number :	1
Document Author Name(s) :	EMMA PENNERY
Document Author Title(s) :	Senior Clinical Nurse Specialist, Breast Unit
Authoring Department :	Directorate of Nursing, Rehabilitation & Quality Assurance
Edited by :	
Edited by Title(s) :	Assistant Chief Nurse (Research, Practice & Professional)
Authoriser Name :	Clinical Practice Forum and Nursing and Rehabilitation Advisory Committee
Authoriser Title(s) :	CPF and NRAC
Review Period Months :	12 months
Review date :	
Review details :	
Reviewed by Name(s) :	CPF and NRAC
Reviewed by Title(s) :	

Strategy for Nursing Ref No:

CONTENTS

INTRODUCTION

Please refer to the following documents prior to undertaking a role development :

- *Appendix 1* – The Scope of Professional Practice in Nursing Position Statement
- *Appendix 2* - A Framework for Development of the Scope of Professional Practice in Nursing

*At the [*NHS Trust hosting the study*], when a woman has completed all active treatment for breast cancer they are entered in to a schedule of care known as routine follow-up. Longer term endocrine therapies (such as Tamoxifen) may still be ongoing, but otherwise the patient is deemed disease free and needing only routine surveillance for disease recurrence.*

1. *Gaining Managerial Consent*

It is hoped that during your individual performance review you reflected on your existing skills and experience within your current role and have now secured support for this development from your clinical manager. It is only appropriate for you to undertake this role development profile if you work in a practice area where provision of routine follow-up is relevant to your post and you are engaged in providing this for a minimum of at lease one session per week.

Your clinical manager is required to sign a statement in support of your role development in ***conducting routine follow-up consultations & examinations for patients who have completed treatment for breast cancer***:

- prior to, and on completion of ***a training programme with identified clinical supervisor,*** a period of supported supervised practice and a learning profile.

2. *Identification of a Practice Supervisor*

- You will be assigned a suitable practice supervisor from ***a member of medical or nursing staff experienced and trained in conducting routine follow-up consultations and examinations after treatment for breast cancer,*** they will be able to guide and support you as you develop your skills and knowledge.
- Formal contact with this person will be negotiated allowing you to plan your development, to review your progress and to discuss and resolve any area of difficulty or uncertainty.
- It is recognised that your practice supervisor may not always be readily available. ***An alternative member of nursing or medical staff experienced in routine follow-up*** may be utilised as a resource for practical supervision, information and advice.

3. *The Learning Profile*

- This learning profile has been developed to enable you to take responsibility for your own learning in ***conducting routine follow-up consultations and examinations of patients treated for breast cancer*** and to record your developing competency through reflective practice.
- It is suggested that you reflect on any activity which may contribute to your learning; including reading, discussion or study day attendance and record what you have learnt from this process.
- It is also recommended that you continue to record activities and experiences, which contribute to the maintenance of your competency in ***conducting routine follow-up consultations and examinations for patients who have been treated for breast cancer.*** These may be added to your profile as required.
- There are a number of reflective practice exercises within this learning profile. Each exercise should be individually linked to evidence of appropriate reading and current research based practice.
- You may require more or less practice and should repeat the reflective exercises, as often as it is necessary, until you and your supervisor are happy that you have achieved a competent level of practice.

- You must carefully consider the documentation of events in relation to patient and colleague confidentiality. You may prefer not to record the event in detail but identify in your reflection the particular, relevant, learning experience, which took place.
- You should focus on positive learning experiences as well as those that are negative. Learning may occur from experiences, which are very ordinary and typical as well as those more demanding.
- Along with this learning profile you will need to refer to the ***Hospital Breast Unit Management Policies (2001).***
- Suggested reading references are at the end of your profile.

4. Independent Practice

You must not practice independently until you are confident that you possess the required knowledge, understanding and skills, have undergone a period of supervised practice, can adequately demonstrate your learning through completion of this profile and have a declaration of support to do so from your clinical manager (page 10)

HOW TO USE THIS LEARNING PROFILE

1. Personal Development Record

The knowledge, understanding and skills expected of competent practitioners for ***conducting routine follow-up consultations and examinations after treatment for breast cancer,*** within this Hospital, are identified as intended learning outcomes.

It may first help you to use the self-assessment table on page 17, which refers to each of the learning outcomes. It enables you to identify which specific areas of knowledge and skill in which you initially require development.

To plan your personal development you should now address each learning outcome and identify:

- your existing knowledge, understanding and skills
- your knowledge gaps and requirements
- an action plan to enable you to achieve competent practice.

It will be beneficial to complete this process with your supervisor to enable them to appropriately facilitate, guide and support you and negotiate periodical assessment of your achievements.

Activities which may contribute to your learning prior to and following a period of supervised practice, may include attendance at a study day, reading, discussion or observation of follow-up outpatient clinics.

Practical experience is a vital component of your learning. It allows you to develop a greater understanding of the specific knowledge and skill applied to every individual procedure.

2. Reflective Practice Exercise - Recording The Evidence

In relation to ***conducting routine follow-up consultations and examinations for patients who have been treated for breast cancer,*** the following could contribute to evidence of learning:

- Accounts and reflection on relevant and useful learning activities and experiences, for example, using the reflective practice worksheets within this profile;

- A summary of relevant and useful reading and/or discussion;

- A certificate of attendance on a relevant course or study day/session and accompanying programme;

- Completion of the Worksheet Feedback provided on page 25 with written feedback from your manager regarding the level and depth of your knowledge and understanding; and

- Written feedback of practical assessment from your practice supervisor. For example, using the Practice Assessment Framework provided on page 29.

The evidence you are providing within this profile must be authentic and relevant. There also must be sufficient evidence to infer your competency.

Try imagining that you have never witnessed ***a routine follow-up consultation & examination of a patient after treatment for breast cancer*** before - read through your profile - it should provide a demonstration of the understanding of the knowledge and skills required to become a competent practitioner.

3. *Personal And Managerial Accountability*

- The assessment of your knowledge, understanding and skills by your manager *does not* allow you to relinquish your personal professional accountability for judging your own degree of competence.

- However in order to maintain a high standard of practice within the Hospital, it remains essential that you obtain feedback relating to your competency from an expert practitioner.

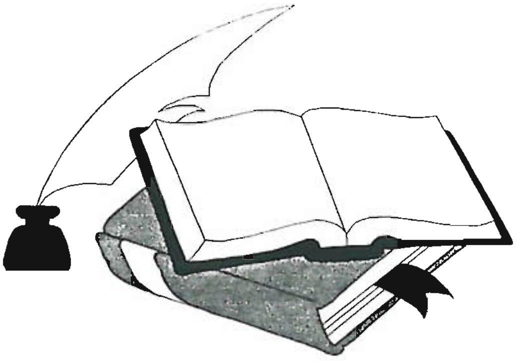
- You will find a Novice to Expert Learning Outcomes form on page 14, which is intended to help you evaluate your progress. To practice independently you must have reached the level of proficient practitioner on the Novice to Expert Learning Outcomes form.

- Your clinical manager should not sign your completed profile until they are satisfied that you have fulfilled the competency requirement of this Hospital.

- It may be beneficial that you and your supervisor arrange to meet your clinical manager together to establish this, before signing and returning your own declaration of competence and intent to practice independently.

- Your personal declaration must be returned to your clinical manager/supervisor, ward sister/charge nurse and the Document Controller (Directorate of Nursing, Rehabilitation and Quality Assurance, Sutton) to serve as a record.

PERSONAL DEVELOPMENT RECORD



ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

DECLARATION OF CLINICAL MANAGER SUPPORT

PRACTITIONERS' NAME:

TITLE/GRADE: ....

CLINICAL AREA: ....

1. I agree to the above named person undertaking preparation for conducting *routine follow-up consultations & examinations for patients after treatment for breast cancer.*

NAME :	
TITLE / DESIGNATION :	
SIGNATURE:	
DATE :	

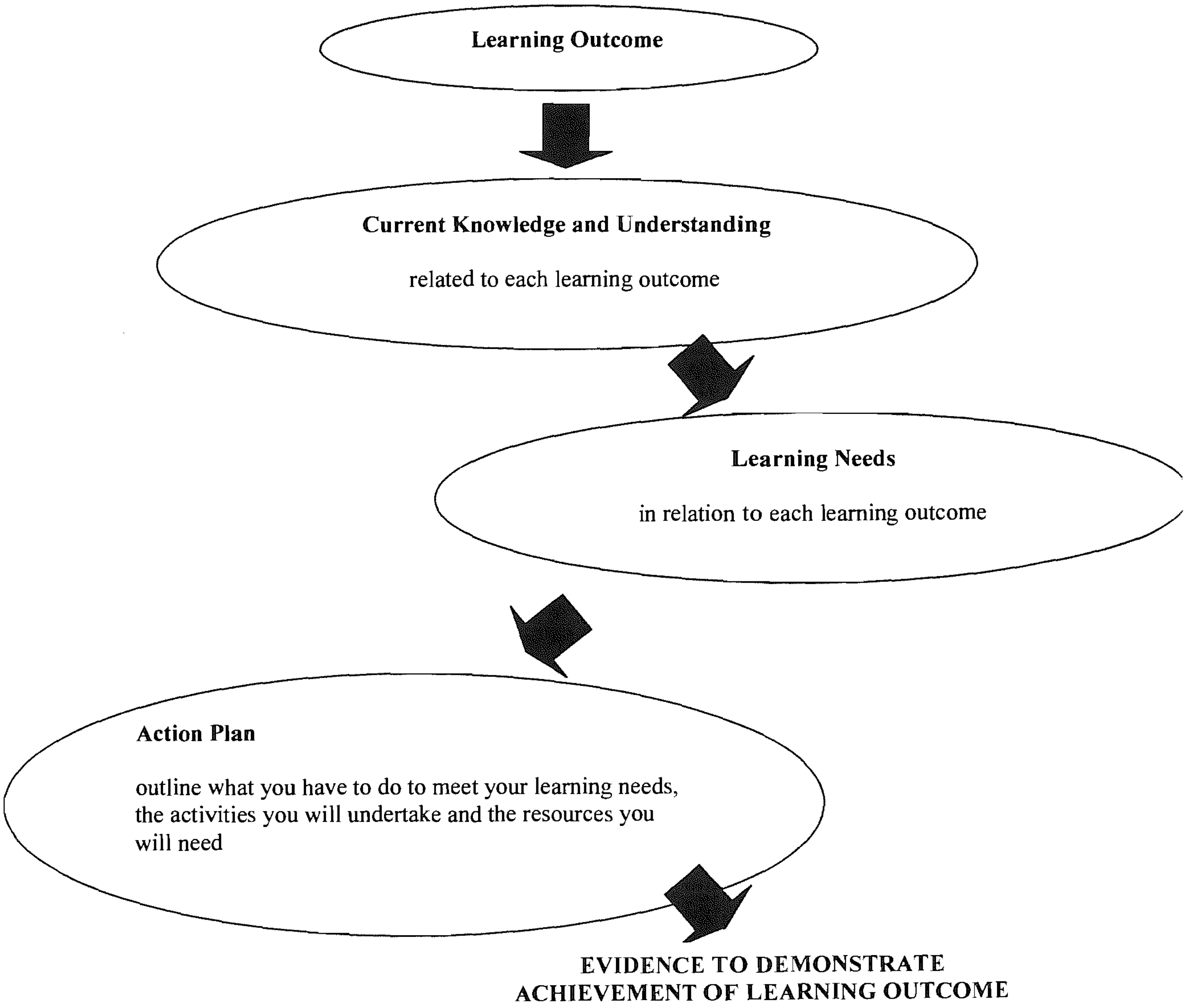
2. I agree to the above named person undertaking *routine follow-up consultations and examinations for patients after treatment for breast cancer*

NAME :	
TITLE / DESIGNATION :	
SIGNATURE:	
DATE :	

Please send a copy of this form to your clinical manager / supervisor, ward sister / charge nurse and the Document Controller, (Directorate of Nursing, Rehabilitation and Quality Assurance, Sutton) and keep the original.

PROFESSIONAL DEVELOPMENT FLOW DIAGRAM

The following diagram is to enable you and your supervisor to methodically review the learning outcomes (competencies) individually. In your written reflections of supervised practice you should review your personal development of the knowledge and skills required for each outcome. You should aim to periodically meet your supervisor on a formal basis, to receive structured feedback and to evaluate and review your role development learning plan.



INTENDED LEARNING OUTCOMES

ELEMENTS OF PRACTITIONER COMPETENCY

Knowledge and Understanding

You are expected to possess knowledge and understanding of the following:

- The normal anatomy and physiology of the breast, chest wall and axilla
- The pathogenesis and natural history of breast cancer
- Principles of examination of the natural breast, a reconstructed breast, the chest wall, axilla and regional lymph nodes in the context of follow-up consultations
- Differences between a normal, untreated breast and axilla versus a treated area
- Treatment modalities and aims of management of early breast cancer including:
    - Surgical treatment options (indications, complications and after care)
    - Reconstruction techniques (complications and after care)
    - Medical treatment modalities (chemotherapy, radiotherapy and endocrine therapy) including rationale for use, duration, indications, complications and short and long term side effects of each
- Pathological variables and their prognostic significance
- Patterns of presentation of local recurrence and primary target sites for metastatic breast cancer
- Relevant symptamology with respect to possible metastatic disease
- Clinical detection and appropriate investigation of new presenting symptoms to identify local and distant metastatic disease
- Indications for referral to the medical team
- Treatment modalities and aims of management of advanced breast cancer
- Early and late complications of loco regional and systemic treatment of breast cancer including:
    - Strategies for the management of treatment induced symptoms (e.g. hot flushes, vaginal dryness, skin and hair changes, erythema, seroma, lymphoedema, amenorrhea, chronic pain)
    - Appropriateness of the use of hormone replacement therapy following the diagnosis and treatment of breast cancer
- Local protocols for follow-up surveillance and screening imaging, including frequency, duration and content
- Accountability with regard to documentation of the follow-up consultation, including correspondence to the General Practitioner
- Key issues relevant to survivorship following breast cancer (e.g. emotional needs, altered body image and related concerns, altered fertility, significance of family history) and appropriate psychological care of the patient
- Professional and legal implications of conducting routine follow-up consultations and examinations for patients who have completed treatment for breast cancer

INTENDED LEARNING OUTCOMES

ELEMENTS OF PRACTITIONER COMPETENCY

Skills

You are expected to possess the following skills:

An ability to:-

- Take a relevant clinical history
- Interpret the relevance of the patient's medical history with regards to breast cancer (including prognostic implications)
- Conduct clinical examination of the normal breast, the post treatment breast and the reconstructed breast
- Recognise clinical variations between a treated and untreated breast and axilla
- Interpret and assess the relevance of symptoms reported in the follow-up consultation
- Clinically detect potential local recurrence in the breast or axilla
- Recognise the signs and symptoms of potential distant metastatic breast cancer
- Explain the selection of and process of investigations for the detection of metastatic disease to the patient
- Initiate referrals (as appropriate) to medical staff and other members of the multidisciplinary team for specialist intervention (including psychological care)
- Interpret and explain the relevance of the patient's family history of breast cancer
- Provide the patient with appropriate emotional support in response to their needs
- Recognise expected physiological changes in keeping with breast cancer treatment
- Recognise and act on complications of treatment (short and long term)
- Educate and provide accurate advice and information to patients
- Correctly and accurately complete documentation, including dictation of a letter to the General Practitioner (with appropriate terminology and content)

NOVICE TO EXPERT LEARNING OUTCOMES

Advanced Beginner	Competent	Proficient	Expert
Demonstrates knowledge & understanding of the professional and legal issues in relation to follow-up consultations & examinations, including local policies	Ability to use their knowledge & understanding of the professional and legal issues in relation to follow-up consultations & examinations, including local policies	Efficiently able to use knowledge & understanding of the professional and legal issues in relation to follow-up consultations & examinations, including local policies	Expertly able to support others, and act as a proficient role model during the teaching of others about follow-up consultations & examinations
Demonstrates knowledge & understanding of normal anatomy and physiology of the breast, chest wall and axilla	Able to apply knowledge & understanding of treatment altered anatomy & physiology in order to identify expected changes in keeping with such treatments	Efficiently able to identify expected treatment induced changes to anatomy and physiology following treatments for breast cancer	Expertly able to support others, and act as a proficient role model during the teaching of others about treatment induced changes to anatomy and physiology and how to recognise them
Demonstrates knowledge & understanding of the indications, contra-indications and side effects of treatments for breast cancer	Ability to apply knowledge to follow-up consultations & examinations, recognising the relevance of the above to the history taking, assessment and clinical examination	Efficiently able to apply knowledge to follow-up consultations & examinations, recognising the relevance to the history taking, assessment and clinical examination	Expertly able to support others, and act as a proficient role model during the teaching of others about breast cancer treatments and the relevance of the effects of these to history taking, assessment and clinical examination
Demonstrates knowledge and awareness of the emotional support the patient may require after treatment for breast cancer and the advice and information required by the patient/family/carer	Able to appropriately support the patient emotionally with consideration of the family/carer, including the provision of advice and information	Efficiently able to appropriately support the patient emotionally, providing advice and information, in order to address psychological needs, with consideration of the family/carer	Expertly able to act as a proficient role model demonstrating emotional support of the patient after breast cancer treatments and meeting the needs of the family/carer
Demonstrates knowledge and understanding of the metastatic potential of breast cancer	Able to apply knowledge & understanding of the metastatic potential of breast cancer to follow-up consultations & examinations and indicate the relevance of this knowledge in relation to interpreting new symptoms reported	Efficiently able to apply knowledge & understanding of the metastatic potential of breast cancer to follow-up consultations & examinations and explain in detail the relevance of this knowledge in relation to interpreting and assessing new symptoms	Expertly able to support others and act as a proficient role model during the teaching of others about the metastatic potential of breast cancer and the relevance of this to follow-up consultations & examinations and responding to new symptoms
Demonstrates knowledge and understanding of the rationale for and nature of follow-up surveillance after treatment for breast cancer	Able to apply knowledge and understanding to conducting follow-up surveillance after treatment for breast cancer and seeks assistance and/or advice where appropriate	Efficiently able to evaluate technique for conducting follow-up surveillance after treatment for breast cancer – recognising difficulties, their cause and future preventative measures	Expertly able to support others and act as a proficient role model during the teaching and evaluation of others in conducting follow-up surveillance after treatment for breast cancer

Demonstrates knowledge & understanding of the professional and legal issues in relation to documentation	Able to complete relevant documentation following follow-up consultations and examinations after treatment for breast cancer	Efficiently able to apply knowledge to completion of relevant documentation following follow-up consultations and examinations after treatment for breast cancer	Expertly able to act as a proficient role model during the teaching of others about completion of relevant documentation following follow-up consultations and examinations

SELF-ASSESSMENT OF CURRENT KNOWLEDGE, UNDERSTANDING AND SKILLS IN RELATION TO THE LEARNING OUTCOMES

At what level is your knowledge and understanding or skills in relation to the following learning outcomes? (Please tick a box.) Where you already feel confident about your knowledge, understanding or skill in relation to a learning outcome, note that you will need to support this claim with evidence on the personal development record sheets.

LEARNING OUTCOMES:	NOT LEARNT BEFORE	NOT VERY CONFIDENT	NEED IMPROVEMENT	CONFIDENT
Knowledge and understanding of:				
The normal A & P the breast, chest wall and axilla				
The pathogenesis and natural history of breast cancer				
Principles of examination of the natural breast in the context of follow-up consultations				
Principles of examination of a reconstructed breast in the context of follow-up consultations				
Principles of examination of the chest wall & axilla in the context of follow-up consultations				
Differences between a normal, untreated breast and axilla versus a treated area				
Surgical treatment options (complications and after care)				
Reconstruction techniques (complications and after care)				
Medical treatment modalities (chemotherapy, radiotherapy and endocrine therapy) including rationale for use, duration, indications, complications and short and long term side effects				
Pathological variables and their prognostic significance				
Patterns of presentation of local recurrence and primary target sites for metastatic breast cancer				
Relevant symptamology with respect to metastatic disease				

Clinical detection and appropriate investigations used in the identification of local and distant metastatic disease				
Indications for referral to the medical team				
Treatment modalities and aims of management of advanced breast cancer				
Early and late complications of loco regional and systemic treatment of breast cancer including: Strategies for the management of treatment induced symptoms (e.g. hot flushes, vaginal dryness, skin and hair changes, erythema, seroma, lymphoedema, amenorrhea, chronic pain)				
Appropriateness of the use of hormone replacement therapy following the diagnosis and treatment of breast cancer				
Local protocols for follow-up surveillance and screening imaging, including frequency, duration and content				
Accountability with regard to documentation of the follow-up consultation, including correspondence to the GP				
Key issues relevant to survivorship following breast cancer (e.g. emotional needs, altered body image and related concerns, altered fertility, significance of family history) and appropriate psychological care of the patient				
Professional and legal implications of conducting routine follow-up consultations and examinations for patients who have completed treatment for breast cancer				
Skills – an ability to:				
Take a relevant clinical history				
Interpret the relevance of the patient's medical history (including prognostic implications)				
Conduct clinical examination of the normal breast				
Conduct clinical examination of the post treatment breast				
Conduct clinical examination of the reconstructed breast				
Recognise clinical variations between a treated and untreated breast				

and axilla				
Interpret and assess the relevance of symptoms reported				
Clinically detect potential local recurrence in the breast or axilla				
Recognise the signs and symptoms of potential metastases				
Explain the selection of and process of investigations for the detection of metastatic disease to the patient				
Initiate referrals (as appropriate) to medical staff and other members of the multi-disciplinary team for specialist intervention (including psychological care)				
Interpret and explain the relevance of the patient's family history of breast cancer				
Provide the patient with appropriate emotional support in response to their needs				
Recognise expected physiological changes in keeping with breast cancer treatment				
Recognise and act on complications of treatment (short and long term)				
Educate and provide accurate advice and information to patients				
Correctly and accurately complete documentation, including dictation of a letter to the General Practitioner (with appropriate terminology and content)				

INITIAL ASSESSMENT INTERVIEW

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

Role Development

Practitioner's name: ....

Supervisor: ....

Date of assessment: ....

This assessment should be completed with your practice supervisor to review your existing skills and knowledge. You should utilise the flow diagram on page 11, to document your knowledge gaps and requirements. Your learning plan should begin here.

At the end of the interview set another date to meet your manager for a formative assessment of your progress.

Supervisor's signature: ....

Practitioner's signature: ....

Date of assessment: ....

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

Worksheet

1) Describe/draw the breast, demonstrating the position of regional lymph nodes

2) List 3 clinically detectable differences between a normal, untreated breast/axilla and one that has been exposed to surgery and radiotherapy treatment

3) List 5 pathological variables and indicate their positive or negative influence on breast cancer prognosis

4) List 6 potential complications following breast reconstruction surgery

5) List 3 potential long term side effects of chemotherapy treatment

6) List 3 potential signs/symptoms of locally recurrent breast cancer

7) Approximately, what percentage of breast cancer recurrence happens within the first 3 years after completion of adjuvant therapy?

8) List the 4 primary target sites for breast cancer distant metastases in the order that they are most likely to occur

9) For each of the above sites, list one potential symptom which may indicate presence of metastatic breast disease in that area

10) List 6 symptoms of treatment induced menopause

11) Suggest 4 interventions for the management of menopausal induced hot flushes/night sweats

12) Detail the local protocol for follow-up surveillance after treatment for breast cancer, including the duration and frequency of outpatient visits, the content of the consultation and examination, and the nature and frequency of screening imaging

13) Detail the local protocol for the duration and dosage of Tamoxifen use

14) List 5 key survivorship issues that may impact on a woman after completion of treatment for breast cancer

15) Explain what documentation is required in relation to conducting follow-up consultations and examinations after treatment for breast cancer, and indicate the importance of accurate record keeping

REFERENCES

References relevant to ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

(NB these should be included alphabetically and preferably in the Harvard system)

Clinical Outcomes Group (1996) Guidance for Purchasers on Improving Outcomes in Breast Cancer: The Manual. NHS Executive, Crown Copyright, London

Denton S (1996) Breast Cancer Nursing Chapman & Hall, London

Dixon J (1995) ABC of Breast Disease BMJ Publishing Group, London

Dixon J., Sainsbury R (1993) Handbook of Diseases of the Breast Churchill Livingstone, London

GIVIO Investigators (1994) Impact of follow-up testing on survival and health related quality of life in breast cancer patients, Journal of American Medical Association, 271 (20), 1587-1592

Howell A, Baildam A, Bundred N, Evans G, Anderson E (1995) Should I take HRT doctor? Hormone replacement therapy in women at increased risk of breast cancer and survivors of the disease. Journal of the British Menopause Society, October, 9-17

Irvine D, Brown B, Crooks R, Browne G (1991) Psychosocial adjustment in women with breast cancer. Cancer 67, 1097-1117

Luker K, Beaver K, Leinster S, Glynn Owens R, Degner L, Sloan J (1995) Information needs and sources of information for women with breast cancer. Journal of Advanced Nursing, 23, 1-9

Marsden J, Baum M, Sacks N (1998) Hormone replacement therapy in women with previous breast cancer. TEM, Vol 9, No. 1, 32-38

Pennery E, Mallett J (2000) A preliminary study of patients' perceptions of routine follow-up consultations and examinations of patients after treatment for breast cancer after treatment for breast cancer. European Journal of Oncology Nursing, 4 (3), 138-145

Schapira D (1993) Breast cancer surveillance – a cost effective strategy. Breast cancer Research and Treatment, 25 (1), 107-111

WORKSHEET FEEDBACK

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

MANAGER'S COMMENTS:

FUTURE ACTION REQUIRED BY LEARNER:

Manager's Name: ....

Designation: ....

Signature: ....

Date: ....

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

Date: .... **Time:** ....

Procedure supervised by :–

Print Name: ....

Signature: ....

Was the procedure successful? Yes/No: ....

1. **Give a clear and detailed description of the event.**
   Guide: Review each intended learning outcome and reflect on how they influenced your approach to this particular procedure.

2. **What went particularly well during the procedure?**
Guide: Reflect on the actions and behaviours of yourself and others.

3. **What did not go particularly well during the procedure?**
Guide: Were there any complications or anything you would have changed or done differently?

4. **What alternate actions or behaviours may have been possible to improve the procedure?**

5. **Discuss what you have learnt from this experience.**

The Scope of Professional Practice (1992) recommends principles for adjustment to nurses' post-registration roles. They conclude that these principles should 'replace the system of certification of specific tasks' (paragraph 24).

The document continues that 'Any local arrangements must ensure that registered nurses, midwives and health visitors are assisted to undertake, and are enabled to fulfil, any suitable adjustments to their scope of practice' (paragraph 25).

It is hoped that these reflective practice exercises will enable the nurse to link current research to a critical analysis of each procedure. This process will allow the nurse to demonstrate evidence of learning and acquisition of competency.

Please reference any articles you may have read, following the format, Author, (Date of Publication), Title of Journal/Book, including volume number and page references. The article may be general to the procedure or reflect a particular incident that occurred during supervised practice.

Additional References:

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER

PRACTICE ASSESSMENT FRAMEWORK

For use with your practice supervisor

Date: ....

Components	Performance:		Comments and required action by learner (add dates next to action)
	Skilled	Requires further practice	
Identification of Patient			
Conducts consultation appropriately: • Elicits information about new symptoms/problems • Asks questions and responds to prompts • Provides appropriate information and emotional support in response to individual need			
Conducts examination appropriately: • Accurate and thorough clinical examination of treated breast/chest wall/axilla; contralateral breast/chest wall/axilla; regional lymph nodes			
Acts on new symptoms detected appropriately: • Provides reassurance as appropriate • Initiates referral to medical team as appropriate • Organises relevant investigations			
Completes appropriate documentation (GP's letter)			
Organises routine screening imaging at appropriate intervals			

PRACTICAL ASSESSMENT FEEDBACK

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER

SUPERVISOR'S COMMENTS:

FUTURE ACTION REQUIRED BY LEARNER:

Supervisor's Name: ....

Designation: ....

Signature: ....

Date: ....

FORMATIVE ASSESSMENT

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER

Role Development

Date: ……………………………..

This assessment should provide the practitioner with structured feedback on the progress of their role development. The learning plan should be evaluated and new targets set.

Supervisor's signature: ……………………………………………………………………………………………

Practitioner's signature: ……………………………………………………………………………………………

Date of next assessment: ……………………………………………………………………………………………

SUMMATIVE ASSESSMENT

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER

Role Development

It is hoped that you have now developed the knowledge, understanding and skill to practice wisely and competently. In this final assessment interview you should review your completed learning profile with your manager. It should demonstrate your progress to a competent practitioner and support your declaration that you are able to independently practice this skill to the benefit of patients in your care. On completion of this interview you must ensure that your clinical manager signs that they are aware of your accountability to practice (page XXXIII).

Manager's signature: ....

Practitioner's signature: ....

Date: ....

DECLARATION OF COMPETENCE FORM

ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION OF PATIENTS AFTER TREATMENT FOR BREAST CANCER

Please REMOVE and RETURN this page ***on completion*** of your learning profile.

You and your Divisional Nurse Director will be contacted if this form is not received by the Document Controller, (Directorate of Nursing, Rehabilitation and Quality Assurance, Sutton) within *8 months.* In this circumstance the original agreement with your clinical manager to complete this Role Development Profile becomes invalid and the Divisional Nurse Director will review the situation prior to any continuation with this profile.

I have discussed the completed learning profile and self-assessed competency in ROUTINE FOLLOW-UP CONSULTATION & EXAMINATION AFTER TREATMENT FOR BREAST CANCER with *(add in name of practitioner).*

Print Name of Clinical Supervisor / Manager: ....

Signature: ....

Ward / Unit: ....

Date: ....

I have completed the learning profile and I am proficient to provide *ROUTINE FOLLOW-UP CONSULTATIONS & EXAMINATIONS AFTER TREATMENT FOR BREAST CANCER*

Print Name: ....

Signature: ....

Ward / Unit: ....

Date: ....

Please send a copy of this form to clinical manager/supervisor, ward sister/charge nurse and the Document Controller (Directorate of Nursing, Rehabilitation and Quality Assurance, Sutton) and keep the original.

APPENDIX 1 – THE SCOPE OF PROFESSIONAL PRACTICE IN NURSING POSITION STATEMENT

1. *Background*

1.1 The Scope of Professional Practice document was published by the UKCC in 1991. The document is intended to empower and liberate nurses by enabling them to be flexible and holistic in meeting the care needs of patients and clients.

1.2 The skills and knowledge for the practice of nursing has traditionally been based upon pre-registration education, which equipped nurses to perform it at a certain level and to encompass a particular range of activities. In the case of any deviation from that range of activities nurses have previously had to rely on the medical profession to approve these so called 'extended roles'. (Department of Health and Social Security 1977). The UKCC consider that this has perpetuated a task-focused, rigid, defensive and medically dependent nursing profession.

1.3 The intention of the Scope of Professional Practice document is to achieve greater professional autonomy by placing decisions about the boundaries of nursing practice with the nursing profession. As such, the UKCC is encouraging a more responsive, liberal and dynamic nursing profession by demolishing artificial and restrictive barriers to nursing practice.

1.4 Following publication of the Scope of Professional Practice document the Department of Health withdrew its guidance on the 'Extended Role of the Nurse' (Department of Health 1992).

2. *Position Statement*

2.1 The Nurse is accountable for their professional practice both to the UKCC and The Royal Marsden NHS Trust. These areas of accountability overlap and are inextricably linked.

2.2 The UKCC state that 'a Nurse must act always in such a way as to promote and safeguard the well being and interests of patients and clients' (UKCC, 1992 a:2) and 'must honestly acknowledge any limits of personal knowledge and skill and take steps to remedy any relevant deficits in order to effectively and appropriately meet the needs of a patient sand clients (UKCC 1992 b:6).

2.3 However, a nurse's employment at The Royal Marsden requires that he/she acts in accordance with the conditions stipulated and includes adherence to policies, procedures and practice guidelines. As an organisation, The Royal Marsden takes vicarious liability for the actions of the Nurse. This means that any wrongful act which the Nurse commits during the course of their duties is the legal responsibility of the Trust. In assuming this vicarious liability, The Royal Marsden has the right to expect the nurse to act reasonably and competently with the full knowledge and approval of the organisation. Furthermore, the organisation cannot be expected to assume vicarious liability for actions which have occurred outside of their knowledge and approval. As nursing practice boundaries shift there is more potential risk than ever before.

2.4 In an attempt to support the increased risk associated with role developments, a framework has been developed so that the nurse is aware of the constraints as well as the freedoms in which they can develop their role at The Royal Marsden. The framework elaborates upon the principles described in the Scope of Professional Practice document which is designed to provide guidance for the nurse in considering adjustments to their range of practice, while safeguarding the provision of skilled nursing care to the public.

2.5 It is important for nurses working within The Royal Marsden to acknowledge that the framework is intended to support and facilitate, rather than inhibit, role developments.

2.6 Further advice in relation to the Scope of Professional Practice can be sought from the Nursing and Rehabilitation Research and Practice Development Manager or the Chief Nurse and Director of Quality Assurance.

3. *References and Recommended Reading*

Chelsea and Westminster Healthcare NHS Trust (1995) Scope of Practice Position Statement Chelsea and Westminster Hospital, London

Department of Health and Social Security (1977) The Extending Role of the Clinical Nurse: Legal Implications and Training Requirements. HC (77) 22 Department of Health and Social Security; London

Department of Health (1992) Withdrawal of guidance on the Extended Role of the Nurse EL (92) 38 NHS Management Executive; London

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1989) Exercising Accountability, UKCC; London

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992a) Code of Professional Conduct. UKCC; London

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992b) The Scope of Professional Practice. UKCC; London

APPENDIX 2 - A FRAMEWORK FOR THE DEVELOPMENT OF THE SCOPE OF PROFESSIONAL PRACTICE IN NURSING

1. *Background*

1.1 This framework should be read in conjunction with the Scope of Professional Practice in Nursing Position Statement (The Royal Marsden NHS Trust, 1999).

1.2 The purpose of the framework is to elaborate upon the principles described in the Scope of Professional Practice (UKCC 1992), which are designed to provide guidance for the nurse in considering adjustments to their range of practice, while safeguarding the provision of skilled nursing care to the public.

1.3 This framework is intended to provide structure to the enthusiasm, support and facilitation for role developments, which exists within the organisation. The framework describes the manner in which role developments should be approached within this organisation to ensure that role developments are those which the organisation has agreed to and that they are managed in a responsible and systematic way in an attempt to support the increased risk associated with role developments.

1.4 Throughout the document the term 'role development' will be used to refer to the undertaking of activities which have previously not fallen within the scope of nursing practice and for which the nurse has not received education and training. Therefore, this will generally refer to activities not encompassed within pre-registration training.

2. *Decision Making And Consultation In Relation To Role Developments*

2.1 The Scope of Professional Practice document provides opportunities for collaborative work between the professional groups upon which healthcare depends.

2.2 Professional boundaries refer to the points at which one professional group hands over care to another. The exclusive ownership of care activities by one professional group can often create barriers to an efficient service. Therefore, in certain situations, it may be considered desirable for a nurse to incorporate certain identified activities into his/her role in order to provide a more flexible and responsive service. Clearly, justification for role developments must be directed towards meeting the needs and serving the interests of the patient or client.

2.3 Nurses wishing to develop their role should seek support for this from their Manager.

2.4 Consultation with the Chief Nurse/Director of Quality Assurance may be necessary in order to explore the full range of issues implicated by role developments.

2.5 The Nursing and Rehabilitation Advisory Committee has the responsibility for approving role developments in nursing. The Clinical Practice Forum will, therefore, through a process of critical peer review, seek to ensure that role developments occur in line with the framework. All nurses have the responsibility to inform the Committee of all role development initiatives. All areas of nursing are invited to nominate a representative to join the Clinical Practice Forum.

3. *The Formulation Of Protocol/Clinical Practice Guidelines*

3.1 The decision to develop either a protocol versus clinical practice guidelines will be determined by the area of practice to be undertaken. In both cases the purpose of such will be to describe the activity to be incorporated into the Nurses' role and to set out the minimum standards or principles of good practice for this activity.

3.2 The protocol or clinical practice guidelines should be developed via the work of a group of relevant individuals. Where the area of practice will represent an overlap of professional roles the relevant professional groups should contribute to this process. The protocol should represent a union between research, experience and expert opinion.

3.3 The protocol or clinical practice guidelines should be submitted to the Clinical Practice Forum for critical peer review and then to the Nursing and Rehabilitation Advisory Committee for approval.

3.4 An outline of the way in which the developed role will be evaluated should also be developed by the working group and submitted to the Clinical Practice Forum.

3.5 Help and support with preparing protocols/clinical practice guidelines is available from the Nursing and Rehabilitation Research and Practice Development Manager and the Chief Nurse and Director of Quality Assurance.

4. Individual Competence Acquisition

4.1 An educational framework has been developed to support competence acquisition in relation to role developments. The framework has been developed to enable the individual to take responsibility for planning, managing and evaluating learning in relation to the role development and to provide the opportunity for the individual to maintain a record of their developing competence. The philosophy underpinning this approach is that individuals will develop competence in a flexible and self-directed way, which is appropriate to their learning style and learning needs.

4.2 The specification of expected knowledge, understanding and skills required in order to be competent in the area of practice should be identified as intended learning outcomes.

4.3 Consideration for the learning activities which will contribute to meeting these learning outcomes should be made. The exact nature of these learning activities will depend upon the area of practice to be undertaken. However, this should include a period of practice supervision from a competent colleague.

4.4 It is essential that nurses, in judging whether they have met the intended learning outcomes, receive structured feedback in relation to their knowledge and skills from a colleague with the relevant expertise.

4.5 A record of learning should be made which will provide evidence to demonstrate the acquisition of the required knowledge and skills as indicated by the intended learning outcomes. This record should be retained by the nurse. It is recommended that all ongoing activities and experience which contribute to the maintenance of this competence are included.

4.6 An individual must not practice independently until confident that they possess the required knowledge and skills, can adequately demonstrate their competence and have a declaration of support to do so from their manager. Nurses who have undertaken role development prior to joining the Trust should discuss with their Divisional Nurse Director the basis upon which they may carry out that developed role at The Royal Marsden.

5 Execution of the Developed Role

5.1 Execution of an activity which is considered to be role development will not automatically and universally be performed by a nurse who is competent to do so.

The UKCC state that the Nurse:

' ....must ensure that any enlargement or adjustment to the Scope of Professional Practice must be achieved without compromising or fragmenting existing aspects of professional practice and care'. (1992; para 9.4)

Contextual factors such as workload and competing interests and needs of the patient/client must be considered. The context for a nurse undertaking an activity should be considered at the outset of this process.

6. *Evaluation of the Developed Role*

6.1 An evaluation of the role development should be undertaken once a change to the Scope of Professional Practice is established. This should occur whether the role development occurs on an individual or team basis.

6.2 Further advice regarding the evaluation process can be sought from the Nursing and Rehabilitation Research and Practice Development Manager.

7. *References*

Chelsea and Westminster NHS Trust (1995) Scope of Professional Practice in Nursing Position Statement.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992) The Scope of Professional Practice UKCC London

Appendix K

Role Development Profile: Ordering Diagnostic Investigations

(clinical details only, see previous profile for professional content)

ROLE DEVELOPMENT PROFILE

REQUESTS FOR SPECIFIED DIAGNOSTIC EXAMINATIONS INVOLVING EXPOSURE TO IONISING RADIATION

PLEASE NOTE
BEFORE UNDERTAKING THIS AREA OF DEVELOPMENT SUPPORT MUST HAVE BEEN SECURED FROM YOUR CLINICAL MANAGER

Name : ....

Clinical Area : ....

Date : ....

Document Control :

Version Number : 1
Document Author Name(s) : EMMA PENNERY
Document Author Title(s) : Senior Clinical Nurse Specialist, Breast Unit
Authoring Department : Directorate of Nursing, Rehabilitation & Quality Assurance
Edited by :
Edited by Title(s) : Assistant Chief Nurse (Research, Practice & Professional)
Authoriser Name : Clinical Practice Forum and
Nursing and Rehabilitation Advisory Committee
Authoriser Title(s) : CPF and NRAC
Review Period Months : 12 months
Review date :
Review details :
Reviewed by Name(s) : CPF and NRAC
Reviewed by Title(s) :

Strategy for Nursing Ref No:

INTENDED LEARNING OUTCOMES

ELEMENTS OF REFERRER COMPETENCY

Knowledge and Understanding

You are expected to possess knowledge and understanding of the following:

- The Ionising Radiation (Medical Exposure) Regulations 2000
- The Royal Marsden Hospital Radiation Protection Policy (75)
- The Royal Marsden Hospital Radiation Protection Policy, Part 3b 1 'Identifying the person who is entitled to refer patients for a medical exposure (Referrer)'
- Your ward/department local protocol for requesting diagnostic examinations involving ionising radiation
- Radiation production, protection and statutory obligations relating to ionising radiation
- The X-ray examination(s) and/or nuclear medicine test(s) you will request and the rationale for their use in your local protocol
- The justification for the individual diagnostic investigations involving ionising radiation you request
- The medical information required by the Practitioner and the Operator to enable them to decide if there is sufficient clinical indication for the diagnostic examination requested
- The potential risks of over exposure to ionising radiation and the need to reduce unnecessary exposure due to inappropriate or unnecessary investigations being performed
- The typical effective does of ionising radiation for the diagnostic examination you will request
- The risks of exposure to ionising radiation when pregnant or breast feeding
- The need to identify women who are or may be pregnant and take appropriate action
- The risks of exposure in infants and childhood, thus the need for infants and children to receive doses of ionising radiation for diagnostic examinations
- Professional, legal and health and safety issues related to requesting diagnostic examinations involving exposure to ionising radiation
- Your accountability when acting as a referrer for a diagnostic examination involving exposure to ionising radiation

INTENDED LEARNING OUTCOMES

ELEMENTS OF PRACTITIONER COMPETENCY

Skills

You are expected to possess the following skills:

An ability to:-

- Select according to your lour local protocol the appropriate examination(s) for the appropriate clinical management of the patient
- Provide the patient/family/carer with the education and support they require prior to the diagnostic examination proposed
- Undertake the necessary checks for pregnancy or the possibility of pregnancy prior to requesting the diagnostic examination involving exposure to ionising radiation
- Gain the patients verbal consent to undertake the diagnostic examination
- Complete the request card with all the required demographic, clinical details and required diagnostic examination
- Work with other staff involved in medical exposure as appropriate
- Hand over patients who are outside the remit of the local protocol to which you work
- Perform safe and effective practice in all situations

REQUESTS FOR SPECIFIED DIAGNOSTIC EXAMINATIONS INVOLVING EXPOSURE TO IONISING RADIATION

Worksheet

1. Describe the responsibilities of the practitioner, operator and referrer as outlined in the ionising radiation regulations 2000

2. What are following committees?

   i) Medical Exposures
   ii) Group Trust Radiation Protection
   iii) Local Radiation Protection

3. What are the terms of reference of these above 3 groups?

4. Name three risks and three benefits of exposure to radiation when undergoing diagnostic examinations

5. Identify the factors that need to be considered in order to justify the decision to undertake a diagnostic exposure to ionising radiation

6. Identify the specific diagnostic examinations and the circumstances in which you can request these as outlined in your local protocol

7. For two diagnostic examinations for which you will act as referrer outline the possible clinical indications that would lead to the request for the test.

8. What factors affect the radiation dose administered?

9. With reference to the 'Making the best use of a Department of Clinical Radiology' (1998) look up the typical effective doses (mSv), the equivalent number of chest x-rays and approximate equivalent period of natural background radiation for the following examinations.

10. When is contrast media used and what are the contra-indications to its use?

11. List the essential information that should be provided on a request card for a diagnostic examination involving exposure to ionising radiation.

12. Why is it necessary to keep the doses resulting from radiation exposure as low as is reasonably practical?

13. What are the potential risks of exposing

    i) a pregnant woman to ionising radiation
    ii) a woman who is breast feeding to nuclear medicine exposure
    iii) an infant or young child to ionising radiation or nuclear medicine exposure

14. Who can refer individuals for medical exposure to ionising radiation as part of a research programme?

15. Who would you go to gain further information about diagnostic examinations involving exposure to ionising radiation?

16. Explain your understanding of the professional and legal issues you should consider whilst undertaking this new role.

REQUESTS FOR SPECIFIED DIAGNOSTIC EXAMINATIONS INVOLVING EXPOSURE TO IONISING RADIATION

WORKSHEET

1.

i. Practitioners are responsible for justifying and authorizing exposures to ionising radiation in accordance with employer's procedures.
ii. Operators carry out the practical aspects of medical exposure to ionising radiation in accordance with the employer's procedures.
iii. Referrers request the diagnostic examination in accordance with the employer's procedures and departmental protocols.

2.

i. The Medical Exposures Committee (MEC) is a sub-committee of the Radiation Protection Committee whose membership will include representatives from the various Trust's directorates as required
ii. The Group Trust Radiation Protection Committee members include the Radiation Protection Adviser, representatives from the Trust's directorates where relevant and a representative of the Trust's Group Health and safety Committee.
i. The Local Radiation Protection Committee members include a Radiation Protection Supervisor to ensure personnel comply with the local rules and a Radiation Protection supervisor to advise the Trust on compliance with the Ionising Radiation Regulations;99 (IRR99).

3.

i. MEC is responsible for institution and maintenance of Practitioner and Operators as defined by the Regulations. MEC will record the level of training of any Practitioner or Operator who is placed on the list.
ii. GRPC is responsible for doing all that is reasonably possible to meet the protection requirements of the legislation associated with the use of ionising

radiation. They advise on the safety aspects of all work involving radiation and inform the Health and Safety Executives in accordance with IRR99

iii. Local Radiation Protection Committee ensure that the personnel comply with the local rule that have been established for areas that have been designated as control areas, and they also advise the Trust on compliance with IRR99.

4.

i. Risks:

- exposure to ionising radiation may increase the overall lifetime risk of developing cancer
- continued exposure to ionising radiation in a young child can increase the risk of leukaemia in later life
- exposure to ionising radiation can damage an unborn child (foetus) if the patient is pregnant

ii. Benefits:

- facilitates early detection/diagnosis of malignant disease
- the dose is minimal for most procedures
- facilitates measurement of treatment efficacy and can contribute to treatment safety, e.g. correct positioning of lines

5.

i. Is the procedure the most appropriate with regards to the clinical history and nature of the information required?
ii. Is the procedure necessary for that patient at that time?
iii. Does the request comply with local and national policies and procedures?
iv. Is the patient pregnant or still breast-feeding?
v. What is the performance status of the patient (age and condition)?
vi. What is the relevant clinical history and when was the patient last exposed to ionising radiation?

vii. Has the patient had the procedure explained and given consent accordingly?

6.

i. Mammography – annual mammograms
ii. Mammography – additional views as recommended by the reporting radiologist.

7.

i. Follow-up consultations and examinations of patients after treatment for breast cancer - annual routine mammogram

8.

i. The type of examination required
ii. The area of the body being examined, including the extent of the areas being investigated during that one procedure
iii. The size of the patient

9.

Procedure	Typical effective dose (mSv)	Equivalent no. of chest x-rays	Background radiation
Chest x-ray	0.02	1	3 days
Lumbar Spine	1.3	65	7 months
Bone Scan	4	200	1.8 years
CT Head	2.3	115	1 year
CT abdo/pelvis	10	500	4.5 years

10.

Contrast media is used for specific procedures such as Bone Scans, CT, Barium, Thyroid, PET. Lung perfusion/ventilation, ETDA, Dynamic Cardiac.
Contra indications include allergy, pregnancy, breast feeding, caution with children, patient becomes radioactive.

11. &12.

Not applicable - not within remit according to policy for nurses requesting diagnostic investigations

13.

i. The patient's name, date of birth and address (when known)
ii. The patient's hospital number
iii. The type of examination requested
iv. The clinical indication to ensure the Practitioner is able to justify the exposure to ionising radiation
v. The patient's pregnancy status and date of last menstrual period when appropriate
vi. Whether the patient is breast feeding if a nuclear medicine procedure is required or a mammogram for females of child bearing age
vii. Relevant past examinations, including the provision of current medical records and films
viii. The patient's diagnosis, relevant past and present treatments and their concurrent medical condition
ix. The name of the patient's consultant, the name of their ward and department
x. The bleep/contact number of the referrer
xi. The date
xii. Whether transport is required
xiii. The NHS/PP status
xiv. The signature of referrer

14.

1. To keep within the levels set by the Local diagnostic reference levels
2. To avoid unnecessary over exposure to radiation
3. To comply with medico-legal exposure procedures
4. To ensure that the patient's overall lifetime risk of cancer from the examination is less than 0.1
5. Diagnostic medical exposure adds about one sixth to the population dose from background radiation

15.

1. Foetal development may be impaired; spontaneous miscarriage; the foetal lifetime risk of cancer may be increased
2. The women will not be able to continue breast feeding as the nuclear medicine exposure will be transmitted to the baby via the breast milk
3. Increases the lifetime risk of cancer particularly developing haematological cancers.

16.

1. The Practitioners who are involved with the research programme
2. The named Referrers (mainly research nurses) who are involved with the research programme and who have undertaken and completed the study day and worksheet for requesting diagnostic imaging and who have been authorized by MEC.

17.

1. The Radiation Protection Adviser (Stephen Evans)
2. The Superintendent for Diagnostic Imaging (Shelagh Smith)
3. CNS Radiation Protection (Sarah Hart)
4. Medical Consultant for Diagnostics (David McVicar)
5. Medical Consutlant Nuclear Medicine (Gary Cook)
6. Any other members of MEC

18.

i. I am only able to act as a Referrer within the remit of the Policy for 'Nurses Requesting Diagnostic Investigations Involving Ionising Radiation' and must act within policies and protocols at all times
ii. I must complete the request form as recommended so that the operator and practitioner can assess the benefits and risks of the exposure to the patient
iii. I should only refer if absolutely necessary
iv. I should only refer for a mammogram on an annual basis unless further views have been recommended by a reporting Radiologist.

Emma Pennery, Senior Clinical Nurse Specialist Breast Unit
Completed 25/11/01

Appendix L

Breast Cancer Stages

Breast Cancer stages

The stage of a cancer is the term used to describe the size of a tumour and the extent of spread. There are different ways of describing staging, such as the one outlined below.

Stage 0

In situ (confined to the breast ducts; not developed the ability to spread).

Stage I

Tumour less than 2cm. No spread.

Stage II

Tumour 2-5cm with or without lymph node involvement. No spread to other parts of the body.

Stage III

Tumour more than 5cm or tumour any size but is fixed either to chest wall, muscle or skin, or has spread to lymph nodes above collarbone.

Stage IV

Tumour any size. Lymph nodes may or may not be involved, but cancer has spread to other parts of the body.

Appendix M

Explanatory Invitation Letter & Consent Form

(Phase Three)

dd/mm/yy

Dear

We would like to invite you to take part in a research study that aims to compare provision of your routine follow-up within Outpatients by different professionals. These are the clinic visits you attend for check-ups after you have finished all your treatment. It is hoped that the results of this study will lead to an improvement in the quality of follow-up care provided for patients after completing treatment for breast cancer. Other patients, when questioned, suggest improvements in follow-up visits could be made with regards to ensuring any emotional needs or requests for information/general questions are addressed and sometimes these aspects of care are more appropriately provided by nurses.

If you consent to take part you will be randomised to receive your follow-up care from either a doctor or a breast care nurse (a computer ensures this selection is entirely random and cannot be influenced by either your wishes or those of your carers). The physical care given (in terms of examinations, tests and number of visits) will be the same in each group. Both professionals are fully trained to provide follow-up care. The nurse clinic will run along side Mr. Gui's clinic ensuring direct, same day access back to the doctors if any problems arise or if you request it.

If you agree to take part, you will be asked to complete one short questionnaire prior to commencing routine follow-up and two further questionnaires at each follow-up visit thereafter until the completion of the study. In addition, a small number of participants will be asked to have a taped interview with a data collector who will attempt to expand on some of the answers you have previously given in the questionnaires. All information collected from the questionnaires, interviews and some from your clinical notes, will be anonymous and stored securely in order to protect your confidentiality.

Please be assured participation in the study is entirely voluntary and if you do not wish to take part, or chose to withdraw at any time, this will in no way affect your future care or the attitudes of your carers towards you. If you do consent to take part in the study your legal rights will not be affected in any way.

We would be most grateful if you would complete the enclosed slip and return it in the prepaid envelope by *dd/mm/yy*. On receipt of this form, those wishing to take part in the project will be allocated to either the doctor or the nurse group and will be advised of this and the arrangements for future appointments accordingly. If you have any questions relating to any aspect of this study, please contact the Breast Care Nurses on their direct line, 020 7xxx xxxx. If the office is unattended please leave a message and your call will be returned as soon as possible.

Yours sincerely

The Breast Care Team

STUDY TO COMPARE ROUTINE FOLLOW-UP BY DIFFERENT HEALTH CARE PROFESSIONALS

I would like to participate in this project and await confirmation of which professional (doctor or nurse) will be providing my follow-up care within outpatients.

OR

I would not like to participate in this project and will receive follow-up care from the doctors within outpatients as previously expected.

(Please delete one reply by crossing it out)

NAME:

SIGNATURE:

Patient casenote number:

ROYAL MARSDEN NHS TRUST

WRITTEN PATIENT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: **A Randomised Prospective Trial to Compare Nurse versus Conventional Medical Follow-up of patients after completion of Treatment for Breast Cancer**

Ethics Committee Protocol No: **1521**

SECTION 1 - To be signed by the patient

I, ... consent to participate (to the participation of ....) in the above research study.
The purpose and nature of this study has been fully explained to me by ....
..........**Emma Pennery**..

I understand that my participation in this study is entirely voluntary and that I may withdraw from it at any time without giving a reason and without giving jeopardy to my further care.

I also understand that if I decide to withdraw from the study, I will continue to receive the best conventional treatment that is available. If I have any further questions regarding the study at any time, I should contact ....**Emma Pennery**...

Signature of Patient .... Date ....
(or Parent/Guardian)

SECTION II - To be signed by the Clinical Nurse Specialist

I, ...**Emma Pennery**.. declare that the purpose and nature of the above research study has been explained to the above person in writing and verbally. This explanation included a description of the procedures involved, possible benefits to the patient, potential risks or side effects and the expected duration of the patient's participation.

Signature of Clinical Nurse Specialist .... Date ....

SECTION III - To be signed by a witness

I, ... declare that in my opinion the patient (or parent/guardian) has understood the purpose and nature of the above study. He/she was given the opportunity to ask relevant questions and his/her consent was given freely.

Signature of Witness .... Date ....

Designation ....

*SECTION IV - To be signed by the Patient **after** the taped interview*

I, ... consent to the transcript and use of the tape recording for the purpose of the above research study.

Signature of Patient .... Date ....

Appendix N

Follow-up Reminder Letter Sent After Each Visit With the 3 Monthly Questionnaires

(Phase Three)

Ms …………..
………………..
………………..
………………
………………

dd/mm/yy

Dear Ms.
Re: *Study to compare Routine Follow-up by different Health Care Professionals*

Following your recent Outpatient appointment on xxth August 200x, we would be most grateful if you could complete the enclosed questionnaires.

You may recall these are being completed by women following visits to Outpatients, in order that we may study the effectiveness of follow-up care given by different health care professionals. Evaluating your perceptions after each visit allows us to assess whether individual needs change over time. We appreciate the time taken to complete them but value your continuing contribution.

Please return the questionnaires at your earliest convenience in the prepaid envelope provided. We would like to remind you that all information collected from the questionnaires will remain anonymous.

If you have any questions relating to any aspect of this project, please contact Emma Pennery, Senior Breast Care Nurse Specialist on 020 7xx xxxx. If the office is unattended please leave a message and your call will be returned as soon as possible. Thank you again for your kind participation.

Warmest regards
The Breast Care Team

Appendix P

Functional Assessment of Cancer Therapy [Breast]

(FACT-B) Questionnaire

FACT-B

Hospital No: Date: Trial No:

Below is a list of statements that other people with your illness have said are important. By circling one (1) number per line, please indicate how true each statement has been for you since your last appointment

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

How much does your physical well-being affect your quality of life? Not at all 1 2 3 4 5 Very much so

	SOCIAL/FAMILY WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
GS7	I am satisfied with my sex life	0	1	2	3	4

How much does your social well-being affect your quality of life? Not at all 1 2 3 4 5 Very much so

By circling one (1) number per line, please indicate how true each statement has been for you since your last appointment

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

How much does your emotional well-being affect your quality of life? Not at all 1 2 3 4 5 Very much so

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

How much does your functional well-being affect your quality of life? Not at all 1 2 3 4 5 Very much so

By circling one (1) number per line, please indicate how true each statement has been for you since your last appointment

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
B1	I have been short of breath	0	1	2	3	4
B2	I am self-conscious about the way I dress	0	1	2	3	4
B3	One or both of my arms are swollen or tender	0	1	2	3	4
B4	I feel sexually attractive	0	1	2	3	4
B5	I am bothered by hair loss	0	1	2	3	4
B6	I worry that other members of my family might someday get the same illness I have	0	1	2	3	4
B7	I worry about the effect of stress on my illness	0	1	2	3	4
B8	I am bothered by a change in weight	0	1	2	3	4
B9	I am able to feel like a woman	0	1	2	3	4

	SUPPLEMENTARY QUESTIONS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
ES1	I experience hot flushes	0	1	2	3	4
ES2	I am able to raise my arm and move/ use it normally	0	1	2	3	4
ES3	I have problems around the area of my affected breast (e.g. itchy, dry, flaky skin, hard, red)	0	1	2	3	4
ES4	I feel less feminine as a result of my disease or treatment	0	1	2	3	4
ES5	I find it easy to look at myself naked	0	1	2	3	4
ES6	I worry about my health in the future	0	1	2	3	4

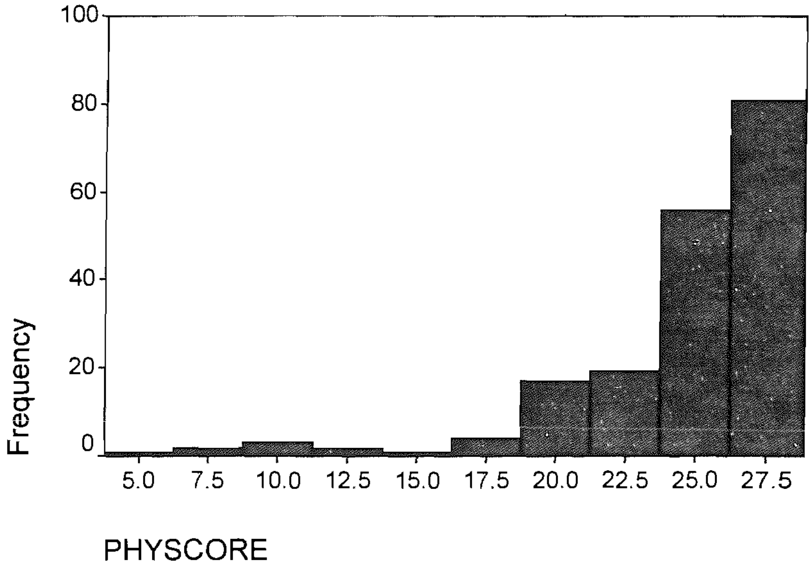
Appendix Q

Histograms of the Distributions of Subscale Scores:

FACT-B Questionnaires (Phase Three)

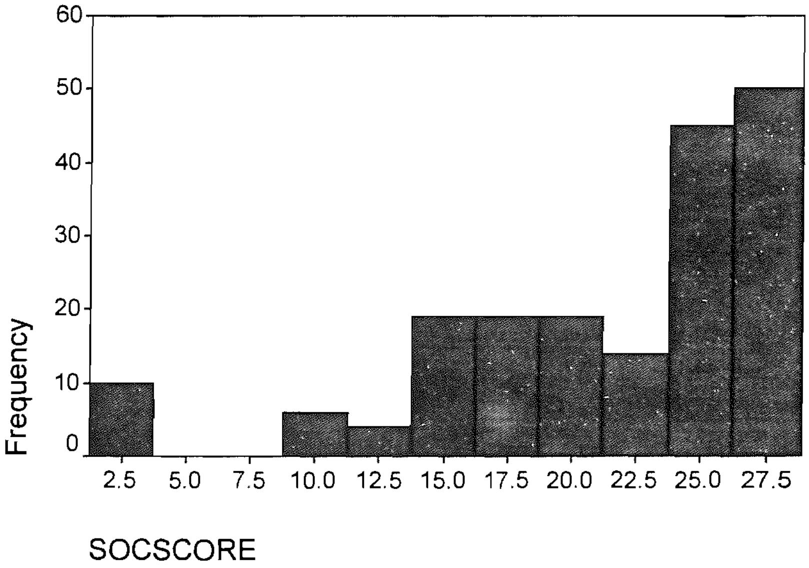
Physical well-being

Scores for patients seen by nurse



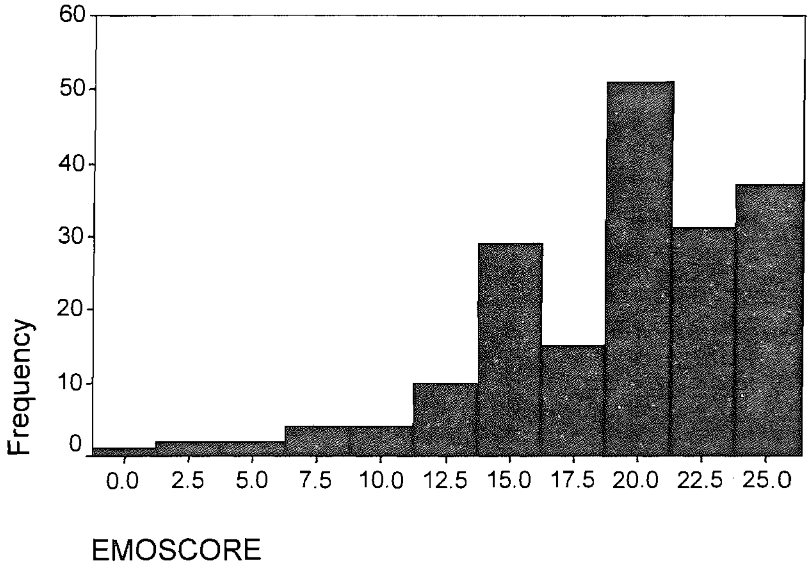
Social well-being

Scores for patients seen by nurse



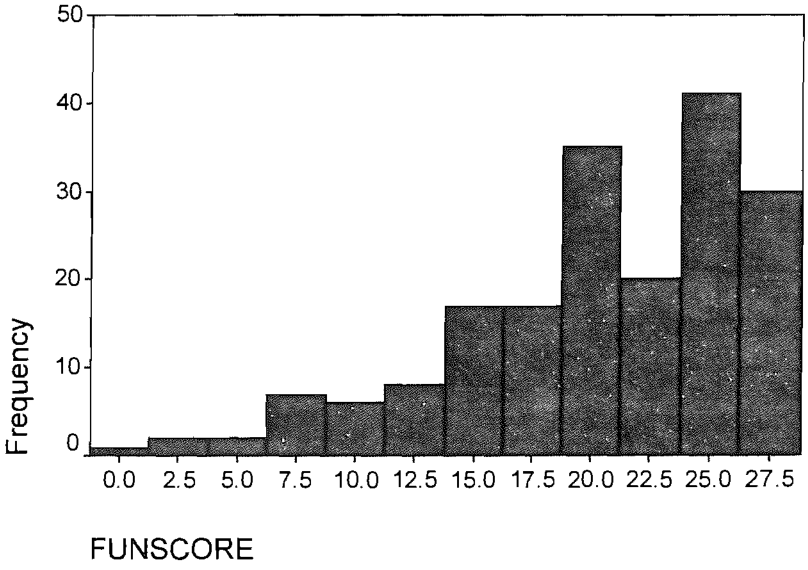
Emotional well-being

Scores for patients seen by nurse



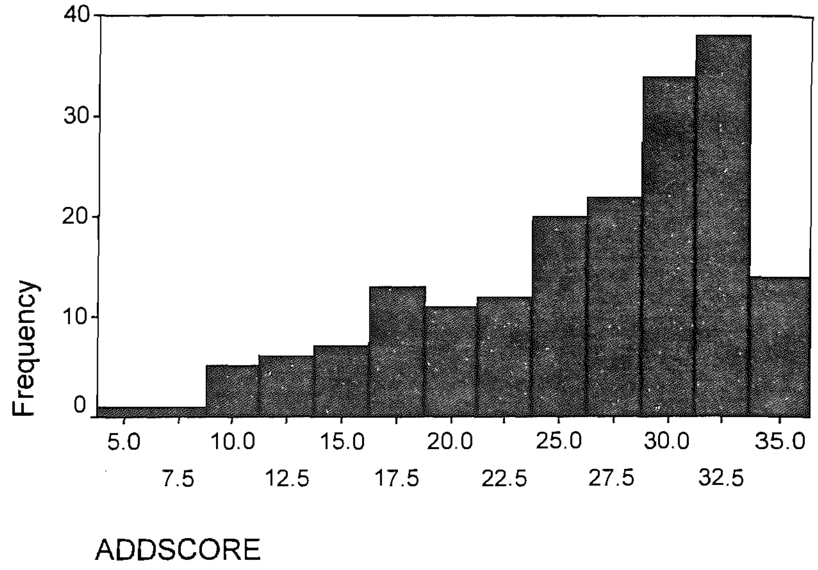
Functional well-being

Scores for patients seen by nurse



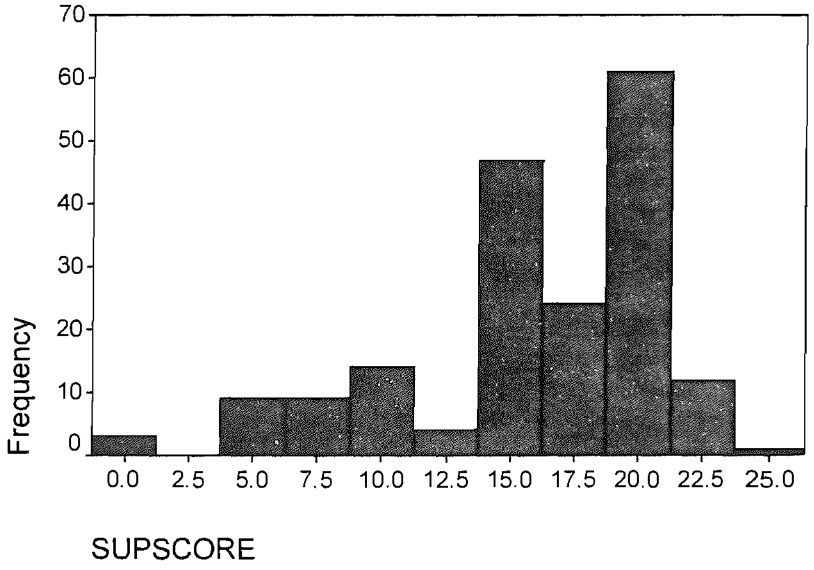
Additional Concerns

Scores for patients seen by nurse



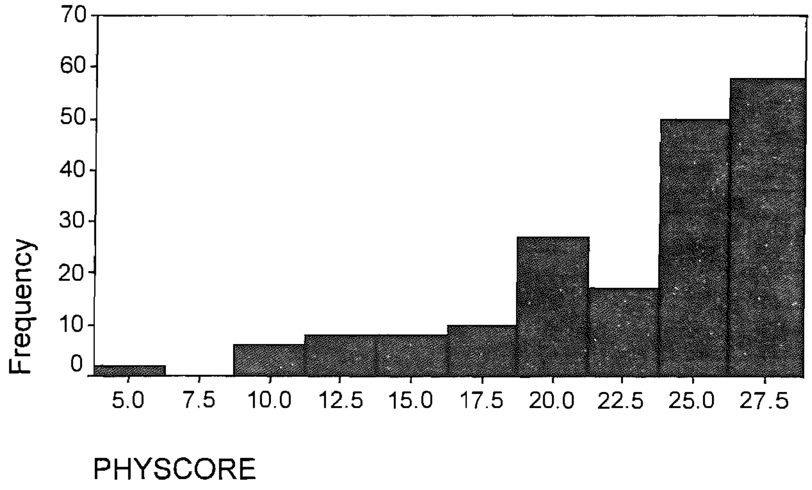
Supplementary Questions

Scores for patients seen by nurse



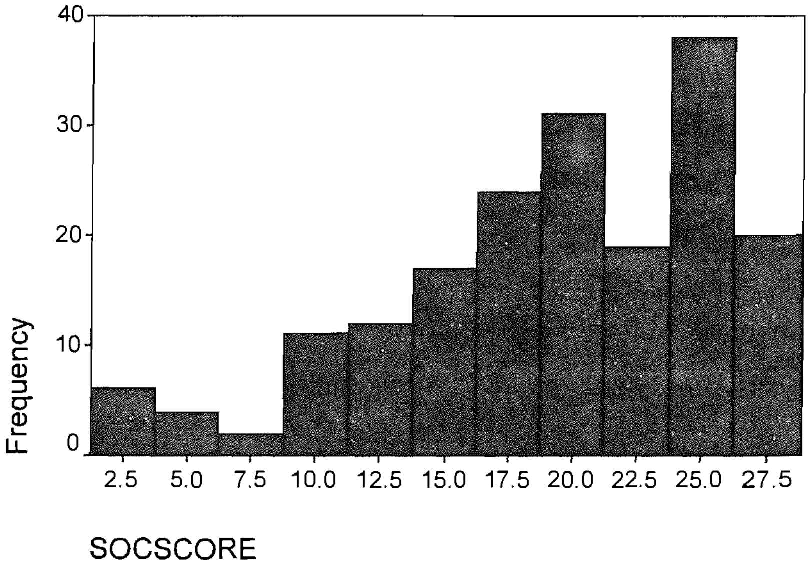
Physical well-being

Scores for patients seen by Dr



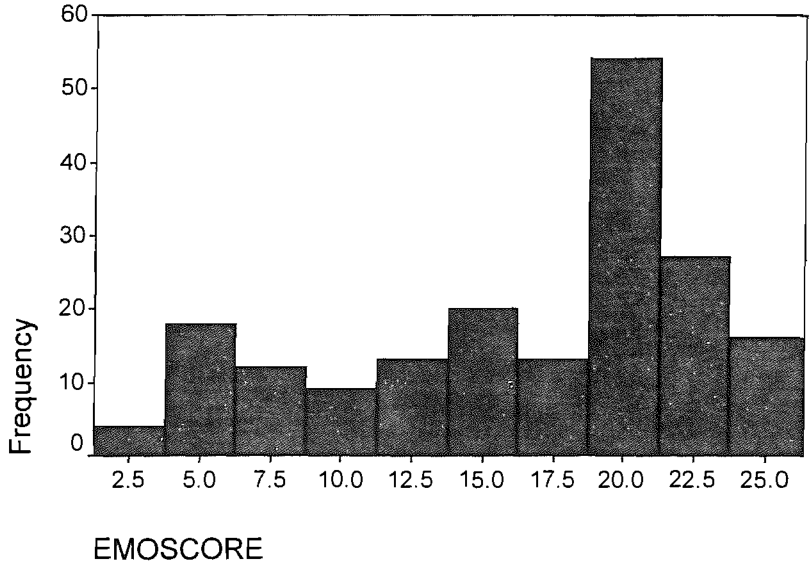
Social well-being

Scores for patients seen by Dr



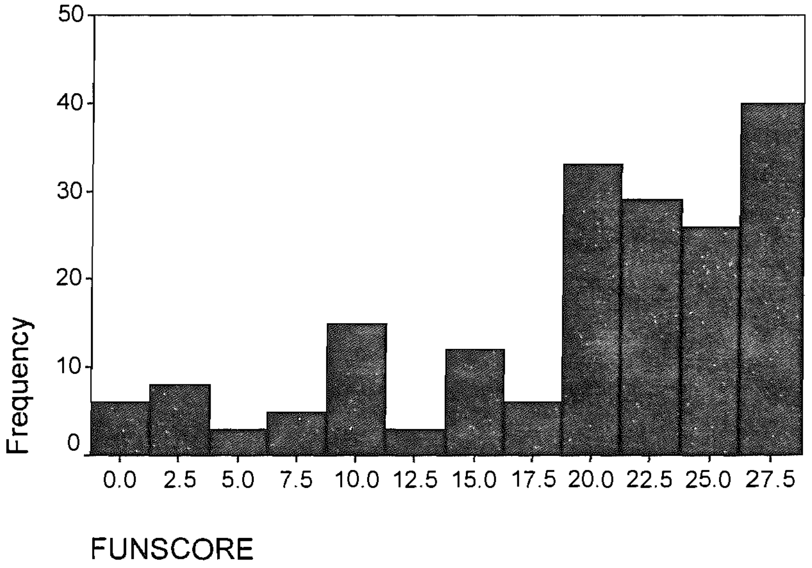
Emotional well-being

Scores for patients seen by Dr



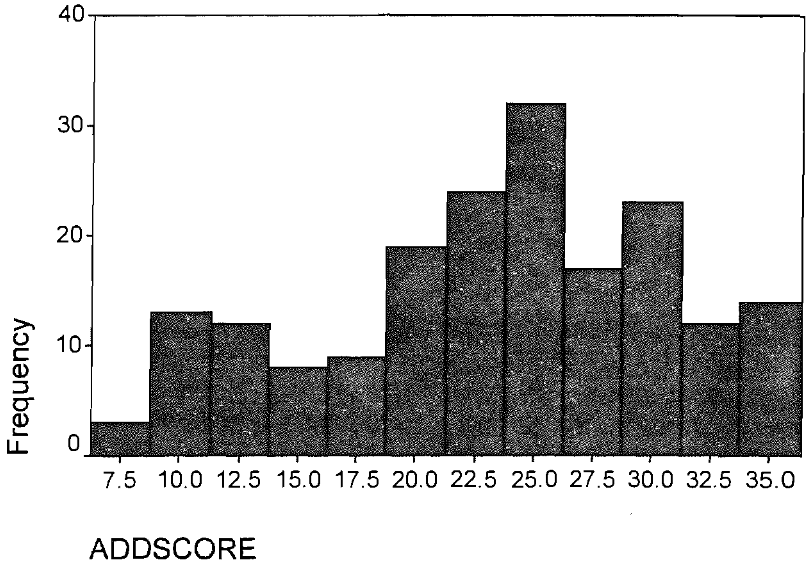
Functional well-being

Scores for patients seen by Dr



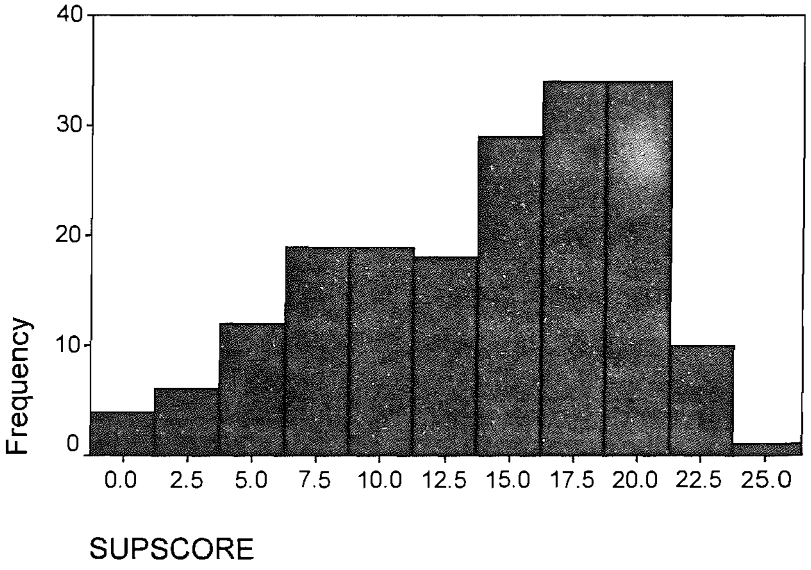
Additional Concerns

Scores for patients seen by Dr



Supplementary Questions

Scores for patients seen by Dr



Appendix R

Your Views of Follow-up Care Questionnaire

YOUR VIEWS OF FOLLOW-UP CARE

Trial no: ☐☐☐☐
Questionnaire no: ☐☐

The questions below are aimed at helping to improve the quality of care provided during follow-up. They ask about the organisation of care, the information, advice and support given to you during consultations, hospital visits and phone-calls with the doctor or nurse specialist, and your general views of your follow-up care.

The following questions relate to the last few months of your follow-up care with either the doctor or nurse specialist. We would like you to think carefully about each question and to answer it as honestly as you can. Please answer in relation to the care you are receiving from either the doctor or nurse specialist. Don't spend too long on any question - your first reaction will probably be more realistic than a long thought out answer. If you are unsure about how to reply to any question, please give the best answer you can and write your comments beside the question. This questionnaire is anonymous and confidential. It will not be seen by the nurses or doctors involved in your care, and your answers will not affect your care in any way. The information that you give will be used to help improve the service we provide for people like yourself.

Most of the questions require you to tick boxes, giving one response for each question.

EXAMPLE

1. The staff are smartly dressed.

If the staff were **not at all** smartly dressed, you would answer like this:-

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
☑	☐	☐	☐	☐

Questions in the final section ask you to respond in writing in your own words. Your written responses may be as long or as short as you want. Please check that you have answered all the questions.

Please note **today's** date ☐☐ ☐☐ ☐☐

Please note the time you **started** filling in this questionnaire ☐

Please note the time you **finished** filling in this questionnaire ☐

Please answer these questions in relation to your follow-up care since you came into this study

A: Organisation of care

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. My appointments or phone calls with the doctor/nurse have been arranged to suit my convenience	☐	☐	☐	☐	☐
2. I have been kept waiting for my appointments or phone calls	☐	☐	☐	☐	☐
3. I have been able to see (or speak to) the same person at each appointment or phone call	☐	☐	☐	☐	☐
4. Each time I saw or spoke to the nurse/doctor, (s)he did not seem to know what had been happening	☐	☐	☐	☐	☐
5. No matter how busy the doctor/nurse was, (s)he made time for me	☐	☐	☐	☐	☐
6. The nurse/doctor was able to deal with any problems I had	☐	☐	☐	☐	☐
7. The doctor/nurse kept a regular check on me to see how I was	☐	☐	☐	☐	☐
8. I feel the care I am receiving allows me to get on with my own life and make good use of my time	☐	☐	☐	☐	☐

B. Information and advice

1. The nurse/doctor told me all I wanted to know about about my illness	☐	☐	☐	☐	☐
2. I was not given enough information about my medication and its side-effects	☐	☐	☐	☐	☐
3. I was given as much information as I wanted about my diet	☐	☐	☐	☐	☐
4. I was given as much information as I wanted about social and financial support	☐	☐	☐	☐	☐
5. I was not given enough information about my mobility	☐	☐	☐	☐	☐
6. The doctor/nurse gave me information just when I needed it	☐	☐	☐	☐	☐
7. The nurse/doctor gave me practical advice about managing my illness and symptoms	☐	☐	☐	☐	☐

Please answer these questions in relation to your follow-up care since you came into this study

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
8. I knew who to contact if I had a problem	☐	☐	☐	☐	☐
9. I felt uncomfortable about contacting the doctor/nurse if I had a problem between appointments or phone calls.	☐	☐	☐	☐	☐
10. After talking with the nurse/doctor, I have a good idea of what changes to expect in my health over the next few weeks and months.	☐	☐	☐	☐	☐
11. I did not have enough information about the organisation of my care	☐	☐	☐	☐	☐
12. I felt I knew exactly who was looking after me	☐	☐	☐	☐	☐

C: Personal experience of care

1. The doctor/nurse did not seem to understand what I was going through	☐	☐	☐	☐	☐
2. I saw the nurse/doctor as a friend	☐	☐	☐	☐	☐
3. The doctor/nurse took no interest in me as a person	☐	☐	☐	☐	☐
4. The nurse/doctor explained what was wrong with me	☐	☐	☐	☐	☐
5. The doctor/nurse gave me a chance to say what was really on my mind	☐	☐	☐	☐	☐
6. I felt that my own views of my illness were being fully considered	☐	☐	☐	☐	☐
7. I felt that the nurse/doctor listened to what was worrying me	☐	☐	☐	☐	☐
8. I felt able to express myself and ask questions	☐	☐	☐	☐	☐
9. After talking to the doctor/nurse, I felt much better about my problems	☐	☐	☐	☐	☐
10. I feel the nurse/doctor did not spend enough time talking with me	☐	☐	☐	☐	☐
11. The doctor/nurse really seemed to know about my particular case and situation	☐	☐	☐	☐	☐

Please answer these questions in relation to your follow-up care since you came into this study

D: Satisfaction with care

How satisfied are you with:-

	Not at all satisfied	Barely satisfied	Quite satisfied	Very satisfied	Completely satisfied
1. the thoroughness of the care you have received?	☐	☐	☐	☐	☐
2. the extent to which the doctor/nurse looked into all the problems you mentioned?	☐	☐	☐	☐	☐
3. the information given to you about your disease?	☐	☐	☐	☐	☐
4. the support given to you about your disease?	☐	☐	☐	☐	☐
5. the extent to which you have been involved in decisions about your care?	☐	☐	☐	☐	☐
6. the extent to which your own worries and concerns have been considered?	☐	☐	☐	☐	☐
7. the nurse or doctor's awareness of your needs?	☐	☐	☐	☐	☐
8. the extent to which your family have been considered?	☐	☐	☐	☐	☐
9. the way in which your symptoms have been managed?	☐	☐	☐	☐	☐
10. the way in which the doctor or nurse and GP communicate about your care?	☐	☐	☐	☐	☐
11. the way you have been cared for overall?	☐	☐	☐	☐	☐

E: THANK YOU FOR PERSEVERING THIS FAR! PLEASE ANSWER THE FOLLOWING QUESTIONS WHICH ASK FOR YOUR VIEWS IN YOUR OWN WORDS. PLEASE BE HONEST!

1. What (if anything) has been particularly troubling you over the last few months?

2. Please comment on how much these troubles have been helped by the care you have received from the doctor/nurse?

3. Overall how would you rate the **support** you have received? *(please make a mark on this arrow which best represents your views)*

Dreadful ←————————————————→ Excellent

4. What has been particularly good about your follow-up care?

5. What has not been so good about your follow-up care?

6. Has the frequency of your appointments and/or phone calls been:- a) too infrequent ☐ b) about right ☐ c) too frequent ☐ ?
Please comment if a) or c)

7. If you would have liked more support please explain what further help or advice you would have liked.

8. Is there any way in which your follow-up care could have been improved?

9. Has there been anything missing that was important to you?

10. Would you like to make any further comments about your experience of follow-up care?

11. If you were asked to choose your follow-up care again, what would you choose?

PLEASE TICK ONLY ONE BOX: *Follow up with:-*

a)	Nurse Specialist (with back up from the doctor only when necessary)	☐	c)	Both hospital doctor and nurse specialist routinely	☐
b)	Hospital Doctor only	☐	d)	No preference	☐

If you answered c) would you want to see/speak to **both** the doctor and the nurse specialist

THIS TIME PLEASE TICK ANY THAT APPLY (you may tick more than one)

a) at every appointment ☐
b) at alternate appointments ☐
c) nurse more frequently than doctor ☐
d) doctor more frequently than nurse ☐

Ideally how often would you want to see/speak to the doctor ____________________
nurse specialist ____________________

Please remember to fill in the time you finished this questionnaire on the front page. Thank you very much for your time.

SUPPLEMENTARY QUESTIONS (Please indicate which professional you see)	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
I have confidence in the physical examination carried out by my doctor/nurse	☐	☐	☐	☐	☐
The nurse/doctor had an understanding of my illness	☐	☐	☐	☐	☐
The doctor/nurse showed willingness to listen to all of my concerns	☐	☐	☐	☐	☐
I was not impressed by the human qualities (e.g. politeness, respect, sensitivity, kindness) of my doctor/nurse	☐	☐	☐	☐	☐
I had adequate time devoted to me during my consultation	☐	☐	☐	☐	☐

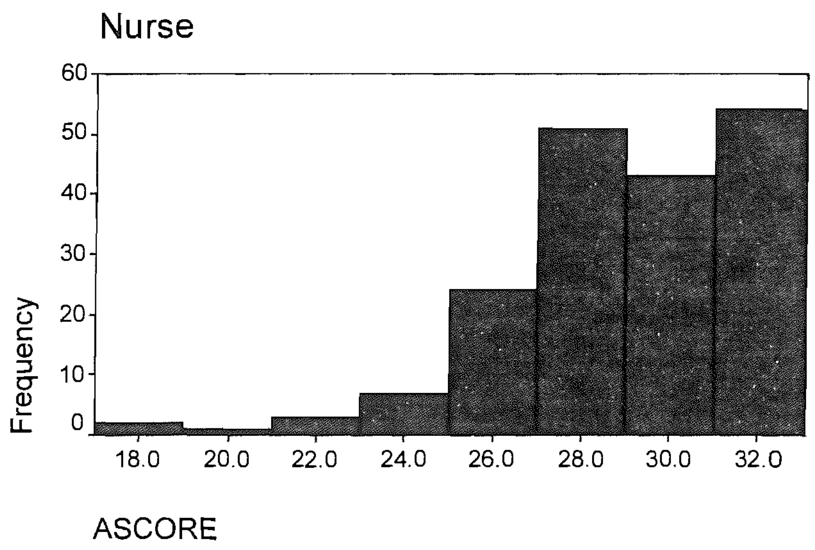
Appendix S

Histograms of the Distributions of Subscale Scores:

'Your Views of Follow-up Questionnaire (Phase Three)

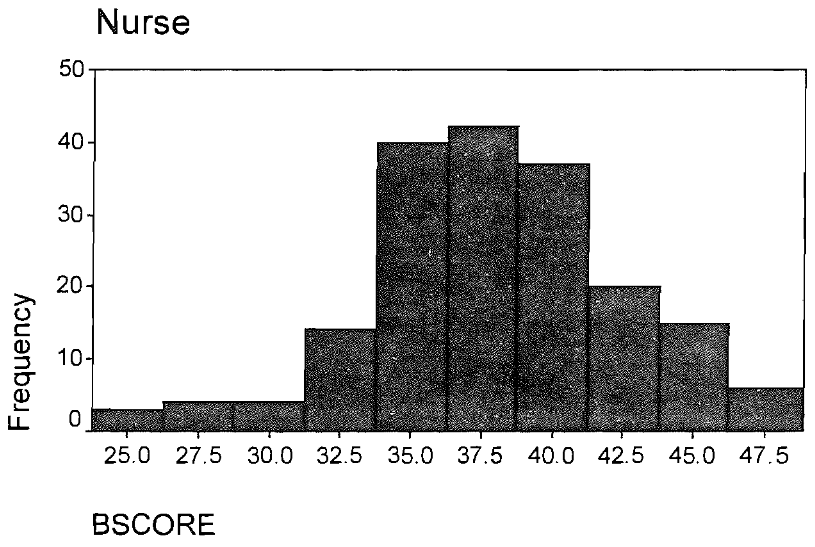
Section A:Organisation of Care

Scores for patients seen by nurse



Section B:Information & Advice

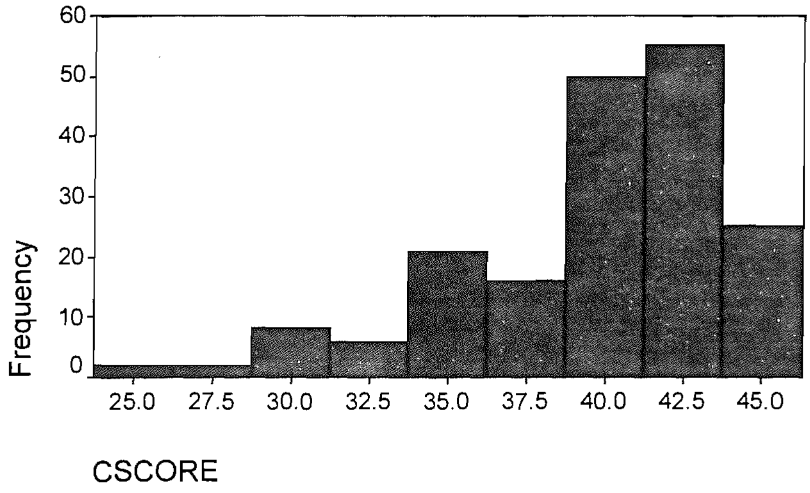
Scores for patients seen by nurse



Section C:Personal Experience of Care

Scores for patients seen by nurse

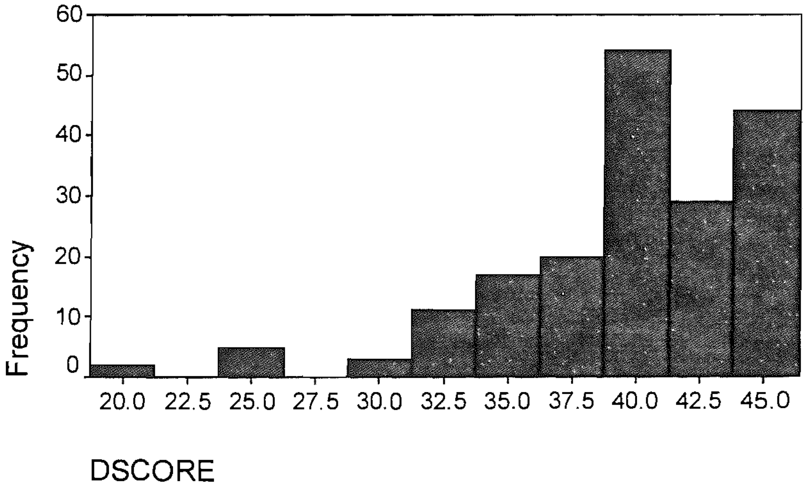
Nurse



Section D:Satisfaction with Care

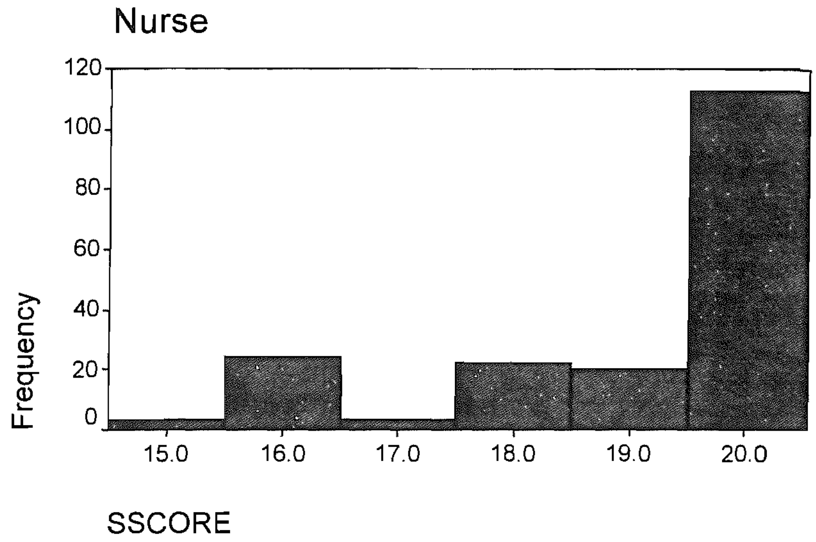
Scores for patients seen by patients

Nurse



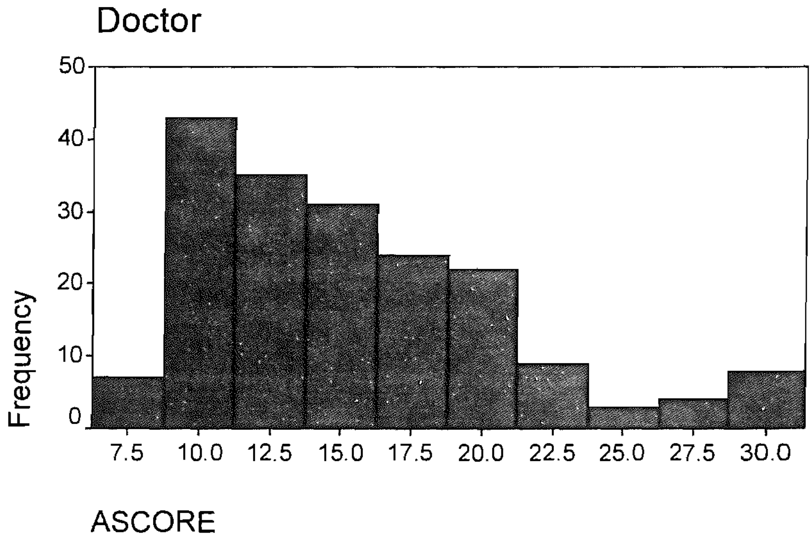
Supplementary Questions

Scores for patients seen by nurse



Section A:Organisation of Care

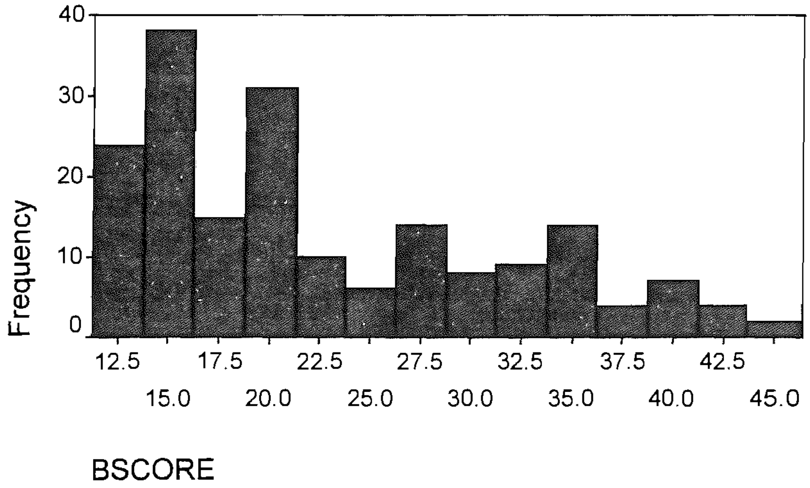
Scores for patients seen by Dr



Section B:Information & Advice

Scores for patients seen by Dr

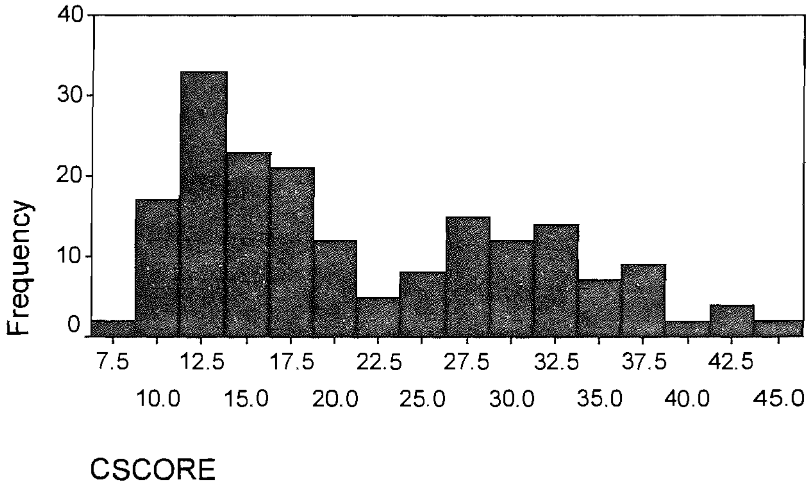
Doctor



Section C:Personal experience of care

Scores for patients seen by Dr

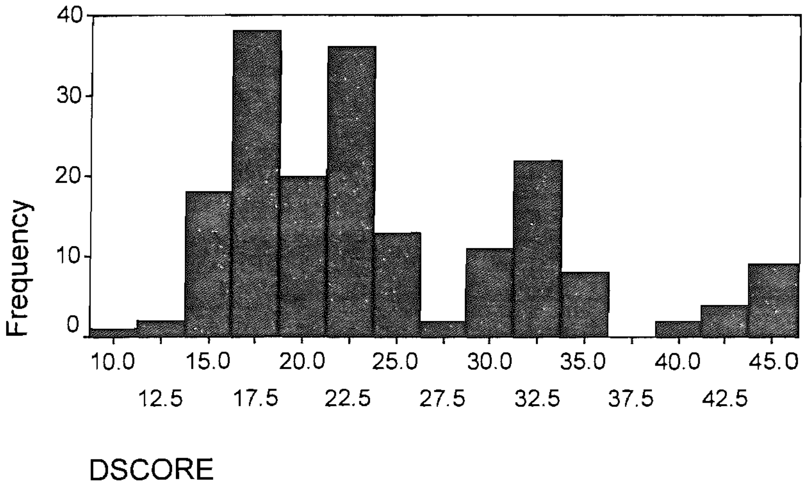
Doctor



Section D:Satisfaction with Care

Scores for patients seen by Dr

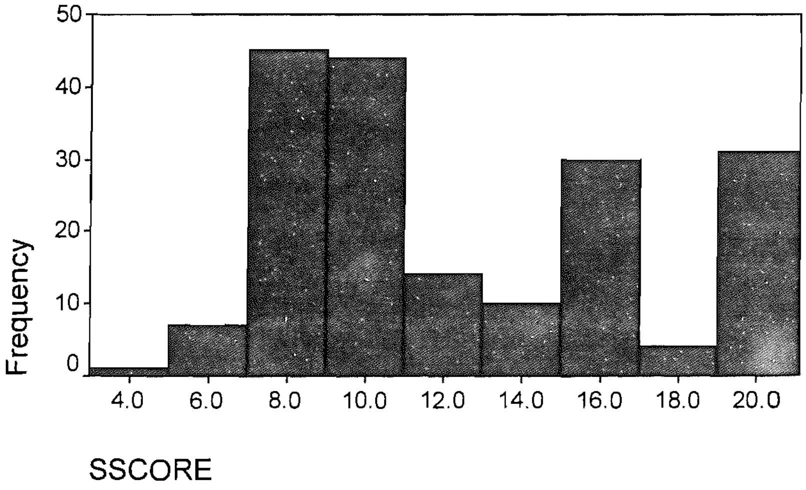
Doctor



Supplementary Questions

Scores for patients seen by Dr

Doctor



Appendix T

Application for copyright use of FACT-B Questionnaire & Letter of Permission

Patron Her Majesty The Queen

[redacted]

Professor David Cella
Center on Outcomes
Research and Education
Evanston Northwestern Healthcare
1000 Central Street
Suite 101
Evanston
IL 60201
USA

18/03/98

Dear Professor Cella

I am principal investigator on a study which aims to develop and evaluate an alternative model of follow-up in the management of patients with breast cancer. An extensive literature review and a preliminary needs assessment study have revealed that the main deficits in care relate to emotional and informational needs.

The first stage of our randomised prospective study will compare nurse-led follow-up with conventional medical follow-up of patients who have completed all treatment for breast cancer. We intend to measure differences in outcome between the two groups using an in-house questionnaire focusing on the follow-up consultation and the FACT-B (version 2) questionnaire (questions 1 to 43).

I would be most grateful, therefore, if you would consider granting us permission to use the FACT-B within this work. We would, of course, be happy to communicate any other information about the study, or the results gained, if you feel this would be of interest to you

I look forward to your reply.

Yours sincerely

Emma Pennery
Macmillan Lecturer Practitioner Breast Care

[illegible]

[redacted]

ENH EVANSTON
NORTHWESTERN
HEALTHCARE

**Center on Outcomes,
Research and Education
(CORE)**

1000 Central Street
Suite 101
Evanston, Illinois 60201
(847) 570-1720
(847) 570-1735 fax

April 1, 1998

Emma Pennery
Macmillan Lecturer Practitioner Breast Care
[redacted]

Dear Ms. Pennery:

Thank you very much for your interest in the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System, specific for breast cancer (FACT-B). We are delighted to hear that you are considering incorporating the FACT-B into your follow-up program for breast cancer patients, and are happy to grant you full permission for use and duplication of the English version as it may best suit your needs.

Please find enclosed a copy of the most current version of the FACT-B (Version 4) for your review and possible use. Since you are familiar with Version 2, I have also enclosed a description of the changes that occurred between version 3 and 4 (last November), a few references relevant to the measurement system, and a copy of the development and validation publication for the breast cancer subscale which was published last Spring in the Journal of Clinical Oncology.

Currently, there is no cost for use of the measure (English version only), and permission is granted with the simple request that you be willing to share relevant components of your research and to notify us of any publications. We also require that all investigators complete a FACIT Collaborator's Project Information Form (enclosed and also in Section 4 of the manual) for any trial/project in which they would like to use a FACIT scale. We very much appreciate the effort taken to complete such a form, as it is extremely useful in our tracking of all collaborators.

Finally, if you are interested, we offer a comprehensive FACIT manual which includes information on: 1) development of the core version (FACT-G); 2) our multilingual translations project and process; 3) scoring and administration procedures with raw score templates for all subscales and a standardized score conversion table; 4) copies of all 25 FACIT scales with reliability and validity reports when available; and 5) relevant references. The manual is available for $75.00 U.S ($95.00 for international shipping) to help partially defray production and shipping costs.

I hope that you will find the enclosure useful. If you have further questions or would like additional information, please do not hesitate to contact me at 847.570.1731 or at k-webster@nwu.edu. We look forward to hearing of your progress. Best of luck!

Sincerely,

Kimberly Webster, M.A.
Director of Communications
Center on Outcomes, Research and Education (CORE)