



*Decision-making in older women with breast cancer: a mixed methods study*

BURTON, Rita Maria

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**Decision-making in Older Women  
with Breast Cancer: A Mixed  
Methods Study**

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*Rita Maria Burton*

A thesis submitted in partial fulfilment of the requirements of  
Sheffield Hallam University for the degree of Doctor of Philosophy  
(Article Based)

June 2017

### **Candidate's Declaration**

I, Rita Maria Burton, confirm that the work presented in this thesis is my own and has not been submitted for any other academic award. Where information has derived from other sources, I confirm that this has been referenced in the thesis. Copyright transfers have been obtained for all previously published material arising from this study, including permission from co-authors to reproduce the work within this thesis.

Signed:

Dated:

## **NIHR Disclaimer**

This thesis presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1209-10071). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.



## **Abstract**

### **Background and aims**

In the United Kingdom one third of all breast cancers are diagnosed in women aged 70 or over. Older women with breast cancer are less likely to be offered or receive standard treatment.

### **Aim**

The overarching aim of this study was to establish the information needs and decision-making preferences of older women diagnosed with primary, operable, oestrogen receptor positive breast cancer and faced with a choice of surgery or primary endocrine therapy (PET).

### **Research design and methods**

This exploratory, sequential mixed methods study comprised a critical review of the literature, qualitative interviews and a quantitative questionnaire. The findings were interpreted and integrated in line with the mixed method ethos.

### **Key Findings**

The findings are underpinned by varied and complex internal and external influences. It is accepted that with increasing age cognitive functioning is compromised and poor health literacy is common. Although, the views of HCPs influenced treatment decisions, contrary to previously reported studies older women in this study wanted active involvement in the decision-making process and demonstrated confidence when making treatment choices. In terms of the content and format of information, unsurprisingly women preferred tailored information delivered face to face by the specialist HCP. In terms of written information women wanted brevity and simplicity. Visual displays of numeric data were unpopular and were found to be confusing for most women.

### **Conclusions and recommendations**

Information and decision support needs varied among this group of women. Understanding how older women define 'involvement in treatment decision-making' would enhance the development of appropriate decision support.

Further work is required in the development of data collection tools, particularly questionnaires, appropriate for an older, frail population.

## Acknowledgements

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This PhD will be a huge surprise to my son, Greg who has no idea I have been doing it!

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## Abbreviations

BCS	Breast conserving surgery
BTAG	Bridging the Age Gap in Breast Cancer
CPS	Control Preference Scale
DESI	Decision support intervention
DM	Decision-making
DRS	Decision Regret Scale
ER+	Oestrogen receptor positive
ET	Endocrine therapy
HCP	Healthcare professional
HES	Hospital Episode Statistics
IORT	Intra-operative radiotherapy
MM	Mixed methods
PBI	Partial breast irradiation
PET	Primary endocrine therapy
RCT	Randomised Control Trial
WBI	Whole breast irradiation
WLE	Wide local excision

## **Article-based PhD**

This thesis is written as an 'Article-based (AB) PhD'.

Although the format is substantially different to the traditional monograph PhD the regulations and assessment criteria for award remain the same.

An AB PhD includes between three and five articles that are produced by the candidate during the period of their candidature.

The articles, together with an introductory chapter, an explanation of the research question, the methodology and methods and a concluding chapter describe a coherent programme of research undertaken by the candidate.

## Structure of this PhD thesis

This section aims to inform the reader of the structure of this thesis and provide a brief outline of the contents of each chapter.

### Overview

The thesis begins by providing an overview of the wider 6 year programme of work funded by the National Institute of Health Research entitled 'Bridging the Age Gap in Breast Cancer: Improving Outcomes for Older Women. (NIHR Programme Grant: RP-PG-1209-10071, Project leads: Lynda Wyld, Malcolm Reed and Karen Collins, 2012-2018)

This section will demonstrate how the work presented in this thesis is nested within and contributes to the overall aims the main study.

### Chapter 1

Chapter 1 provides the context to the PhD. The incidence of primary breast cancer and current UK survival rates for breast cancer. Any differences between younger and older women (>70 years of age) are evidenced. An overview of standard breast cancer treatments and how advances in both surgical and non-surgical treatments have given rise to the possibility of a choice of breast cancer treatment are discussed. This is followed by a discussion of the information needs and decision-making preferences of older women when faced with a choice of breast cancer treatments, specifically with the choice of surgery or PET for operable breast cancer. This chapter thereafter establishes the gap in knowledge and outlines the aims and objectives of the PhD.

### Chapter 2

Chapter 2 contains the first article entitled: ***'Information Needs of Older Women Faced with a Choice of Primary Endocrine Therapy or Surgery for Early-Stage Breast Cancer: A Literature Review'***. This article forms the background of this PhD and provides the rationale for undertaking this study. This chapter also contains a critical commentary of the article and an

update of the current literature (since the original search in January 2013 to the time of submission of this PhD in 2017).

### **Chapter 3**

This chapter provides a detailed examination of the methodological approach adopted within this thesis, namely mixed methods. It outlines the philosophical stance of mixed methods and a justification for the design chosen.

### **Chapter 4**

Chapter 4 outlines the methods used within this PhD. It details the sequential mixed methods design comprising of both qualitative (semi-structured interviews) and quantitative methods (postal survey) and provides the rationale for using this approach. Details of the study sample, eligibility, participant recruitment and access, the development of the interview schedule and questionnaire survey, data collection methods, data handling and data analysis are all discussed. Finally details of the research ethical approval and local governance approvals are described

### **Chapter 5**

Chapter 5 contains the second published article entitled: ***'The information and decision support needs of older women (>75 yrs) facing treatment choices for breast cancer: a qualitative study'***. This article reports the findings from the qualitative semi-structured interviews undertaken and forms the qualitative component of this mixed methods study. The author presents a critical commentary on the article using the NICE (2012) qualitative appraisal tool as a framework. This chapter also contains a reflexive account of the extent to which the values, actions and experience of the researcher impacted on the author's role as a researcher.

### **Chapter 6**

Chapter 6 contains the third article entitled; ***'Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer.'*** This

article reports the findings from a questionnaire survey and forms the quantitative component of this mixed methods study. The author presents a critical commentary on the article in order to expand upon and add further detail that it was not possible to address in the published article.

## **Chapter 7**

This article contains the fourth published article entitled; '***The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer***'. This paper provides a deeper exploration and understanding of older women's decision-making using data from the qualitative semi-structured interviews in this PhD and data from the main Bridging the Age Gap in Breast Cancer (BTAG) study. As in previous chapters the author presents a critical commentary to expand on elements that it was not possible to address in the published article.

## **Chapter 8**

This chapter integrates the findings of the various PhD components and provides a mixed methods summary of the literature review, the semi-structured interviews and the questionnaire using a triangulation protocol. The findings from this mixed methods integration are reviewed.

## **Chapter 9**

This chapter revisits the research questions and the aims of the study and summarises the findings before examining them in the light of previous literature. Strengths and limitations of the study will be addressed.

## **Conclusions and Recommendations**

This thesis will conclude by outlining the contribution to current clinical, methodological and theoretical knowledge this study has made and what further work may be necessary to further understand the information and decision preferences of older women faced with a choice of treatment for their primary operable breast cancer

## Articles in this PhD

**Burton, M.**, Collins, K.A., Wyld, L., Caldon, L., Reed, M.W. "Information Needs of Older Women Faced With a Choice of Primary Endocrine Therapy or Surgery for Early Stage Breast Cancer: A Literature Review" *Current Breast Cancer Reports* (2014) 6:235-244

**Burton, M.**, Collins, K.A., Lifford, K.J., Brain, K., Wyld, L., Caldon, L., Gath, J., Revell, D. and Reed, M.W., 2015. "The information and decision support needs of older women (> 75 yrs) facing treatment choices for breast cancer: a qualitative study" *Psycho-Oncology*, 24(8), pp.878-884.

Morgan, J.L.; **Burton, M.**; Collins, K.; Lifford, K.J.; Robinson, T.G.; Cheung, K.L.; Audisio, R.; Reed, M.W.; Wyld, L. on behalf of the Bridging the Age Gap Trial Management Team. "The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer". *Psycho-Oncology* 2015; DOI: 10.1002/pon.3853.

**Burton, M.**, Kilner, K., Wyld, L., Lifford, K.J., Gordon, F., Allison, A., Reed, M.W., Collins, K.A. "Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer". *Psycho-oncology*. 2017 Mar 23. doi: 10.1002/pon.4429. [Epub ahead of print]

### Details of the Journals

***Psycho-oncology*** - Journal of the psychological, social and behavioural dimensions of cancer.

Impact factor: 3.256

ISI Journal Citation Reports © Ranking: 2015: 2/39 (Social Sciences Biomedical); 18/76 (Psychology); 18/129 (Psychology Multidisciplinary); 86/213 (Oncology)

### ***Current Breast Cancer Reports***

Impact factor: 0.84\*



\*This value is calculated using ResearchGate data and is based on average citation counts from work published in this journal. The data used in the calculation may not be exhaustive. Impact factor for 2016 will be available in summer 2017.

## Preface

This article based PhD is nested in a wider 6 year programme of work funded by the National Institute of Health Research entitled 'Bridging the Age Gap in Breast Cancer: Improving Outcomes for Older Women' (BTAG).

## Overview of the Bridging the Age Gap in Breast Cancer

### Programme of Research

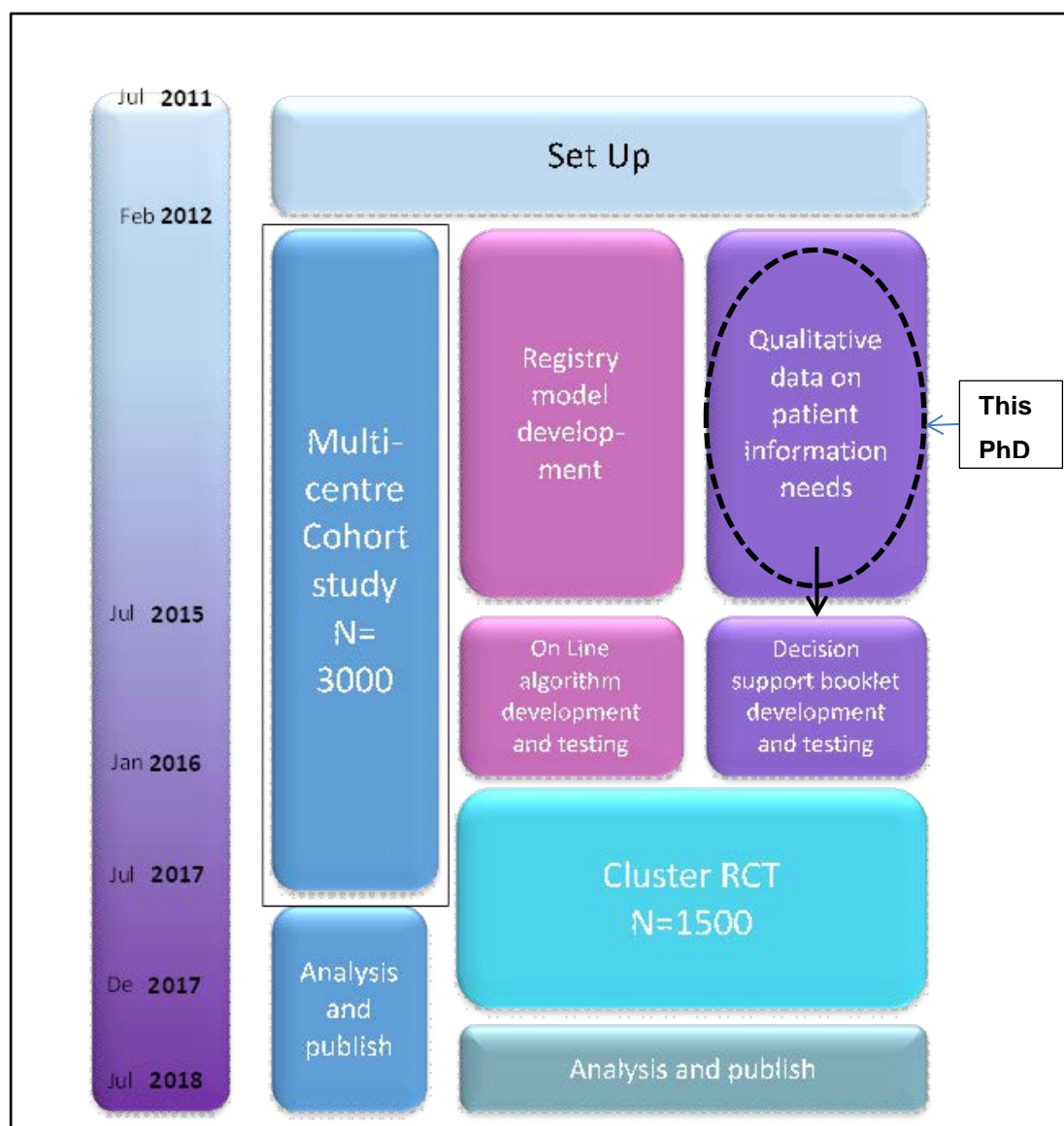
Breast cancer affects 13000 UK women over age 70 annually and causes the deaths of 6733 per year. Patients over 70 years of age have seen less than half of the reduction in cancer mortality compared to younger women. This is, in part, due to sub-optimal treatment as a result of concerns about poor treatment tolerance. Older women have not benefitted from the advances in chemotherapy (and trastuzumab) and many do not undergo surgery, being offered instead anti-oestrogen tablets. The use of anti-oestrogens as sole treatment for otherwise operable breast cancer is called Primary Endocrine Therapy (PET). PET is a good alternative to surgery in older frailer women as they have equivalent overall survival rates, although rates of local disease control are inferior. At present there is no guidance for Health Care Professionals (HCPs) on the level of frailty or ill health in older women with breast cancer, which suggests that PET may be a superior option to surgery. There is little research to guide best practice in older patients. There is also little known about the information and support needs of older women with breast cancers, or their preferences for engagement in cancer treatment decision-making. Such information and the production of national evidence-based guidance, is needed to optimise the treatment of older women and bridge the age gap in cancer outcomes.

### The BTAG programme comprises 6 main components:

1. Prospective multicentre cohort study to determine current UK practice and permit analysis of optimal care using state of the art data modelling techniques.
2. Retrospective registry and Hospital Episode Statistics (HES) data modelling study to supplement the data from the cohort study and give longer term follow-up on outcomes than that provided by the cohort study.

3. Clinician practice variance study to determine how UK practice varies by centre and assess the impact of clinician preference.
4. **Development of a decision support tool for older women to assist older women in making evidence based choices about their preferred care**  
**This PhD is contained within this element of the wider programme of research.**
5. A pragmatic cluster randomised controlled trial (RCT) to test and validate a combined clinician facing web-based breast cancer outcomes algorithm and a decision support intervention (DESI) to support shared decision-making in older women faced with the choice of either PET or surgery.
6. A process evaluation running alongside the RCT to evaluate the process and outcomes of the DESI (including validation of measures, intervention implementation and effect, acceptability of the intervention and the facilitators and barriers to embedding the intervention into everyday clinical practice). These component parts are summarised diagrammatically in Figure 1 below. An executive summary of the parent study 'Bridging the Age Gap in Breast Cancer' is provided in Appendix 1

**Figure 0.1: Components of the BTAG Programme**



## Summary of the PHD

This mixed methods exploratory sequential study is embedded within a wider NIHR Programme Grant summarised above (The Bridging the Age Gap Breast Cancer Study (BTAG)). Specifically this article based PHD will provide a clinical, methodological and theoretical contribution to the current evidence base. It comprises of a critical review of the current literature, in-depth qualitative interviews and a quantitative questionnaire which has acquired data focused on the information of older women with breast cancer and their preferences for engagement in cancer treatment decision-making. This data informed the development of a decision support intervention for older women with operable breast cancer when faced with a choice of surgery or PET.

## Scope of this PhD

During July 2012, the researcher was employed as a research fellow on the BTAG study outlined above. The researcher role within the BTAG programme was primarily focused on the development of a patient decision support intervention. This involved the development of the protocol and subsequently responsibility for gaining ethical approvals and research and development governance for all the study sites involved in this phase of the study. The researcher was responsible for undertaking the literature review, participant recruitment and data collection and analysis focused on establishing the information needs and decision-making preferences of older women with operable breast cancer when faced with a choice between surgery or PET. Initially this phase of the study was purely qualitative using interviews as a sole means of data collection. However, in order to quantify the findings of the interview data it was decided that by incorporating a quantitative component and thus undertaking a mixed methods study would increase applicability, confirmability and permit stronger inferences to be made (Teddlie & Tashakkori 2009). A questionnaire was therefore developed and data collected and analysed. This was then integrated with the qualitative data analysis and the insights derived from the literature review. To the researcher's knowledge, there are no other published studies that have examined the information needs and decision-making preferences of

older women diagnosed with primary breast cancer and who are faced with a choice of surgery or PET, thus this PHD will provide a new methodological and theoretical contribution to the existing literature.

## Research outputs

**Burton, M.**, Kilner, K., Wyld, L., Lifford, K.J., Gordon, F., Allison, A., Reed, M.W., Collins, K.A. "Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer". *Psycho-Oncology* 2017 Published online 24/3/17 DOI 10.1002/pon.4429

Morgan, J.L., **Burton, M.**,\* Collins, K., Lifford, K.J., Robinson, T.G., Cheung K.L., Audisio, R., Reed, M.W., Wyld, L., on behalf of the Bridging the Age Gap Trial Management Team. "The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer". *Psycho-Oncology* 2015; DOI: 10.1002/pon.3853.

**Burton, M.**, Collins, K.A., Lifford, K.J., Brain, K., Wyld, L., Caldon, L., Gath, J., Revell, D., Reed, M.W. 2015. "The information and decision support needs of older women (> 75 yrs) facing treatment choices for breast cancer: a qualitative study" *Psycho-Oncology*, 24(8), pp.878-884.

Lifford, K.J., Witt, J., **Burton, M.**, Collins, K., Caldon, L., Edwards, A. ... Brain, K. (2015). "Understanding older women's decision-making and coping in the context of breast cancer treatment". *BMC Medical Informatics & Decision-making* . 15 (45),

**Burton, M.**, Collins, K.A., Wyld, L., Caldon, L., Reed, M.W. (2014) "Information Needs of Older Women Faced With a Choice of Primary Endocrine Therapy or Surgery for Early Stage Breast Cancer: A Literature Review" *Current Breast Cancer Reports* 6:235-244

## Published Abstracts

Morgan, J. L., K. Collins, **Burton, M.**, Reed, M. W., Wyld, L. "Healthcare professionals' opinions of treating older women with operable breast cancer: A mixed methods study." *European Journal of Surgical Oncology* (2014) 40, no. 11: S14-S15.

Lifford, K., Brain, K., Edwards, A., Collins, K., **Burton, M.**, Caldon, L., Reed, M., Wyld, L. On behalf of the Bridging the Age Gap Management Group.

"The development of a decision support intervention for older women with a choice of surgery or primary endocrine therapy to treat breast cancer."

*Nottingham 3<sup>rd</sup> Symposium on primary breast cancer in older women (poster)*

*March 2015. Published in Future Oncology*

Volume:11 Issue:4 Supplement: S Pages: 19-20 Meeting Abstract:

P11 Published: 2015

Lifford, KJ., Brain, K., Collins, K., **Burton, M.**, Witt, J., Caldon, L., Edwards, A., Wyld, L., Reed, M. On behalf of the Bridging the Age Gap Management Group. "Developing collaborative decision support interventions for older women (75 years plus) with breast cancer." *International Congress of Behavioural Medicine (oral), Groningen, The Netherlands, Aug 2014.*

*Abstract published in International Journal of Behavioural Medicine*, Volume: 21 Supplement: 1 Pages: S75-S75 Meeting Abstract: O239 Published: AUG 2014

Richards, P., Ward, S., Morgan, J., Francis, M., Collins, K., **Burton, M.**, Nettleship, A., Lifford, K., Reed, M., Wyld, L. "Bridging The Age Gap in Breast Cancer – improving treatment decisions for older women using routine data" *European Journal of Cancer Care. Special Issue: National Cancer Intelligence Network Cancer Outcomes Conference 2015, 8-10 June 2015, Europa Hotel, Belfast June 2015, Volume 24, Issue Supplement S1*

### **Poster Presentations**

**Burton, M.**, Collins, K., Lifford, K., Reed, M., Armitage, F., Wyld, L. "Bridging the Age Gap in Breast Cancer Trial (BTAG) Update". On behalf of the Bridging the Age Gap Team *Fourth symposium on Primary Breast Cancer in Older Women. 3 March 2017*

**Burton, M.**, Armstrong, F., Collins, K., Richards, P., Nettleship, A., Lifford, K., Wyld, L. "Developing an On-line Decision Tool for Health Care Professionals to aid Collaborative Decision-making with Older Women with Breast Cancer" *10<sup>th</sup> European Breast Cancer Conference, Amsterdam 8-11<sup>th</sup> March 2016*

**Burton, M.**, Armstrong, F., Collins, K., Richards, P., Nettleship, A., Lifford, K., Wyld, L. "Developing an On-line Decision Tool for Health Care Professionals



to aid Collaborative Decision-making with Older Women with Breast Cancer"  
*Sheffield Hallam University, Health and Wellbeing Faculty Research Day*  
July 2016. *Received second prize in the poster competition*

**Burton, M.**, (joint first authors), Caldon, L., Lifford, K., Brain, K., Wyld, L.,  
Reed, M. *European Breast Cancer Conference* 19-21 March 2014 (Glasgow)  
"The Information and decision support needs of older women (>75 yrs)  
facing treatment choices for breast cancer: a qualitative study". Collins K,

Lifford, K., Brain, K., Collins, K., **Burton, M.**, Witt, J., Wood, F., Caldon, L.,  
Edwards, A., Wyld, L., Reed, M. "Developing collaborative decision support  
interventions for older women (≥75 yrs) with breast cancer." On behalf of the  
Bridging the Age Gap Management Group., *European Association for  
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### **Oral presentations**

**Burton, M.**, Collins K. "Decision-making in older Older Women Choosing  
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Wellbeing Faculty Research Day* 1<sup>st</sup> July 2016

**Burton, M.**, Collins K. Presented on behalf of the Bridging the Age Gap in  
Breast Cancer study team "Establishing Decision Support and Information

Needs of Older Women Choosing Treatment for Breast Cancer" Presented  
on behalf of the Bridging the Age Gap in Breast Cancer study team *Sheffield  
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# Chapter 1: Introduction

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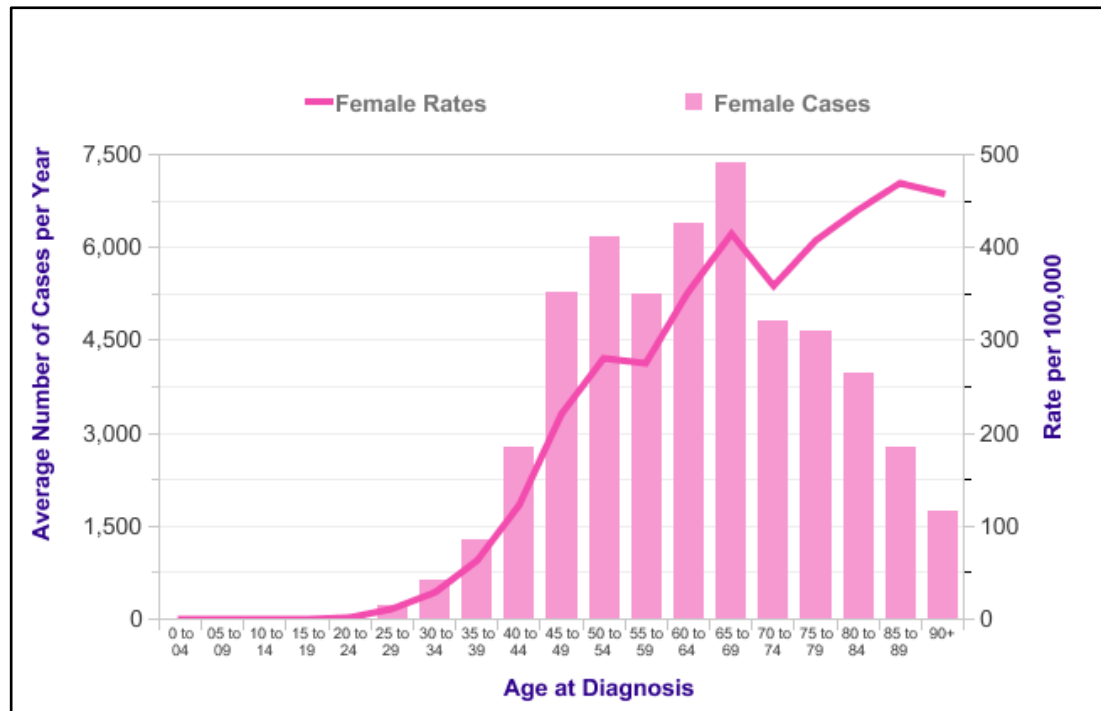
## **1. Chapter 1: Introduction**

This chapter provides the context for this article based PhD thesis. It provides an outline of the incidence and survival outcomes of breast cancer and the standard treatment available to women with primary breast cancer. It is not the intention of this chapter to provide an in-depth account of the treatment of breast cancer but to provide the context of the PhD. The development of each treatment option is outlined before examining how these developments have culminated in treatment options being available to both the HCP and the patient. Consideration was given to the changing view of the patient as an active partner in health care decisions and how this has led to changing practice in breast cancer treatment in older women. This chapter will conclude by identifying the gap in knowledge which this thesis will address.

### **1.1. Background**

Globally breast cancer is the most common cancer affecting women (WHO 2017) and is the leading cause of cancer death among females, accounting for 23% of the total cancer cases and 14% of cancer deaths worldwide (Jemal et al. 2011). In the UK, breast cancer it is the third most common type in England and the most common cancer in women (ONS 2010). One in eight women will develop breast cancer at some point in their lives, with age being the strongest risk factor (Cancer Research UK, 2012). Eighty percent of breast cancers occur in the over 50's and almost a third in the over 70s (Moller, Flatt & Moran 2011).

**Figure 1.1: Number of female breast cancer cases per year by age at diagnosis (2012-2014)**



Reproduced from the Cancer Research UK

## 1.2. Stages of Breast Cancer

When there is uncontrolled, abnormal growth and division of cells in either the lobules or the ducts of the breast which spreads to the surrounding tissue invasive breast cancer occurs. Breast cancers are staged according to The Union Internationale Contre le Cancer (UICC) staging system. Stages 1-3 (known as early breast cancer) refer to breast cancer which is confined locally to the breast tissue and the lymph glands in the axilla. Stages 1 and 2 are referred to as early breast cancer and is always operable. Stage 3 is sometimes referred to as locally advanced breast cancer and is sometimes operable and sometimes curable, but not always. Stage 4 disease has spread via the bloodstream and lymphatic system to other parts of the body (Hermaneck, Henson, Hutter & Sabin1987) and is often called secondary or metastatic breast cancer. Stage 4 disease is not curable and treatment is rarely surgical and is usually with palliative intent. This study is concerned with older women ( $\geq 75$  years) with operable breast cancer i.e. all in stages 1 and 2 and those patients with stage 3 disease who have surgical options and the potential for cure.

### **1.3. Breast Cancer Treatment Options (non age specific)**

#### **1.3.1. Surgery**

William Halsted's radical mastectomy was initially 'considered to be the ideal cancer operation' and the only effective treatment for breast cancer (Halsted 1894). Described in 1894, this operation included resection of the breast, pectoral muscles, and regional lymphatics. This operation was based on the accepted science of the time that breast cancer spread slowly and only entered the bloodstream at a later phase of the disease, therefore performing this type of operation 'would remove all the cancer in the body' (Fisher 2005; Lerner 2013).

Despite the poor cosmetic appearance and the associated lymphoedema this was standard surgery for almost 70 years. A number of developments in the understanding of cancer biology and growing reports of recurrence of cancer following mastectomy led some to perform a modified mastectomy, which left the pectoral muscles intact (Patey & Dyson 1948) or a lumpectomy, (or breast conserving surgery (BCS) as it is now more commonly referred to), which took only the tumour and a small amount adjacent normal breast tissue (Crile 1972). This treatment was variously accompanied by adjuvant therapies including chemotherapy and radiotherapy (Fisher et al. 1968, Atkins, Hayward, Klugman & Wayte 1972) for selected patients. Evidence from a randomized controlled trial published in 1985 demonstrated that BCS plus radiotherapy was an effective alternative treatment to mastectomy for some cases breast cancer (Fisher et al. 1985).

Today surgery, either mastectomy or, where appropriate, BCS, commonly accompanied by adjuvant or neo-adjuvant therapies is considered standard treatment. The technicalities of breast surgery are outwith the scope of this PhD suffice to say that they may also now include mastectomy and reconstruction, oncoplastic reshaping of the breast to extend the indications for breast conservation. In addition about 40% of women have axillary nodal disease at presentation. Until 15-20 years ago, all women with breast cancer underwent axillary node clearance as part of their surgery. In modern practice, whilst axillary clearance is still often used in women with definite

nodal disease at diagnosis, for those whose axillae appear clinically normal, sentinel node biopsy is now the standard of care (Krag et al. 2007). In recent years options for axillary radiotherapy in place of surgery are being adopted following trial data (Donker et al. 2014)

#### **1.4. Adjuvant therapy**

Adjuvant therapy is additional cancer treatment given after the primary treatment to lower the risk of cancer recurrence locally or systemically. This may include radiotherapy, hormone therapy, chemotherapy and targeted therapy, (also known as biological therapy).

##### **1.4.1. Radiotherapy**

The introduction of X-rays at the end of the 18th century opened the doors for the development of radiotherapy and mammography. The discovery of radium allowed the introduction of interstitial radiation for breast cancer therapy (Cooper 1942). Pfahler & Parry (1930) reported favourable five year results of routine post-operative radio-therapy for stage II breast cancer but it was McWhirter's 1948 study (McWhirter 1948) that provided the initial evidence required to support it as routine practice following breast surgery. McWhirter (1948) followed a simple mastectomy with three weeks of radiation to the axilla and chest wall. The results were impressive with a 62% five year cure rate compared to current radical mastectomy only cures rates which ranged between 35-45% at the time. More recently the Early Breast Cancer Trialists' Collaborative Group (EBCTCG 2006) have updated their meta-analysis of long-term outcome in women with early stage breast cancer and they conclude that radiotherapy is effective in eradicating much of the microscopic local disease foci that may persist following surgery. It also states that when not used after surgery local disease recurrence can metastasize increasing the possibility of dying from breast cancer.

Radiotherapy is not without its side effects. These range from minor skin irritation to fibrosis of the skin and underlying tissue, to the more serious cardiac damage resulting in reduced cardiac function (Gagliardi et al. 2010; Olivotto et al. 2013). Following BCS it is known that true recurrences of breast cancer (as opposed to second primary cancers) usually occur in the

same breast quadrant (Salvadori 1999) therefore the question of whether whole breast irradiation (WBI) is necessary has been investigated. When compared to WBI, irradiating a smaller area of the breast, partial breast irradiation (PBI) has the advantages of reduced fibrosis of the breast and underlying tissues, thereby reducing the risk of cardiac damage (Borger et al 1994) without affecting local recurrence rates or overall survival in selected sub groups of patients.

Partial breast irradiation is an attractive option for patients as it requires fewer treatment sessions, a factor known to influence the surgical choice of women with early breast cancer. Forty-seven percent of mastectomy patients would have been more likely to choose BCS if a shorter duration of radiotherapy had been offered to them (Rippy et al. 2014). However, there is conflicting evidence surrounding the improvement in cosmetic outcome of the breast following PBI. Polgar, Fodor, Major, Sulyok & Kasler (2013), suggested an improved appearance and no difference in recurrence at 10 year follow up with the use of PBI compared to WBI. Currently in the UK PBI is not given as part of routine practice. More recently intra-operative radiotherapy (IORT) has been investigated and although overall survival is unaffected on relatively short term follow up, local recurrence rates are considerably higher when compared with whole breast irradiation (Vaidya, et al. (2014). Consequently IORT is not yet recommended for use outside of trials in the UK, although is currently the subject of a NICE review which may recommend its adoption in some sub-groups of patients (NICE Draft Guidelines, Feb 2017).

The impact that radiotherapy has on improving local disease control and survival is not in question but further investigation is required to understand the variation in treatment effect between individuals and to identify the optimal dosage, frequency, timing and method of application of radiotherapy (Clarke et al.2005 & EBCTCG, 2011). Larger fractions over a shorter period are being investigated with radiotherapy regime durations dropping from 7 weeks, to 5 weeks and now 3 weeks (the current norm), with trials ongoing looking at a single week (The Fast Forward Trial) (Brunt et al. 2016).



Targeting is also better with CT guided target volume delineation to spare the heart (Latty, Stuart, Wang & Ahern 2015).

### **1.4.2. Systemic therapies in the treatment of breast cancer**

There are three broad categories of drug strategies used in the treatment of breast cancer; hormone therapy, chemotherapy and targeted therapy. Again an overview is presented as detailed review is out with the scope of this thesis.

### **1.4.3. Hormone therapy**

Some hormones cause certain cancers to grow. Hormone therapy, also known as endocrine therapy, aims to remove hormones or block their action to prevent tumours from growing. Where cancer cells are known to be hormone receptive, (ER+), hormone therapy (known as endocrine therapy) is used to reduce the production of hormones or block their action. Oestrogen, is known to encourage growth in some breast cancers therefore anti-oestrogen drugs, such as tamoxifen are given to pre-menopausal patients with early breast cancer to block oestrogen from stimulating further growth. In postmenopausal women with oestrogen dependent breast cancer an aromatase inhibitor, e.g. anastrozole, letrozole or exemestane is used to prevent the production of oestrogen. In high risk pre menopausal women, ovarian suppression therapies may also be added.

Hormone therapies may produce side effects to a lesser or greater degree. The most common side effects being vasomotor symptoms including hot flushes and night sweats (Carpenter, Johnson & Wagner 2002). The symptoms mimic those of the menopause but the symptoms can be more severe than women going through 'natural' menopause (Carpenter 2002). Five years is the usual treatment duration for hormone therapy but patients may discontinue earlier when the side effects have too greater an impact on their quality of life (Gibson 2009; Loibl 2011; Zhu, Bensoussan, McNicol, Chen & Lu 2013). Recent data from the ATLAS and ATTOM trials have suggested that antioestrogen therapies for higher risk women should be extended to 10 years (Cuzick et al. 2010; Davies et al. 2013; Gray et al. 2013).

The Early Breast Cancer Trialists Collaborative Group (EBCTCG) (2006) overview of tamoxifen in early breast cancer suggests that the survival benefit of 5 years is approximately 25%. Aromatase inhibitor therapies have a slightly better side effect profile and reduce disease free but not overall survival relative to tamoxifen (Cuzick et al. 2010)

#### **1.4.4. Chemotherapy**

Chemotherapy is a systemic treatment for breast cancer using a combination of different cytotoxic drugs that aim to destroy or prevent further growth of the malignant tumour. In breast cancer, the decision to use chemotherapy depends on the size, grade, the oestrogen receptor (ER) status, human epidermal growth factor type 2 receptor (HER2) status and the general health of the patient. More recently multigene arrays have been used to make chemotherapy decisions (Oncotype DX) (Sparano et al. 2015). Patients with a grade 3 tumour i.e. a fast growing, poorly differentiated tumour and/or HER2 positive are more likely to be offered or receive chemotherapy after surgery. Used as a neo-adjuvant therapy, chemotherapy aims to shrink the tumour thereby making surgery less extensive (Fisher et al. 1998).

Chemotherapy is known to have significant side effects (Partridge, Burstein, Winer 2001). Short-term side effects such as fatigue, vomiting, hair loss, depression, myelosuppression, thromboembolism, myalgia and neuropathy occur during the course of treatment and usual end shortly after treatment completion (Shapiro & Recht 2001; Zhang, Liu, Li & Tripathy 2007; Frisk, Kallstrom, Wall, Fredrikson & Hammar 2012). Long-term side effects, such as weight gain, cardiac dysfunction, leukaemia and cognitive impairment appear later in treatment or after completion and may last for many years (Shapiro & Recht 2001; Ramalingam 2002).

#### **1.4.5. Targeted therapy**

In addition to chemotherapy a targeted therapy may also be used to treat women with HER-2 positive breast cancer. Trastuzumab is the targeted therapy used to treat women with the subtype of early breast cancer that

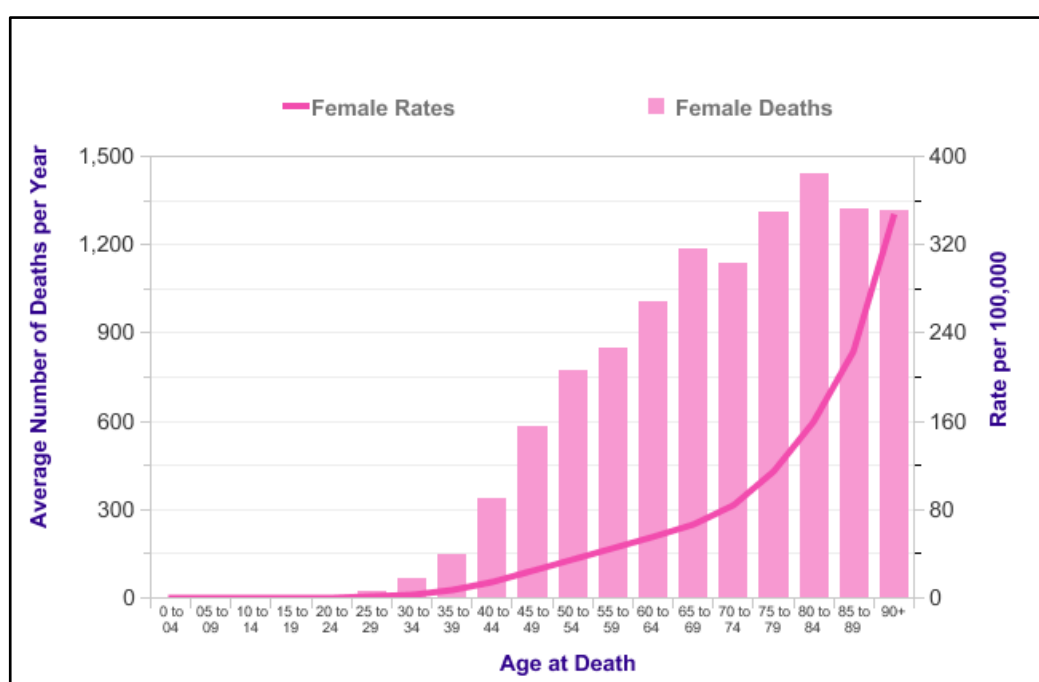
expresses high levels of the HER 2 receptor (Slamon et al. 2001; Vogel et al. 2002; Piccart-Gebhart et al. 2005; Romond et al. 2005; Slamon et al. 2011).

Common side effects of hair loss and vomiting in chemotherapy are not present in targeted therapy but they do include flu-like symptoms and in some patients, severe diarrhoea and possible cardiac problems (Metzger, Saini, Azim & Awada. 2012; Breast Cancer Campaign).

## 1.5. Breast Cancer Treatment in Older Women

Older women experience worse survival for breast cancer when compared to younger women with relative five year survival rates reducing from 89% for 45-49 year olds to 69% for women  $\geq 80$  years (Coleman et al. 2011).

**Figure 1.2: Average number of breast cancer deaths per year and age-specific mortality rates, Females, UK, 2012-2014**



Reproduced from Cancer Research UK

### 1.5.1. Treatment Guidelines

Published guidelines give minimum standards for the diagnosis and treatment of non-metastatic breast cancer (NICE 2009; Gnant, Thomssen & Harbeck 2015). Older women are less likely to be diagnosed via triple assessment or have a needle biopsy so the exact nature of the breast cancer (ER receptor status) is not always clear leading to less efficient and effective

treatment (Busch 1996; Wyld , Garg, Kumar, Brown & Reed 2004; Lavelle et al. 2007).

## **1.6. Surgery**

There is evidence demonstrating that older women in the UK are less likely to receive primary surgery (the standard treatment), radiotherapy or chemotherapy and are more likely to receive endocrine therapy as a sole treatment (Bouchardy et al. 2003; Money Penny 2004; Wyld, et al. 2004; Lavelle et al. 2007; Bastiaannet, et al. 2010; Lavelle et al. 2012; Morgan, Wyld, Collins & Reed 2014a). Tumour characteristics i.e. large tumour or grade of tumour, co-morbidities or poor general health making the patient unfit for surgery or the patient declining surgery (Lavelle 2014) have been cited as possible explanations for reduced surgery rates. However, to date there is limited evidence to support these claims.

Lavelle and colleagues (2007a) suggest that when women present with tumours equivalent to those in younger women they do not receive equivalent treatment, (Lavelle et al. 2007a). Similarly when patients are deemed 'unfit for surgery' there is little quantifiable evidence to support this. After accounting for the effect of tumour characteristics, co-morbidity and health status, Lavelle and colleagues (2007 b) concluded that women aged 80 years and over, were less likely to have surgery. Further work examining the significance of co-morbidities in the lower surgery rates in older women concluded that co-morbidities could only account for some of the variation but that increasing age predicted lack of primary surgery (Audisio et al. 2004; Lavelle 2012). Co-morbidity was found to predict non-standard treatment in other studies (Ballard-Barbash, Patsky, Harlan, Nayfield & Kessler et al. 1996; Giordano, Hortobagyi, Kau, Theriault & Bondy. 2005; Audisio et al. 2004; Naeim et al. 2006). Despite the differences, increasing age is identified, across all studies, as a predictor of under-treatment.

## **1.7. Primary Endocrine Therapy**

Primary endocrine therapy (PET), namely tamoxifen, was introduced in the early 80s as a stand-alone treatment for early operable breast cancer in older patients. (Preece, Wood, Mackie & Cushieri 1982; Bradbeer & Kyngdon,

1983). The results were encouraging with 75% of the breast cancers either shrinking or growth being halted. The introduction of ER status testing in the 1980's enabled the identification of patients who were more likely to respond to PET (Hind & Wyld 2004; McCarty, Miller, Cox, Konrath, & McCarty 1985). The use of PET has proved to be a popular treatment choice, particularly in the UK with 42% of women over the age of 70 (Wyld et al. 2004) and 55% of women over 80 (Moneypenny 2004) treated with PET. Rates in the rest of Europe vary widely ranging from 3% in Italy to 32% in Sweden. In the USA, PET is not a common option for older women. This may be due to a more defensive medical practice and also surgical fees cannot be charged by surgeons for prescribing tamoxifen which will be a major disincentive to PET (Morgan et al. 2014a).

Under-representation of older women in breast cancer treatment trials (SIGN 2005; NICE 2009) raises debate about the extent to which the findings of studies and the subsequent guidelines can be applied to treatment of older (not defined) women with early breast cancer (Balducci, Extermann & Carreca. 2001; Ring et al. 2010). Despite this, primary surgery is recommended as standard treatment in older women (Cancer Reform Strategy Department of Health 2007, Biganzoli et al. 2012).

In support of this recommendation the findings from a systematic review comparing surgery and endocrine therapy with endocrine therapy alone in women  $\geq 70$  years, Hind and colleagues (2006) concluded that there was poorer progression free survival in those who received endocrine therapy alone. This was further supported by Morgan, Wyld and Reed (2014b).

### **1.8. Adjuvant Therapy**

A similar picture emerges when radiotherapy and chemotherapy are examined. Increasing age strongly predicts the non-receipt of radiotherapy following breast conserving surgery, even when patient preference is taken into account (Busch et al. 1996; Mandelblatt et al. 2000). There is some justification for radiotherapy omission in women who have a short predicted life expectancy and low risk tumours (ER positive, small, excised with clear margins) and the recent PRIME trial demonstrated that whilst there is a small

increase in rates of local recurrence in such cases, survival rates are the same (Kunkler, Williams, Jack, Cameron & Dixon 2015).

Despite international guidelines recommending chemotherapy should be considered for fit older women with high risk cancers and evidence showing that chemotherapy given to older women ( $\geq 70$  yrs) with primary breast cancer has the potential to reduce local recurrence by 12% and death by 13% chemotherapy is received less often by this group of women (Mandelblatt et al. 2000; Ring 2010). There is some justification for more cautious use in older women as trial data to show benefits are lacking in this age group and adverse effects, including treatment related deaths from neutropenic sepsis, are more common in women over 70 (Muss et al. 2007; Giordano et al. 2005)

### **1.9. Improving Health Care Outcomes and Increasing Patient Autonomy**

Over the past four decades there has been a gradual shift in direction from a paternalistic style of health care to one of greater patient involvement. 'No decision about me, without me' was the mantra of Andrew Lansley, a previous Secretary of State for Health, in the 2010 White paper 'Equity and Excellence: Liberating the NHS' (Department of Health 2010). This paper built on earlier papers, (Working for patients 1989, Patients Charter 1991, Choosing Health: making healthier choices easier 2004) which aimed to make shared decision-making and patient treatment and health care choice the norm. More recently cancer strategies have been developed that aim to improve prevention, earlier detection and diagnosis of cancer, promote survival rates treatment delivery, patient experience and end of life care for all cancer patients. (Achieving World Class Outcomes-a cancer strategy for England 2015-2020). In 2015 NHS England, announced the establishment of an independent taskforce to implement the NHS Five Year Forward View (2014). This strategy places the patient experience on a par with clinical outcomes such as survival. This plan also commits to the empowerment of patients by providing information about their condition and possible treatment

to enable them to make more informed decisions about the treatment choices they make.

NICE guidance (2004) highlighted the importance of the providing people with cancer, high quality, up-to-date, tailored information and support. In the Macmillan report 'Cancer in the UK 2014: State of the nation' it states that:

*"To achieve the best results and enhance experience, people affected by cancer should be listened to and engaged as full partners in a collaborative relationship of shared decision-making. Good information is a vital step on the way towards creating a culture of shared decision-making. Without support to interpret information, there is a risk that people affected by cancer will not understand the information they are given or find it overwhelming and unhelpful."*

(‘Cancer in the UK 2014: State of the nation pg 31)

Providing tailored information to support decision-making for older women requires consideration of age-related factors such as frailty, comorbidities and potentially compromised vision and hearing and cognition.

### **1.10. The Impact of Patient Choice on Non-standard Treatment**

The UK national cancer reform strategy states that 'patient choice' or 'poor health' are the only two legitimate reasons non-standard treatment should be given (Department of Health 2007). Patient choice is cited as one reason why older women may be receiving non-standard or sub-optimal treatment for breast cancer (Wyld et al. 2004; Lavelle et al. 2014). Very few studies have investigated the impact of patient choice on breast cancer treatment received by older women (Lavelle et al 2014; Sowerbutts et al. 2015) There is also little research that examines the way in which older patients with breast cancer make treatment decisions or how this can be supported.

Tang and colleagues (2011) undertook a review of 268 women with the aim of profiling the characteristics of older women (>70 years) with operable primary breast cancer and the relationship with patient treatment decision-making. The authors report that given a 'genuine choice' (defined as a 'free' choice of treatment options given to patients based on the judgement of joint assessment by the clinical team who considered age and medical fitness) over half of the women (56%) chose PET as the sole treatment in preference

to surgery. This group of women were on average seven years older and had more co-morbidities than those who chose surgery. In contrast, Lavelle and colleagues examined the impact of patient choice on rates of surgery and concluded that the lower rates of surgery among women 85 years and older could not be explained by patient choice alone (Lavelle 2014). However, the pattern of decreased surgery rates was not so significant in women 70-74 years. Women who reported themselves to be 'passive' in the treatment decision-making process, i.e. leaving the treatment decision to the HCP, were just as likely to receive surgery as those who considered themselves as 'active' in the process. Receipt of adjuvant radiotherapy was also examined by Tang and colleagues (2009). They reported offering adjuvant radiotherapy to 82% (n=55) of older women who had BCS with 68% (n=44) going on to accept it. The reason given for non-acceptance of radiotherapy was that the patients' preferred to 'watch and wait' as they were also receiving adjuvant anti-oestrogens. A breakdown by age, related to those who were offered or received radiotherapy, was not given. In contrast to the Tang study, Lavelle and colleagues reported that 95% of women age 80 years and older, in their study, did not receive radiotherapy and noted that as age increased the odds of receiving radiotherapy decreased (Lavelle 2014).

Chemotherapy in the treatment of older women with operable breast cancer is under-utilised (Ring 2010). Again it follows a pattern of increasing age and decreased use. Studies examining the reasons for low usage report that clinicians base recommendations on the basis of age and not on medical assessment of fitness (Protiere, Viens, Rousseau & Moatti 2010; Ring 2010). Clinicians are also more likely to cite co-morbidities and frailty as reasons not to offer chemotherapy however there is only recorded evidence to justify omission of treatment in two-thirds of cases (All Party Parliamentary Group Breast Cancer Report 2013). The impact of patient choice on chemotherapy rates in older women with breast cancer is a poorly researched area and one which Ring and colleagues highlight as requiring attention (Ring et al. 2010).

### **1.11. Factors Affecting Patient Treatment Decision-Making**

Age, race, culture, media, prior experience of cancer and its treatment, body image, HCP interactions, HCP preferences, information received and level of



education have all been cited as influencing decision-making in breast cancer (Hawley et al. 2007; Bleicher, Abrahamse, Hawley, Katz & Morrow. 2008; Singh et al. 2010; Hamaker et al. 2013, Morgan et al. 2014b).

The influence of age on breast cancer decision-making is unclear with some reports of older women preferring a passive role within the clinical consultation (Davison, Degner, & Morgan, 1995; Degner 1997; Wallberg et al. 2000; Jenkins, Fallowfield, & Saul 2001; Lobb, Kenny, Butow & Tattersall 2001; Levinson, Kao, Kuby & Thisted 2005; Ciambone 2006; Bleicher et al. 2007; O'Leary et al. 2007; Husain 2008) whilst others have reported a preference for an active role (Cassileth, Zupkis, Sutton-Smith & March et al. 1980; Guadagnoli & Ward 1998; Kenny, Robertson, Ellis, Elston & Blarney. 1998; Crooks 2001; Bruera, Willey, Lynn Palmer & Rosales. 2002; Schou, Ekeberg, Ruland & Karesen 2002; Janz, et al. 2004; Caldon, Walters, & Reed, 2008; Collins et al. 2009) still others reporting age is unrelated to role preference (Hack, Degner & Dyck 1994; Bleicher et al. 2008).

The influence of race, culture and ethnicity on decision-making is also unclear. There is evidence to show non-white women feel they were less involved in decision-making and experienced more decision regret than white women (Degner et al. 1997; Keating et al. 2003 Lantz et al. 2005; Katz et al. 2005; Janz et al. 2008). Polacek, Ramos & Ferrer (2007) suggest the evidence is unclear because researchers are not engaging the most affected people.

Across a number of patient populations a higher level of education is associated with patient preference for involvement in decision-making (Degner, Sloan & Venkatesh 1997; Giordana et al. 2008, O'Donnell & Hunnskaar 2007). A pooled analysis by Singh and colleagues (2010) demonstrated that when education level was corrected, race and age were not factors in preference for involvement in decision-making.

There is evidence to suggest that doctors influence the treatment decision-making in breast cancer (Katz, Lanz & Zemencuk, 2001; Morrow et al. 2001; Molenaar et al. 2004; Gort, Broekhuis, Otter & Klazinga. 2007; Morrow et al. 2009). Influence can be exerted in a very overt way by making the decision

for the patient without patient input to more subtle means, such as, the control of information, rushing clinical discussions and deliberately steering conversation to achieve the HCPs preference (Canter 2001). Despite many patients reporting they made their own treatment decision it is possible this is simply a product of the HCPs managing the treatment discussion and their decision simply reflects the HCPs preference (Hamaker 2013).

In an article by O'Brien and colleagues (2011) of younger women (mean age 50-62 across the study phases) verbal and non-verbal facilitators and barriers to women's involvement in treatment decision-making were identified both from the perspective of the patient and the HCP. Patients' identified the need for the HCP to explain why they were being invited to participate in the decision-making process, explain the risk of cancer recurrence, enhance the patients' understanding of the information provided, give an explanation of the treatment options, allow time for treatment decision-making, give a recommendation or guidance about options and make the women feel at ease to facilitate their involvement. Most, but not all, of these items were also identified by the HCPs, the exceptions being, the need to make the patient feel comfortable and giving a rationale for the treatment options. Perceived barriers to women's' involvement were lack of interest by the HCP in the women's concerns and not being 'invited' to participate (O'Brien et al 2013).

The significance of the HCP in the decision-making process was explored in this study and is reported in chapter 7. An opportunity arose which allowed an examination of the differing perspectives on decision-making of both the patient and a number of HCPs including, 20 breast surgeons, 13 breast care nurses and 1 geriatrician based within the breast clinics engaged in this study.

Evidence has consistently demonstrated that patient involvement in treatment decision-making leads to improved satisfaction with treatment and psychological outcomes and reduced 'decisional regret' following treatment for breast cancer (Bottomley & Jones 1997; Steginga, Occhipinti, Wilson & Dunn 1998; Reaby 1998; Mandelblatt et al. 2003; Andersen, Bowen, Morea, Stein & Baker 2009 ). Involvement in decision-making is frequently described

in relation to patient preference for the style of decision-making within a clinical consultation. Three preferences for patient decision-making have been identified; active, collaborative or passive decision-making. 'Active' decision-makers are those who prefer to make their own health care decisions; 'collaborative' are those who wish to share the decision-making; and 'passive' refers to those who defer decision-making to others, frequently the HCP (Strull 1984; Degner & Sloan 1992, Ekdahl, Andersson & Friedrichsen 2010). Early studies examining the preference of patient involvement in treatment decision-making, not specifically breast cancer, generally concluded that older patients prefer a passive role (Bilodeau & Degner 1996; Silliman, Dukes, Sullivan & Kaplan 1998; Jenkins; Fallowfield & Saul 2001; Cox, Jenkins, Catt, Langridge & Fallowfield. 2006; O'Leary, Estabrooks, Olson & Cumming 2007; Hawkins, Kreuter, Resnicow, Fishbein & Dijkstra 2008). However, this view is not universal with some older breast cancer patients preferring a collaborative or active role in treatment decision-making (Caldon, Walters & Reed 2008; Biganzoli et al. 2012). It is difficult to be confident about the relevance of much of this research as the studies have only a small number of patients age 75 years and older and frequently the sample includes a small proportion with breast cancer.

Hack and colleagues (2006) undertook a study to examine the relationship between the preferred and the assumed decisional role and the impact on quality of life, three years post treatment. Whilst those in their study who played an active role in decision-making had improved quality of life and improved physical and social functioning they acknowledged work by Gattellari and colleagues (2001) who found role congruence i.e. the role desired and the role assumed, to be important in reducing anxiety in oncology patients. Although evidence suggests patients' benefit from an active role in treatment decision-making there is also evidence that some patients do not wish to participate in decision-making and find the offer of a choice stressful (Fallowfield, Hall, Maguire, Baum, A'Hern 1994). Fallowfield (1997) suggests that patients should have the right to decline the offer of participation in treatment decision-making and that the desire for clear and accurate information may be more important than autonomy.

## Summary

None of the studies identified in this overview were empirical studies that focused on decision-making in women over the age of 75. In these studies the mean age of the women, where reported, is late 50s - early 60s with one describing 'older' as those over age 50. Extrapolating the findings from these studies may not be appropriate and therefore the influence of patient age, culture, race and education remains unclear and justifies the programme of research undertaken for this PhD.

### 1.12. Treatment decision-making in older women with breast cancer

Previous studies that have focused on the choice women make between different breast cancer treatments, predominantly between mastectomy or breast conserving surgery (Degner et al. 1997; Mastaglia & Kristjanson, 2001; Collins et al. 2009; Sivell et al. 2011; Caldon et al. 2011).

Women  $\geq 75$  years with primary operable breast cancer may face an additional choice; being required to decide between surgery and endocrine therapy or PET alone without surgery. ***Seventy-five is considered by HCPs to be the age at which it becomes clinically acceptable to introduce PET as an alternative treatment option (Mustacchi, Latteier, Bates & Houghton 1998).*** This is a complex issue as it requires the patient to consider available clinical information and balance this with their own preferences and values.

For patients who wish to avoid surgery and the consequent, distress and disruption to their lives, and with evidence of efficacy in up to 80% of oestrogen receptor cancers, PET has much to recommend it. In addition, the very frail elderly may have a pragmatic sense of their own impending mortality and not want any complex treatments but just be allowed to retain their dignity and independence for as long as possible.

Being given a choice of treatment may be unfamiliar to older patients. The notion of considering preferences and values in treatment decision-making may be a difficult concept to grasp for a generation who have grown up with

a paternalistic view of the health care system. Traditionally, older women with breast cancer may have relied on HCPs to decide the most appropriate breast cancer treatment option (Husain et al. 2008).

### **1.13. Information - a prerequisite for decision-making**

Making treatment decisions against a backdrop of limited and uncertain evidence and information presents a significant challenge for both the patient and the HCP. Breast surgery provides more certainty of local cancer control, but is associated with potential adverse effects: pain, temporary hospitalisation, anaesthetic risks and variable degrees of disfigurement to name but a few. In addition surgery may result in a temporary loss of independence and the need for social support, which may or may not be readily available. Evidence from a Cochrane review indicates that PET is associated with inferior rates of local disease control, although overall survival rates may be equivalent in the short term (Morgan et al. 2014a) although in the longer term there is evidence that they may be inferior (Morgan et al. 2014a). In terms of local control PET has a limited median period of efficacy, estimated to be between 2-3 years (Horobin et al. 1991, Wyld et al 2004, Morgan et al. 2014a) with a more recent study suggesting the survival curve begins to diverge after three years (Fennessy et al. 2004). Should PET cease to be effective second line treatment may be necessary. This could be an alternative endocrine therapy or surgery at a point when the patient may be less likely to withstand it (Kenny 1998). Research is underway to develop means of predicting life expectancy using a mix of co-morbidity, functional and cognitive status and anaesthetic assessment (Wyld & Reed 2007; Stotter, Reed, Gray, Moore & Robinson 2015).

Patients' treatment preferences vary with many factors such as prior experience and knowledge of breast cancer, fear of cancer recurrence, personal responsibilities, practical issues surrounding treatment e.g. the need for radiotherapy and pre-existing values all influencing treatment decision-making (Fallowfield, Baum & Maguire 1986; Hughes 1993; Beisecker, Helmig, Graham & Moore 1994; Smitt & Heltzel 1997; Liang et al. 2002; Collins et al. 2009).

### **1.14. The Gap in Knowledge**

Since much of the research into early breast cancer focuses on younger women, little is currently known about the information needs of older women with operable breast cancer or their preferences for involvement in the treatment decision-making process.

Providing 'comprehensive, trustworthy and easy to understand information from a range of sources on ...treatments' (Department of Health 2010) is a complex task. Producing the desired information in a style that is meaningful, taking account of the possibility of failing, age-related cognitive ability is an area which has yet to be examined in older women faced with a choice between PET and surgery in the treatment of primary operable breast cancer. This article based PhD study will provide a clinical, methodological and theoretical contribution to the current evidence base.

### **1.15. Research aims, objectives and research questions**

This PhD study aimed:

To establish the information needs and decision-making preferences of older women with primary, operable, oestrogen receptor positive breast cancer (here after referred to as primary, operable breast cancer) when faced with a choice of surgery or primary endocrine therapy (PET).

#### **Objectives**

To establish the evidence relating to information and decision-making preferences in older women ( $\geq 75$  years) with primary operable breast cancer with a specific focus on the use surgery or PET.

To elicit the views of older women towards preference for information and its source and presentation when facing a choice between surgery and PET.

To elicit the views of older women towards decision-making styles when faced with a choice of surgery or PET.

To determine the influence of the health care professional in treatment decision-making in older women with operable breast cancer.

It addressed the following research questions:

1. "What are the preferences for information, its sources, format and presentation for older women faced with a treatment choice for operable breast cancer?"
2. "What are the preferred decision-making styles in older women faced with a treatment choice for operable breast cancer?"

### **The Researcher**

The researcher who undertook this PhD worked as a physiotherapist for 17 years before taking up an academic career as a lecturer and researcher. The research path has been one largely of work involving older people and away from physiotherapy. Following on from a series of full time research projects involving older people the researcher was given the opportunity to work on an NIHR programme "Bridging the Age Gap in Breast Cancer (BTAG)". The researcher role within the BTAG programme was primarily focused on the development of a patient decision support intervention. This involved the introduction and development of the mixed method study design and subsequently responsibility for gaining ethical approvals and research and development governance for all the study sites involved in this phase of the BTAG study. The researcher was responsible for undertaking the literature review, participant recruitment, development of the interview topic guide, data collection and analysis.

The following chapter is the first article, published in *Current Breast Cancer Reports* that forms part of this Article-based PhD. It reports a critical review of the literature undertaken to establish current knowledge surrounding information needs and decision-making preferences of older women with breast cancer.

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## Chapter 2: Article 1

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## **2. Chapter 2: Article 1**

"Information Needs of Older Women Faced with a Choice of Primary Endocrine Therapy or Surgery for Early-Stage Breast Cancer: A Literature Review"

### **The aims of this article:**

- To establish the evidence relating to information and decision-making preferences in older women ( $\geq 75$  years) with primary operable breast cancer with a specific focus on the use surgery or PET.
- To establish older women towards preference for information and its source and presentation when facing a choice between surgery and PET.

This article is an integral component of this article based PhD as it demonstrates the gap in current knowledge regarding the information needs and preferences of older women diagnosed with breast cancer and offered a choice between surgery or PET

I am the first author on this paper as I conducted the literature search, performed the review and wrote the article. My co-authors supported by acting as second reviewers in the review process and provided input on the structure and writing of this paper.

## Information Needs of Older Women Faced with a Choice of Primary Endocrine Therapy or Surgery for Early-Stage Breast Cancer: A Literature Review

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**Abstract** Primary endocrine therapy (PET) as an alternative to surgery is widely used in the UK for the treatment of older women with operable breast cancer. For women over 70 it has equivalent overall survival to surgery, although local control rates may be inferior. There are trade-offs to be made in deciding between surgery and PET. There has been little research to investigate the information needs of older women or the involvement in decision making they wish to have when faced with this breast-cancer treatment decision. This review examines the information needs of older women (>65 years) regarding the use of surgery or PET for treating operable primary breast cancer, and identifies their preferred format and media for the presentation of this information. The preference for involvement in treatment decision-making among this group will also be considered.

**Keywords** Breast cancer · Older women · Primary endocrine therapy · Breast surgery · Information needs · Decision making preferences · Benefits · Risks · Media · Presentation · Format

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### Introduction

Breast cancer affects 13,000 UK women over age 70 annually, and causes the deaths of 6733 per year [1]. Among patients over 70 years of age there has been less than half the reduction in cancer mortality achieved for younger women [2]. This is partly caused by variance in treatment, resulting from concerns about reduced treatment tolerance secondary to frailty and comorbidity. As a result older women may not receive chemotherapy, trastuzumab, radiotherapy, or surgery, instead being offered primary endocrine therapy (PET), which is treatment with antioestrogen tablets alone and omitting surgery altogether. PET may be an appropriate alternative to surgery for frail women and has equivalent overall survival to surgery (plus adjuvant endocrine therapy), although local disease control is inferior [3].

The choice of surgery or PET is complex. Both options are associated with advantages and disadvantages, which may vary according to health status. Surgery provides greater certainty of local cancer control but is associated with pain, temporary hospitalisation, anaesthetic risks, and a variable degree of disfigurement depending on the type of surgery. PET may be associated with a higher risk of late local disease progression, but enables avoidance of anaesthesia and surgery (which may be mastectomy or wide local excision and axillary surgery). Some older women prefer less aggressive treatments which may enable them to maintain independence and minimise potential adverse events [4, 5]. In effect, by choosing PET an older woman is trading off the risk that she may die of non-breast-cancer-related illness before her cancer becomes resistant to the anti-oestrogen treatment: this is a very difficult concept to discuss from the perspective of both the physician and the patient herself, although many older women have a very pragmatic acceptance of the inevitability of illness and death [6]. Only preliminary information on older women's

views towards PET or surgery exists, and this subject therefore requires further investigation [6].

At present, little is known about the information needs of older women diagnosed with breast cancer and their personal preferences for engagement in cancer-treatment decision making. Such information, and the production of evidence-based guidance, is needed to optimise the treatment of older women.

The purpose of this review is:

1. to investigate the information needs of older women (>65 years) regarding the use of surgery or primary endocrine therapy (PET) for the treatment of operable primary breast cancer;
2. to identify the preferred format and media for the presentation of this information;
3. to establish the preference of older women (>65 years) for involvement in treatment decision making regarding the use of surgery or PET for the treatment of operable primary breast cancer.

## Methods

### Search Strategy

A comprehensive search of the published literature was undertaken during July 2013, using the following electronic databases:

- MEDLINE
- PsycINFO
- CINAHL
- Scopus
- Web of Science
- The Cochrane Library

Three searches were performed, using the search terms below. Controlled vocabulary terms were used where available.

1. “older women” + “breast cancer” + “PET” “Surgery” “information needs”
2. “older women” + “cancer” + “information needs” review articles.
3. “older people” + “cancer” + “information needs”

Limits placed on the search were:

- Date: 1980–present day, (PET was introduced during the early 1980s).
- Participants: Humans, Females.
- Language: English.

### Inclusion Criteria

Articles were deemed to meet the inclusion criteria if:

1. They included patients with a diagnosis of breast cancer;
2. They included women over 65 years (65 is a definition of older in the UK and USA);
3. They included patients treated with surgery, primary endocrine therapy (PET), chemotherapy, and/or radiotherapy; and
4. The focus was on information needs and/or preferred media and format of information and/or preference for decision making.

### Exclusion Criteria

Articles were excluded from the review if:

1. None of the participants in the mixed cancer studies were over 65 years of age;
2. They only assessed clinical effectiveness or outcome of PET or surgery;
3. They were not in the English language.

### Results of the Search

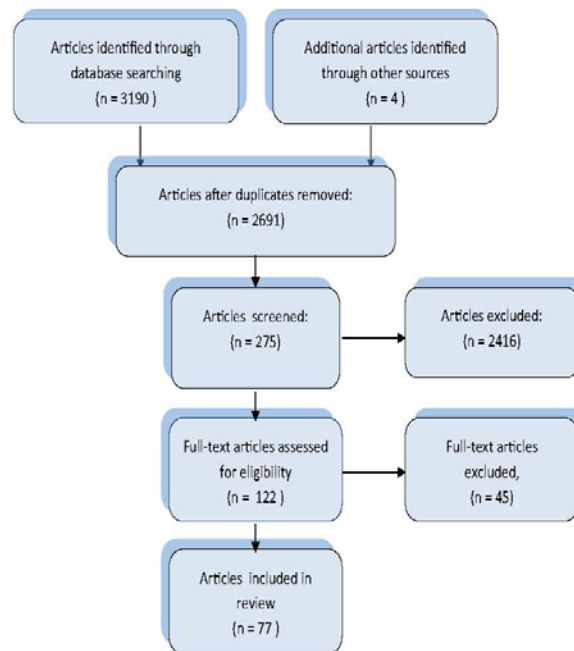
On completion of the searches, titles of papers and (where available) abstracts were scrutinised for possible inclusion in the review by one researcher (MB), and these inclusions were checked for accuracy by the second researcher (KC). Uncertainties were resolved through discussion. A total of 9767 papers were identified from the three searches.

To reduce the number of results generated from the searches, a decision was taken by the study team to focus exclusively on studies where the study sample was exclusively “breast cancer” or where the study sample was a mixed cohort but included patients with “breast cancer”.

This left 3190 papers. After removal of ineligible and duplicate abstracts, 275 titles from searches 1 and 2 were deemed potentially eligible and the abstracts were retrieved. From the abstracts 122 papers were potentially eligible and so the full article was reviewed.

Studies that focused solely on psychosocial needs, quality of life after treatment, decision-making styles, clinical outcome of surgery, or the function of health-care professionals (HCPs) in decision making were excluded. This resulted in 77 papers fulfilling the inclusion criteria and being included within the review. See Fig. 1.

Two of these papers were systematic reviews of older cancer patients, one focusing on unmet support needs of newly diagnosed patients and one focused on information needs regarding cancer, the treatment available, and the

**Fig. 1** Flow chart of review process

preference for involvement in decision making. Thirty-eight papers were breast-cancer studies of mixed-age cohorts which included a proportion of women 65 and older. A further 17 papers were cancer studies (including breast cancer) of mixed-age cohorts including a proportion of those 65 and older. Only six papers included only those aged 65 and older. Two papers focused predominantly on treatment decision making for breast cancer, and two on the information needs and two on the experiences of women with breast cancer. Only one of these papers investigated patient views on their experience of PET or surgery. Of the six papers identified, only one was UK-based. The remaining five were from Canada and the USA. See Table 1 for summary of these papers.

## Literature Review

### Information Needs of Older Women

The results below are based on all 77 reviewed articles. All papers reviewed investigated, either in whole or in part, the information needs of older patients with breast cancer. See Table 2 for a summary of identified information needs.

### Clinical and Treatment Information

At diagnosis, receiving information about the chance of a cure and the spread of the disease were the most commonly

reported concerns of most patients [7–11, 12\*, 13], regardless of age. The need for medical information about the disease, the nature of breast cancer, the symptoms, the diagnostic tests, the treatment options, and prognosis were also reported to be important for older women (>70 years) with breast cancer [14, 15\*, 16].

Within the identified papers, older women had a greater desire than younger women to receive information on the effect of treatment on their functional independence, self-care, quality of life [6, 8, 17, 18], and social life [19, 20]. The effect of treatment on physical appearance or surgical disfigurement and sexual attractiveness were reported by some studies to be more important to younger women [8, 12\*, 20], although other studies did not support this view [21, 22].

Information on the practical aspects of treatment was also important to older cancer patients [15\*, 23–25]. Difficulties of driving or transport, particularly in winter, ease and cost of parking [9, 15\*], dates and times of surgery, or the timing of test results [29] were more of a concern to older patients than the treatment itself [9, 15\*]. For some older patients, such factors influenced their final treatment decision [18].

### Treatment Decision Making for Older Patients

Providing treatment choice to patients presents a considerable decision-making challenge. For the older person diagnosed with cancer, it requires that they consider their own health, functional and social status, and values about quality or

**Table 1** Factors affecting the decision making of older women with breast cancer

Author Country of study	Objectives of study	Study methods, sample and age range	Key findings
Ciamborne D. (2006). USA	To identify factors associated with older women's breast-cancer primary-therapy decision-making processes. To ascertain how women's primary support persons influence decision-making processes and women's choices	30 in-depth interviews. Age range 67–90 years	<ul style="list-style-type: none"> <li>• Women trust doctor to make the right decision</li> <li>• Some want involvement in decision-making but rely on doctor to make final decision</li> <li>• Want a more active role in decision-making</li> <li>• Do not want "too many opinions" of treatment</li> <li>• Certain about the treatment they do not want, e.g. chemotherapy</li> <li>• Do not want treatment that seems debilitating</li> <li>• Age is seen, by the patient, as a reason not to have adjuvant therapy</li> </ul>
Crooks D L (2001) Canada	To investigate the assumptions made in oncology: older women just accept cancer, cannot or prefer not to make treatment decisions, are better off with extensive surgery, and breast or tissue less is unimportant	20 in-depth interviews. Age range 66–94 years	<ul style="list-style-type: none"> <li>• Women feel supported by others in same situation</li> <li>• Prefer verbal, individualised information in non-medical language from doctor</li> <li>• Women given choices are able to choose. 2/20 felt the surgeon knew the best option</li> <li>• Choices about radiation deferred to surgeon</li> <li>• Most who refused chemotherapy had "horrible" vivid memories</li> <li>• Confusion between chemotherapy and tamoxifen</li> <li>• Women received but rejected written information that may have helped them make a decision</li> </ul>
Husain et al. (2007) UK	To investigate the views of women treated by either surgery or PET	21 semi-structured interviews. Age range 70–88 years. Median age 78 years. <15 years from diagnosis	<ul style="list-style-type: none"> <li>• Women relied heavily on medics for direction on treatment choice</li> <li>• Personal experience affected attitudes to surgery</li> <li>• No one expressed problems with PET</li> <li>• Age was said not to affect treatment choice</li> </ul>
Jing-Wen Wong et al. (2011) Canada	To investigate the information needs of women aged >70 years with early-stage breast cancer in relation to adjuvant radiotherapy post lumpectomy	One focus group and 1 interview. 15 women, age range 70–84 years. Median age 76 years Patients post-completion of radiotherapy	<ul style="list-style-type: none"> <li>• Need straightforward information on diagnosis, prognosis, grade of cancer, metastases, treatment options, and rationale for treatment</li> <li>• Need open space to allow for questions</li> <li>• Few used the internet to obtain knowledge. When used, problems with volume of material and credibility of sources</li> <li>• Practicalities, e.g. driving to treatment, created more anxiety than the radiotherapy</li> <li>• Preference for information is variable. Booklet provides information and prompts questions</li> <li>• Promoters of chemotherapy uptake: enough time to discuss side effects, benefits, and</li> </ul>
Kreling et al. (2006) USA	To understand the factors involved in older women's use or non-use of	Six focus groups. 34 women ≥65 years who were eligible for chemotherapy for early-stage breast cancer.	



**Table 1** (continued)

Author Country of study	Objectives of study	Study methods, sample and age range	Key findings
Schonberg M A et al. (2012) USA	indicated adjuvant non-hormonal chemotherapy  To identify factors that influence the breast-cancer treatment decisions of women aged 80 and older	50/50 split between those who had chemotherapy and those who did not.  Medical note review. 65 women aged 80 and older. Age range 80–86 years. Median age 84 years	<ul style="list-style-type: none"> <li>practicalities with doctor and family; family to give emotional and decision-making support</li> <li>Barriers to chemotherapy uptake: use of medical language; hurried appointments; too much general information not specific enough for individual expected</li> <li>Chemotherapy often thought to be not as bad as expected</li> <li>Factors which influence women included: family involvement, side effects, religious belief, previous experience of cancer treatment efficacy, physician's opinion</li> <li>10/65 women initially did not want aggressive treatment but agreed to it after discussion with physician</li> <li>2/65 women wanted as aggressive a treatment as possible from the outset</li> </ul>

quantity of life [27]. Extrinsic factors including the information received and the opinions of health-care professionals and family and friends all contribute to the decision-making process. There is evidence that patient involvement in treatment decision making usually increases treatment satisfaction and reduces anxiety and depression [28–31]. Three main patient decision-making styles have been described: active, those who wish to make their own healthcare decisions; collaborative, those who wish to share decision making; and passive, those who defer decision making to others [32]. Breast-cancer patients generally (not specifically older women) increasingly prefer more active and collaborative roles in treatment decision making [32, 33], although some prefer to defer decisions to others [28, 29, 34, 35]. A recent UK study reported the preferred decision making styles of women with breast cancer

**Table 2** Summary of findings

<b>Information desired on disease and treatment</b>
Chances of cure, spread, or recurrence of disease, and prognosis
Understanding the diagnosis and the rationale for treatment
Recommended treatment plan
Effectiveness and side effects of treatment options
How to avoid and relieve side effects
Effect of treatment on self-care, independence, and social life
Effect of treatment on emotional wellbeing and psychosocial aspects
Practical information, e.g. transport, important in deciding on treatment
<b>The level and amount of information</b>
Preference for amount of information highly variable
Information provision to be tailored to the individual's situation and preferences
Limited need for large volumes of general information
Personal stories of others in similar circumstances are appreciated by some
<b>Receiving information</b>
Simple booklets, jargon-free language, and simple diagrams are preferred
Preference of words to numbers to describe or quantify risk
Verbal information preferred, preferably from the treating clinician
Time given during consultation to ask questions
Information provision needs to change over the treatment pathway
<b>Sources of information</b>
Health-care professionals believed best source of information
Written information poorly used
Family and friends a further source of information for some
The internet used by a minority to find health information
<b>Decision making</b>
Patients may want to play an active part in the decision-making process
With increasing age there is a trend towards relying on the surgeon for the decision
Not all older breast-cancer patients want a passive role
Patient preference for decision making should be investigated
Older breast-cancer patients frequently make decisions on the basis of limited, inaccurate knowledge

by mean age. Those who preferred an active role were on average 57.4 years, those preferring a collaborative role were on average 58.4 years, and those preferring a passive role were on average 61.1 years; less than 20 % of women preferred to defer their treatment decision to others. However, the average age of participants in this study was much younger than 70 (mean age 58.5, with only 10.7 % over 70 years) and the results may therefore be irrelevant to this older age group [32].

There is limited evidence on which to assess the preferences for treatment decision making of older women with breast cancer; however, the evidence suggests that older patients are more passive in their decision making than their younger counterparts [6, 13, 32, 36, 37]. Breast-cancer patients, regardless of age, frequently consult family and friends, who provide anecdotal and possibly erroneous information [38], and tend to delegate responsibility for decisions to their doctors, family, and friends [5, 38–40]. Personal experience of others' cancer is also a factor which affects knowledge of cancer treatments [6]. There is unclear evidence on the use of other media, including newspaper and television, in information seeking and decision making. Mills and Davidson [41] found that television and radio are infrequently used by those over 65 years, but Hughes [42] reported that lay media may be one of the top three sources for information. Talosig-Garcia and Davis [43] found newspapers and magazines to be a very helpful source of information for women.

An American study of 1131 patients with breast cancer, of whom 249 were over 70, revealed a high level of involvement in treatment decision making (52 %), with approximately half the women stating that they had the right amount of involvement [44]. However, over 40 % felt they had too much involvement and a small percentage felt they had too little involvement (7.6 %). Overall the researchers concluded that involvement did not vary with age but there was a trend for less involvement with increasing age. This conclusion was supported by Han et al. [45].

A study of healthy individuals concluded that most women prefer clinical decisions to be taken by their doctor, and that past the age of 45 the desire for participation in treatment decision making decreased [46].

Patients may want to be fully informed and participate in the decision-making process by making their preferences, values, opinions, and fears known regardless of age [18, 22, 23, 47, 48]. However, there is a trend for older patients to prefer the surgeon to make the final treatment decision [11, 20, 22, 45, 49], and this seems to be related to the severity of their illness [50]. Where best practice is known, surgeons are confident in recommending a particular intervention; however, where best practice is unclear surgeons more frequently invite the patient to choose [26].

#### Factors Affecting Treatment Choice

Only one study [6] was identified that examined the factors affecting the treatment decisions of older women faced with a choice of surgery or PET for the treatment of breast cancer. In this study 21 purposively selected breast-cancer patients, who had been treated with either PET or surgery, took part in in-depth qualitative interviews. This study found that the women relied heavily on health-care providers for information; however, this information was not used to make the treatment decision. Women were reported to be listening for cues from the medical team to detect what was being recommended. In line with other studies, the women did not actively question the information given to them by the doctor. A small number of women actively chose treatment contrary to the advice of the medical team, and their decision was on the basis of family experience of breast cancer. Avoidance of surgery was not a factor for women choosing PET; however, previous painful biopsies were a consideration.

#### Amount and Level of Information

Patients with cancer have high information needs and the same is true for breast cancer, irrespective of patient age [51–53, Caldon L, PhD thesis 2011 "Patient and Clinician factors influencing the choice of breast cancer surgery: a qualitative and quantitative study", unpublished data]. Information is a pre-requisite for informed decision making [34, 51, 54]. The type, amount, and level of information preferred differs across the treatment pathway and between individuals [16], and the amount of information collected does not always correlate with the desire to make decisions [4, 17, 49, 55] or with the patient's preferred decision-making style [7, 22, 34, 55]. The amount of information older patients require to make a treatment decision is variable [56]. Some older patients find the type and amount of medical information they receive overwhelming [23], and they have fewer information needs [19]. Others want as much information as possible to help them better understand their treatment options and the rationale for treatment [15, 26]. Other studies report older patients having a lower need for information [11, 12, 14], with a meta-analysis revealing a trend towards younger patients preferring a more active decision-making role and having a greater need for information [57]. In contrast, Cox et al. [22] found little or no difference in the need for information between younger and older patients. Several authors have concluded that information about breast-cancer treatment options needs to be age specific, relevant, and tailored to the patient [15, 23, 47, 58].

Older women rely primarily on the information given by their clinician or breast-care nurse, and subsequently on information given by their family, to make decisions about their treatment [6, 48, 59, 60]. Older women are also less likely than their younger counterparts to question their clinician to gain



further information regarding different treatment options [5]. However, given adequate time during the consultation older patients do seem to seek more detailed information about their condition [59–61]. Older women require information that is simple, balanced, and in sufficient detail to enable them to reach an informed decision independently [15•]. Specific information regarding age-specific incidence, risk factors for breast cancer in older age, signs and symptoms of breast cancer, breast-cancer treatment options, and age-specific prognostic information was most highly regarded [15•].

#### Pacing of Information

Older cancer patients prefer paced information which is repeated to allow time for assimilation [22], with information provided throughout the treatment pathway as information needs change [14]. Patients' recall is impaired in life-threatening situations [42, 62], and information absorption is hindered when individuals are provided with information they find difficult or unpleasant [62] or when they are overwhelmed by the provision of excessive information in a single consultation [64]. Patients' recall is better for information provided at the start of a consultation [64]. Despite barriers, for example to the patient's ability to absorb and recall information when confronted by a diagnosis of cancer, the information that is recalled can persist and gain importance over time, with older patients quoting their clinicians verbatim [63]. Fallowfield et al. [64] proposed that "...information needs to be given systematically, at the right time and via several different routes, to maximise the chances for patients to understand the implications and make really informed choices" [65].

#### Preferences for Format and Media of Information

Older patients prefer information to be given to them verbally by their treating clinician [51, 53, 65]. However, study findings consistently suggest that clinicians often underestimate patients' information needs [8, 66–69]. A recent study of the use of information technology found that only 15 % of the UK population of older people (i.e. those aged 60 and older) had access to a computer. Use of the internet remains low, with only 14 % of adults over 70 years using it for seeking health information [70]. Couper et al. [71] reported that older people (aged over 70) tended to use their computer for word processing and not as a source of information for such complex subjects as breast cancer. Those who did use the internet either rated the information highly but only as a supplement to that provided by the health-care provider, or reported that they struggled with the volume of information and knowing how to assess its credibility [15•]. In summary, the internet has been revealed to be rarely used by the older population to access breast-cancer treatment information [43].

Presenting complex material to older patients who possibly have declining cognitive function is a substantial challenge. Although there is a correlation between comprehension and literacy across all age groups, when compared with a younger age group older adults have poorer numeracy and comprehension of written information [12•, 47, 70, 72–74]. Other factors, including poor hearing and eyesight, may also affect the ability of older patients to make an informed treatment decision [74, 75].

When people have little or no understanding of the choices being presented, it is difficult for them to have any real understanding of the consequences of a choice and what effect it would have on their lives. The use of narratives or stories has been revealed to enhance the ability to assess attributes and weigh them in decision making. Where tables and graphs were used, older breast-cancer patients needed an explanation of the data in order for it to have meaning to them [74] and for them to make a better judgement regarding a treatment choice [73, 76, 77]. The provision of personal cancer stories within the information was also regarded as useful in helping them understand and cope with the disease and its treatment [15•, 21]. The combined use of anecdotes and pictograms was reported to enhance understanding and decision making among women aged under 79 years diagnosed with breast cancer [78].

Simple booklets [50] with short explanations of risks and benefits of treatment, free of medical language and with clear diagrams [15•, 21], were requested by older women undergoing adjuvant therapy. It was found that older women did not respond well to complex information and that the heterogeneity of the population would necessitate many different formats.

Tailoring or customising information also reduces cognitive load. Stories or narratives based on the experiences of people like themselves emphasise the meaning a choice would have on women's lives. This is particularly effective when the story triggers a memory [79]. Tailored health materials are reported to be more effective than general material at enhancing behavioural change [76].

Evidence suggests that presenting risks and benefits to experts and the general public as frequencies rather than probabilities is more meaningful and carries more weight in decision making [76]. This is contrary to the findings of Fausset and Rogers [74], who report that older people (mean age 71, range 65–75) performed better using percentage values than frequencies. In the Hughes study [42] of a younger population (mean age 41, range 21–80) choice of treatment was unrelated to the way the information was presented. There was no difference in choice of mastectomy or breast-conserving surgery whether description or probabilities were used to present risk.

The framing of information provision also affects the meaning older patients attribute to it. A review by Edwards



et al. [80] examining the effect of framing of risk information concluded that the evidence of the effect of framing was weak. There was some indication of framing increasing the uptake of detection behaviours, e.g. screening. There was also limited evidence to suggest patients choose what might be perceived as risky treatments when information is positively framed. Although this review examined clinical studies the results were not stratified by patient age.

Graham, Martin and Browne [81] studied 262 women (no age range given) with breast cancer to identify their preference for language, percentages, or numbers in describing the risk of treatment. Fifty-two percent preferred language and 48 % numerical expression (21 % numbers and 27 % percentages) to describe risk. Those who were younger, i.e. below the mean age of 62, and were more highly educated preferred numerical representation. Strategies suggested included diagrams and risk–benefit tables to aid conceptualisation. Problems around credibility of information given and how to filter the volume of information available were raised. Edwards et al. [80] found no evidence of effect in the way data were presented.

## Conclusions

There is a dearth of evidence on the information needs of older women when faced with a choice of PET or surgery for early-stage breast-cancer treatment. Similarly, there is little information on the preferred format, presentation, or media, nor on the preferred involvement in treatment decision making of older women with breast cancer.

There is some agreement about the required type of information relating to breast cancer and its treatment, and on how this needs to be delivered across the treatment pathway. Information on the effect of the treatment on self-care, physical function, and quality of life seems to be universally desired by older women.

There is limited evidence on which to assess the preference for treatment decision making of older women with breast cancer; however, the evidence suggests that older patients are more passive in their decision making than their younger counterparts [6, 32, 36, 37].

One of the objectives of providing information is to enable women to make informed decisions about their breast-cancer treatment. Patients may want to be fully informed and to participate in the decision-making process by making their preferences, values, opinions, and fears known [18, 22, 23, 47]. However, there is a trend for older patients to prefer the surgeon to make the final treatment decision [11, 20, 22, 45, 49].

The main source of information is the health-care provider: either the clinician or breast-care nurses. There is a preference for personalised information received verbally. The internet is

not widely used by older patients. Written information is the usual format preferred. Simple booklets using clear, jargon-free language are preferred, with the addition of uncomplicated diagrams and stories of women in a similar situation. In describing risk and benefit, there is some evidence that words are preferred to numbers.

The evidence presented is on the basis of limited literature and so cannot be relied upon to give an accurate or complete picture. High-quality research is required to establish the information needs of older women, specifically those over 70 years, their preferences regarding format and media, and their preferred level of treatment decision making when faced with a choice of treatment for early-stage breast cancer.

## Compliance with Ethics Guidelines

**Conflict of Interest** Maria Burton, Karen Collins, Lynda Wyld, and Malcolm Reed declare that they have no conflict of interest. Lisa JM Caldon reports grants from NIHR, during the conduct of the study.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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## 2.1. Reflective Review of Article 1

This article fulfilled objective one of this study which was:

1. To establish the evidence relating to information and decision-making preferences in older women ( $\geq 75$  years) with primary operable breast cancer with a specific focus on the use surgery or PET.

In this section the rationale for the type of review undertaken will be given and, using the NICE qualitative appraisal checklist, (NICE 2012) a quality assessment of studies that focussed on women  $\geq 65$  years identified in the published article will be reported. The ENTREQ statement (Tong, Flemming, McInnes, Oliver & Craig 2012) will be used to provide a framework for the critical commentary of the published review presented in this chapter. Finally the findings from a re-run of the search strategy undertaken in February 2017) are presented to provide an update on the current evidence regarding the evidence in this area.

### Type of Review

The growth of evidence-based practice has led to an increasing number of reviews being published and with them diversity in the terminology used to describe them. The best known type of review is the 'systematic review'. The aim of the systematic review is to report the details of the method used to enable others to reproduce the process (Grant & Booth 2009). The systematic review often adheres to the Cochrane Collaboration guidelines that are exacting and need significant resources to complete. Cochrane describes a systematic review as the summary of:

*"....the results of available carefully designed healthcare studies (controlled trials) and provides a high level of evidence on the effectiveness of healthcare interventions. Judgments may be made about the evidence and inform recommendations for healthcare."*  
(Cochrane <http://consumers.cochrane.org/what-systematic-review>)

Given the resources required it was not feasible to undertake a Cochrane style systematic review within this PhD but it was important to undertake a comprehensive search to produce a more complete picture of the research



surrounding the topic. Therefore the systematic 'systematic search and review' type of review described by Grant & Booth (2009) was chosen.

This type of review

*"...combines strengths of critical review with comprehensive search process. Typically addresses broad question to produce 'best evidence synthesis' (Grant & Booth 2009, pg 94)*

Using the Search, Appraisal, Synthesis and Analysis (SALSA) framework the characteristics of the 'systematic search and review' are:

- Search: Aims for exhaustive comprehensive searching
- Appraisal: May or may not include quality assessment
- Synthesis: Uses narrative and tabular summary of studies
- Analysis: What is known. Recommendations for practice and identifies limitations.

Reproduced from Grant & Booth (2009)

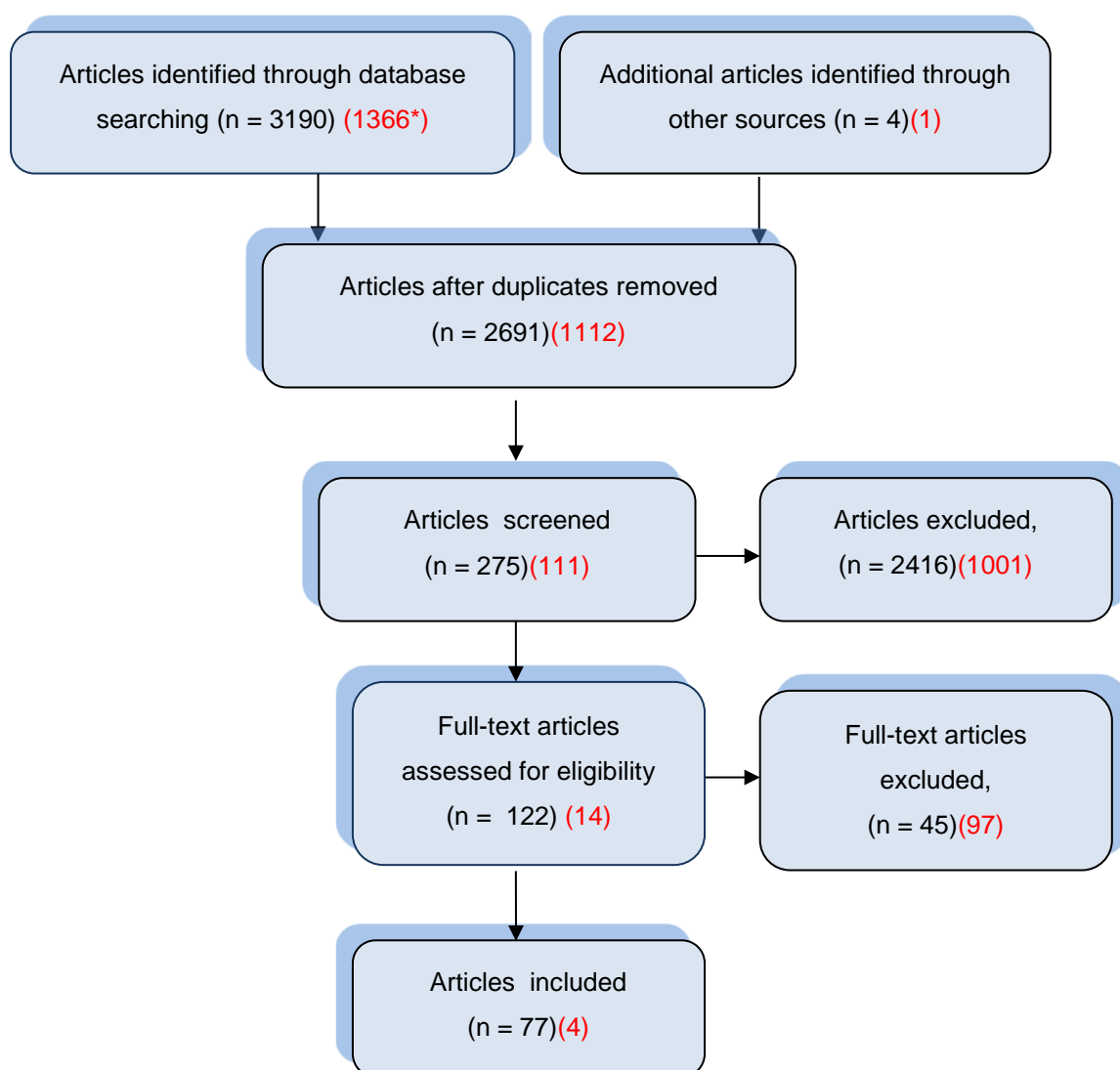
Grant and Booth (2009) state that the review may or may not include a quality assessment. Their definition of quality assessment is wide ranging and does not explicitly mean the use of a formal tool. They refer to the use of inclusion and exclusion criteria and a clearly defined process of synthesis, which were undertaken in this study.

## **2.2. Rationale for the type of review**

'Older' was variably defined within the literature. Since this PhD study aimed to contribute to the evidence surrounding preference for information and treatment decision-making in women who may be offered PET as an alternative to surgery, the age at which this became clinically appropriate,  $\geq 75$  years, was chosen the age of interest. However, it was apparent that there were very few studies that focussed on this age group and therefore a pragmatic decision was taken to use the traditional, age of 65 years (NSPOP 2001) became an eligibility criterion. See Figure 1.3 for review process. (See Appendix 2 for detailed search strategy & Appendix 3 for details of the 4 new articles identified).

Seventy-seven articles met the inclusion criteria but only six research papers focussed on women  $\geq 65$ ; Crooks 2006, Ciambone 2006; Kreling, Figueiredo, Sheppard & Mandelblatt 2006; Husain, Collins, Reed & Wyld 2008; Wong et al. 2011; Schonberg, Silliman, McCarthy & Marcantonio 2012). (See published article for details of these studies). The remaining 71 were from mixed cohort studies, mixed cancer studies or review papers. They were heterogeneous in the age range, research questions posed and methodologies and methods used making synthesis and analysis difficult. Despite being of variable quality it was necessary to include them in the final published review to gain an overview of the situation and identify 'what is known' with regards to information needs and the preference for involvement in decision-making.

**Figure 2.1: Flow diagram showing review process for original and updated search**



\*Text in red are for the updated search figures

### 2.3. Quality Assessment

Undertaking a 'systematic search and review' did not require papers to be quality assessed using a formal tool. However, the strength of evidence of the six focussed papers, identified above, five have been examined using the NICE qualitative appraisal checklist (NICE 2017). (See Appendix 4 for completed checklists). The overall conduct of a study can be graded as follows:

- ++ All or most of the checklist criteria have been fulfilled; where they have not been fulfilled the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled, where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
- - Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter. (NICE 2012)

Of the six focussed studies Schonberg and colleagues (2012) employed a medical notes review whilst the remaining five used a qualitative methodology and therefore could be assessed using the NICE qualitative appraisal checklist. All of the five qualitative studies were graded as +. In each of these papers the criteria that were not addressed, were the lack of description about the role and relationship the researcher had to the participants and the need for more than one method of data collection and a justification for triangulation or for not triangulating. Ciambone (2006) and Crooks (2001) failed to provide details of the procedure for data analysis or how the themes from the interviews were derived. This calls into question the trustworthiness of the findings and highlights the lack of transparency often levelled at qualitative research (Barbour & Barbour 2003; Farmer, Robinson, Elliott & Eyles et al. 2006; Ritchie, Spencer & O'Connor 2013).

The items in the NICE checklist reflect the growing need for transparency in *how* qualitative analysis is undertaken. It is no longer acceptable to report that 'themes emerged' there must be an auditable process that describes to



the reader the thinking and the rationale for the themes derived. As Miles and Huberman (1994) comment,

*"They [qualitative reports] are most often heavy on the 'what'(i.e. the findings and description) and rather thin on the 'how' (how you got to the 'what')"*

(Miles & Huberman 1994 pg 262)

The paper by Schonberg and colleagues (2012) aimed "to identify factors that influence the breast cancer treatment decisions of women aged 80 and older". This was a medical notes review of 2,185 women 80 years and older of which 65 had a diagnosis of breast cancer with various grades or ductal carcinoma in situ. Data for these women were accessed from online medical records between 1994 - 2004 and followed up in 2010. The data included patient demographics, tumour characteristics, the Charlson Comorbidities Index, survival data, and a scoring system, "provided by the physician", to assess the level of detail on decision-making recorded in the records. The authors state that the analyses will provide descriptive information and are careful not to claim any statistical associations or correlations between any factors. Although not described as such the analysis resembles thematic analysis but unfortunately no details are given of how the analysis was undertaken. This study was heavily dependent on the recording of the level of detail about the decision-making process and this was reported to be variable. Medical note reviews are considered the lowest level of evidence (Sackett, Straus, Richardson, Rosenberg & Haynes 2000) and therefore the findings from this study should be used with caution. What is striking about this paper is that despite the lack of scientific rigour it identifies many of the issues raised by the other five papers which may be judged to be methodologically superior.

## **2.4. Critical Commentary of Article 1**

The ENTREQ statement (Tong et al. 2012) was used to guide a critical commentary of the published article presented in this chapter. The aim of the ENTREQ statement is clearly stated in its own name "Enhancing transparency in reporting the synthesis of qualitative research (ENTREQ)". It has no scoring system but provides a checklist of items which the authors

suggest should be addressed when reporting a literature review of qualitative studies.

Assessing the quality of qualitative research is difficult and contentious (Pope & May 2000) as there is little evidence that the quality of reporting reflects the trustworthiness of the findings or the robustness of the study (Dixon-Woods et al. 2007). The aim of the ENTREQ statement is to enhance the reporting of qualitative syntheses (reviews) which will allow the reader to better understand the conduct of the study and processes of the synthesis. The authors accept that it is unlikely that there will ever be standardised reporting guidelines so instead have produced a checklist for consideration when undertaking and reporting review.

The literature review satisfactorily addressed many of the relevant areas identified in the checklist, some of which were reported in the article, and some that were undertaken during the process but not reported (See Table 1.1 for the ENTREQ statement and completed assessment). Possibly the most significant omission was the lack of use of an appraisal tool (item 11 in the checklist) during the review. (This issue has since been addressed and reported earlier in this chapter.)

Items 18 and 19 were not fully addressed (See Table 1.1). Being explicit about the way in which the synthesis occurred would have enhanced the transparency of the review. The purpose of the review firmly directed the information being sought. Each article was read with the specific aim of identifying the current evidence regarding the information needs, its presentation and the decision-making preferences of older women faced with a treatment option for breast cancer. Findings were then categorised into themes. The findings from each article were then compared across others in the same theme.

Item 21 was similarly not fully addressed however the purpose of the review was as described above and therefore it did not require this level of analysis. This review was undertaken with a strong emphasis on the findings being of practical application in healthcare and this was achieved

**Table 2.1: The ENTREQ statement**

Review of *"Information Needs of Older Women Faced with a Choice of Primary Endocrine Therapy or Surgery for Early-Stage Breast Cancer: A Literature Review"*

No	Item	Guide and description	Article Review
1	Aim	State the research question the synthesis addresses.	Purpose of the review clearly stated
2	Synthesis methodology	Identify the synthesis methodology or theoretical framework which underpins the synthesis, and describe the rationale for choice of methodology	The rationale for the choice of methodology i.e. the type of review undertaken, a 'systematic search and review' was not stated in the paper.
3	Approach to searching	Indicate whether the search was pre-planned (comprehensive search strategies to seek all available studies) or iterative (to seek all available concepts until they theoretical saturation is achieved).	The search was pre-planned and aimed to identify all available studies.
4	Inclusion criteria	Specify the inclusion/exclusion criteria (e.g. in terms of population, language, year limits, type of	Inclusion and exclusion criteria were reported.

No	Item	Guide and description	Article Review
		publication, study type).	
5	Data sources	Describe the information sources used (e.g. electronic databases, grey literature databases (digital thesis, policy reports), relevant organisational websites, experts, information specialists, generic web searches (Google Scholar) hand searching, reference lists) and when the searches conducted; provide the rationale for using the data sources.	All electronic databases were reported and the use of hand searching. Other sources were not used but this was not reported. The rationale for the choice of database was not reported
6	Electronic Search strategy	Describe the literature search (e.g. provide electronic search strategies with population terms, clinical or health topic terms, experiential or social phenomena related terms, filters for qualitative research, and search limits).	A full search strategy was written and the main headings were included in the publication. A detailed strategy is appended to this thesis.
7	Study screening methods	Describe the process of study screening and sifting (e.g. title, abstract and full text review, number of independent reviewers who screened studies).	Process reported

No	Item	Guide and description	Article Review
8	Study characteristics	Present the characteristics of the included studies (e.g. year of publication, country, population, number of participants, data collection, methodology, analysis, research questions).	The characteristics of the most relevant studies were included in the main body of the article. All other articles details included were made available on line via the publisher.
9	Study selection results	Identify the number of studies screened and provide reasons for study exclusion (e.g. for comprehensive searching, provide numbers of studies screened and reasons for exclusion indicated in a figure/flowchart; for iterative searching describe reasons for study exclusion )	A PRISMA chart was used to demonstrate numbers identified and excluded. Reasons for exclusion were reported.
10	Rationale for appraisal	Describe the rationale and approach used to appraise the included studies or selected findings (e.g. assessment of conduct (validity and robustness), assessment of reporting (transparency), assessment of content and utility of the findings).	Although not reported in the review an appraisal was made of both the content and utility of the findings.
11	Appraisal items	State the tools, frameworks and criteria used to appraise the studies or selected findings	No quality assessment tools were used during the review as there was such a limited

No	Item	Guide and description	Article Review
			amount of information. Appraisal has since been undertaken and all but one of the studies highlighted in the article were of good quality
12	Appraisal process	Indicate whether the appraisal was conducted independently by more than one reviewer and if consensus was required.	Two appraisers were involved and there were no major differences in the opinion of the selection or appraisal of the included articles.
13	Appraisal results	Present results of the quality assessment and indicate which articles if any, were weighted/excluded based on the assessment and give the rationale.	NA
14	Data extraction	Indicate which sections of the primary studies were analysed and how were the data extracted from the primary studies?	A data extraction template was used to assess all of the papers. This was included for the six studies reported in the article. For the remainder this was available on line via the publisher
15	Software	State the computer software used, if any.	NA
16	Number of reviewers	Identify who was involved in coding and analysis.	NA

No	Item	Guide and description	Article Review
17	Coding	Describe the process for coding of data (e.g. line by line coding to search for concepts).	NA
18	Study comparison	Describe how were comparisons made within and across studies (e.g. subsequent studies were coded into pre-existing concepts, and new concepts were created when deemed necessary).	Comparisons were based on common findings from previous studies.
19	Derivation of themes	Explain whether the process of deriving the themes or constructs was inductive or deductive.	Themes were predetermined on the basis of the aims of the search.
20	Quotations	Provide quotations from the primary studies to illustrate themes/constructs, and identify whether the quotations were participant quotations of the author's interpretation.	No
21	Synthesis output	Present rich, compelling and useful results that go beyond a summary of the primary studies (e.g. new interpretation, models of evidence, conceptual models, analytical framework, development of a new theory or construct).	No

## 2.5. Literature Search Update

The literature search strategy (see Appendix 2) was re-run in February 2017 to identify any articles published since the original search was performed on 4th January 2013.

1367 titles were retrieved and after duplicates and ineligible abstracts 111 remained. After reviewing twenty-five full articles, four were judged to provide new evidence. (See Figure 2.1).

Two of the articles retrieved in the re-run have 2013 dates but they were not identified in the original search. The article by Livaudis and colleagues was not published until May 2013 and was therefore not available at the time of the original search. Although the article by O'Brien and colleagues was originally available electronically in 2011 this would not have been identified through the databases searched. The article was not indexed until December 2013 and so would not have been retrieved in the original search.

There were no studies that specifically addressed the information needs, of older women with operable breast cancer facing a treatment choice between surgery and PET or their preference for involvement in decision-making.

Three studies addressed treatment decision-making in older women diagnosed with breast cancer and one examined sources of information used by women with breast cancer. See Appendix 3 for details of these four studies.

Sowerbutt and colleagues (2015) report the findings of a qualitative study to explore in detail with women over > 70 years of age the factors influencing a decision not to have surgery. The mean age of the women was 86 years (range 76-99). This study explored the reasons why women did not have surgery and concluded that older women with breast cancer have differing priorities and reasons for their treatment decisions. It also suggests that they are not passive in their decision-making as previously been reported. The findings of this study provide further supporting evidence of the diverse nature of treatment decision-making in older women with breast cancer.



O'Brien and colleagues (2013) aimed to describe the perceptions of women with early stage breast cancer regarding their involvement in treatment decision-making. Their findings suggest that patients interpret treatment decision-making in a much broader way than simply their final decisional role. They see it as including both formal (medical personnel) and informal networks (family, friends, & organisations) from which they gather information and discuss the options.

Livaudis and colleagues (2013) examined the link between decision-making responsibility and knowledge of breast cancer treatment. Those with poorer knowledge more frequently reported they had too much responsibility for their treatment decision and higher rates of decisional regret at six months post treatment. Poor health literacy was identified as a contributory problem leading the authors to recommend health care professionals find alternative ways of providing information to support their preferred level of decision-making.

The final study by Schmidt and colleagues (2016) examined the role of different information sources in patient decision-making regarding breast cancer surgery. The two most common sources of information used by patients were written material from surgeons (75%), closely followed by the Internet (69%). Patients were seen to use the internet not only for treatment information but also to investigate their surgeon. This was an American study and many sought additional information from a different surgeon via second, third or more opinions. Use of the internet previously reported in the literature review article in chapter 1 is much lower at approximately 20% for older people so it is surprising to see such a high rate of usage in this study. It is possibly a feature of the cohort, as although the age range, 28-87 is reported no further breakdown is given. It is possible this is essentially a much younger cohort.

In summary re-running the original search strategy did not substantially alter the findings from the original search, but it did provide further detail and support.

Whilst there are studies that do not exclude older women, there remain few studies that provide findings relevant to this population. There also remains a quality issue surrounding the reporting of studies. Although it is reported that older women are included the actual proportion and/or age range is not documented.

Although there was evidence, largely from research in much younger women (Schonberg et al. 2010; Schou, Ekeberg, Ruland, & Karesen 2002; Nold, Beamer, Helmer, & McBoyle 2000), that HCPs were influential in the treatment decision making process it was not until the interviews in this study had been completed that it became clear how significant the impact was for this group of older women. Having recognised this impact, the opportunity was taken to examine the views on treatment decision making of older women with breast cancer and compare them to those of the HCPs, predominantly breast surgeons and specialist nurses. The findings from this examination are presented in chapter 7.

The following chapter will provide a detailed examination of the methodological approach adopted within this thesis, namely mixed methods. It outlines the philosophical stance of mixed methods and a justification for the design chosen.

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## Chapter 3: Methodology

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### **3. Chapter 3: Methodology**

This chapter outlines the rationale for the study and for using a mixed methods design. A review of the traditional research paradigms and an explanation of the development of mixed methods will be undertaken before examining how a '*pragmatic, sequential mixed methods*' research design was chosen.

#### **3.1. Rationale for the study**

Although there is much written about the needs of younger women, i.e. those under 70-75 years of age, there is currently little published research that provides evidence regarding the information and support needs of older women faced with a treatment choice for breast cancer (Husain et al. 2008). This study aims to address this issue.

#### **3.2. Overview of the study design**

This study used a pragmatic sequential mixed methods design (See Figure 3.1) employing a critical review of the literature, qualitative, in-depth, semi-structured interviews and a quantitative, self-completion postal questionnaire to meet the aims and objectives of the study.

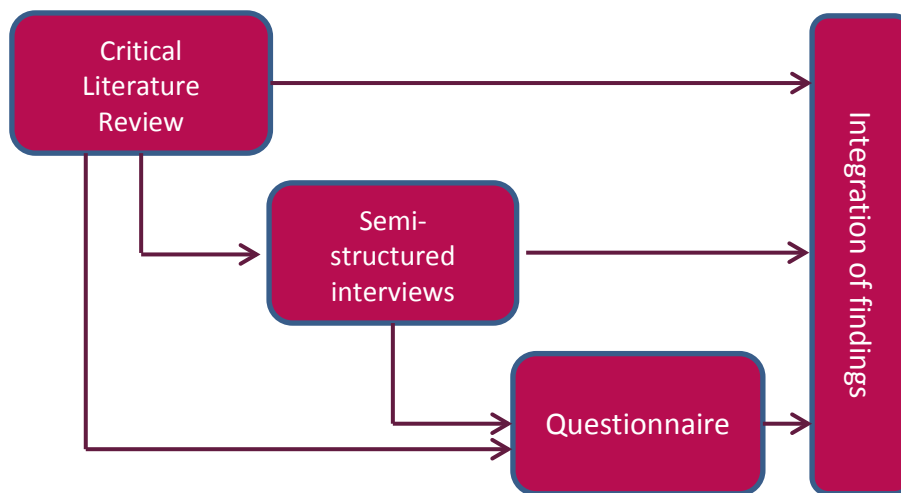
The overall aim of the study was to establish the information needs and decision-making preferences of older women with primary operable breast cancer when faced with a choice of surgery or primary endocrine therapy (PET).

The objectives were

1. To establish the evidence relating to information and decision-making preferences in older women ( $\geq 75$  years) with primary operable breast cancer with a specific focus on the use surgery or PET.
2. To elicit the views of older women towards preference for information and its source and presentation when facing a choice between surgery and PET.

3. To elicit the views of older women towards decision-making styles when faced with a choice of surgery or PET.
4. To determine the influence of the health care professional in treatment decision-making in older women with operable breast cancer.

**Figure 3.1: Overview of the exploratory, sequential mixed methods design**



### 3.3. Methodology

Despite the notion that research is a systematic and clearly defined process the vast array of methodologies and methods from which to choose can be bewildering. Furthermore, the terminology used in the literature is used interchangeably and sometimes in contradictory ways (Crotty 1998). The words 'paradigm', 'epistemology', 'worldview' and more recently 'communities' are all used interchangeably despite being defined clearly. Additionally 'theoretical perspective', 'theoretical stance', 'theoretical foundations', 'underpinning philosophy' and 'methodology' are similarly interchangeably used.

Crotty (1998) suggests that there are two questions which need to be answered when developing a research proposal; what methodologies and methods will be used and how will their use be justified?

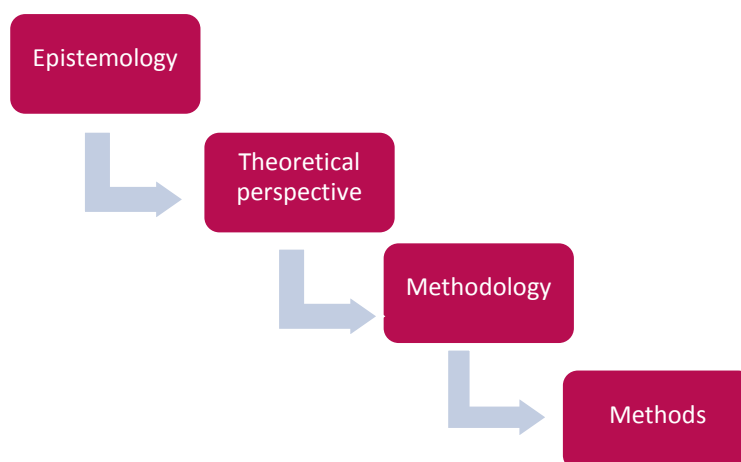
Underlying this justification is the interconnectedness of the basic elements; the epistemology, the ontology, the theoretical perspective, the methodology and the methods (See Figure 3.2).

Epistemology is 'a way of understanding and explaining how we know what we know.' (Crotty 1998). Alternatively it is defined as 'a general orientation about the world and the nature of the research that a researcher holds' (Creswell 2012) and is 'a basic set of beliefs that guide action' (Guba1990). The action it guides in research is the collection and interpretation of data.

Ontology is defined as 'the study of being' (Crotty 1998) and is concerned with the structure of reality and is inextricably linked to epistemology since it is not possible to discuss 'what it means to know' (epistemology) without discussing the 'what is' (ontology) (Crotty 1998:10). This link will become clear when the differing epistemologies are discussed later in this chapter.

The methodological approach taken in a study arises from the worldview or paradigm or epistemology of the researcher (Guba 1990, Crotty 1998, Creswell 2012). Although these philosophical underpinnings may not be overtly expressed within research findings, these underpinnings are needed to inform the basis from which the research design is developed (Creswell 2012).

**Figure 3.2 Depiction of the relationship between the basic elements of research**



(Adapted from Crotty 1998 pg 4)

Research methods are the techniques and procedures used to collect and analyse data. To ensure that the research process can be justified it is important to provide a detailed description of the methods to be used. For example, it is not sufficient to say 'interviews will be carried out'. The type of interview and method of analysis need to be described to provide the rationale and justification for their use (Crotty 1998).

This section will focus on two traditional epistemologies: objectivism and constructionism and two respective theoretical perspectives as Crotty refers to them, positivism, and interpretivism before moving on to the theoretical perspectives of pragmatism and critical realism associated with the development of mixed methods research (Crotty 1998; Creswell 2007, Teddlie & Tashakkori 2009).

### **3.4. Objectivism**

Objectivism is one of a range of epistemologies. Objectivists maintain that there is reality outside of our consciousness and that the aim of scientific investigation is uncover accurate and certain knowledge of this reality.

Objectivism is the underlying theoretical perspective of positivism and post positivism (Crotty 1998).

#### **3.4.1. Positivism**

Positivism is difficult to define precisely as it has evolved over time with 12 distinct versions being identified (Halfpenny 2014). However, a general belief held by positivists is that reality is stable and can be observed and described from an objective viewpoint (Levin & Clowes 1991).

The fundamental feature of positivism is the need to engage with the scientific process, that is, using a highly systematic, well organised, approach to research, consistently using absolute principles (Crotty 1998).

The use of experimental methodology, hypothesis testing and the collection and analysis of predominantly quantitative / numerical data are characteristics of positivism (Ibid). One of the key features that accompany objectivism is the need to separate the researched from the researcher to

reduce bias and minimise involvement which may influence the results or outcome of the study. Positivist research employs deductive logic or reasoning to argue from general observations to the particular. This hypothetico-deductive model involves the testing of a hypothesis, derived from a theory, using statistical methods and tests. This necessitates a need for measurement of the variables under investigation using systems that adhere to mathematical or unit of measurement conventions.

This strict positivist view was first challenged by a number of scientists at the end of the 19<sup>th</sup> century but most influentially by Kuhn (2000) who questioned the logic of requiring objectivity and a context free, value-free stance for the discovery of knowledge. There was an emerging recognition that objectivity could not deliver one 'absolute truth' and this led to a branch of positivism called post-positivism. The key difference between positivism and post-positivism is that positivists believe scientific method can result in truths that can be generalised to the world, post-positivists believe that the interpretation of results and scientific truths need to be set in context with conclusions being only cautiously generalized. Furthermore, Popper (1934) argues that observations alone are insufficient to make generalisations and that data only make sense in the context of a theory that can be tested. Popper rejects the idea that theory can be confirmed and instead proposes that all that can be achieved is that the theory can be shown not to be true, this becoming known as 'falsificationism'. It is far more cautious in its claims for the achievement of true facts through science and Popper developed it in direct opposition to the strict 'logical positivism' that dominated his era. He believes that science will only progress if the theory or null hypothesis is tested. By being able to reject the null hypothesis, support can then be given to the hypothesis or theory under investigation. Gradually there has been acknowledgment that positivism can only provide speculative truths and has limitations in accessing knowledge of the social world (Crotty 1998).

### **3.5. Constructionism**

Constructionism is an epistemology predominantly related to the social world and not the natural world.



Crotty describes a purist view of constructionism as:

*‘...the view that all knowledge, and therefore all meaningful reality as such, is contingent upon human practices, being constructed in and out of interaction between human beings and their world, and developed and transmitted within an essentially social context’*

(Crotty 1998 pg 42)

In its purist sense constructionism is the antithesis of objectivism. As the term suggests, meaning or knowledge is considered to be constructed by human actors and not discovered as a reality outside human consciousness. Constructionists therefore argue there is no objective reality waiting to be discovered in the social world, and that all social meaning relies on human beings engaging with and interpreting the world (Crotty1998).

The less purist view of constructionism holds true for both the social and natural world. For some the natural world is also constructed, in different and contradictory ways.

### **3.5.1. Interpretivism**

The epistemology of constructionism brings with it the theoretical perspective of interpretivism. In contrast to positivists, interpretivists believe that the researcher and the researched co-construct knowledge and that it is impossible to conduct objective, value free research (Crotty 1998)

Constructionism and interpretivism are often associated with qualitative methodologies such as ethnography, phenomenology and grounded theory that dictate the use of narrative type methods of data generation such as interviews, focus groups or observation. Approaches such as thematic or framework analysis are used to organise and identify issues of importance and relevance. The analysis and interpretation of these data rely on inductive logic, moving from the particular to the general (Crotty 1998).

### **3.6. The Choice of Methodology**

The methodologies associated with each of these epistemologies and their respective theoretical perspectives can be broadly categorised into qualitative and quantitative research. The choice of methodology is dependent on the research question and the aims of the study. Quantitative

and qualitative research answer different questions, and produce different forms of knowledge with the essential focus of quantitative research being confirmatory, whilst qualitative research addresses predominantly exploratory questions (Teddle & Tashakkori 2009).

### **3.6.1. Quantitative Research**

Quantitative research is situated primarily within the objectivist epistemology (with a theoretical perspective of positivist / post positivist) and uses an array of techniques to collect, analyse and present numerical data (Teddle & Tashakkori 2009). The purpose of quantitative research is commonly to confirm but may also be to explore the current knowledge base of the research phenomenon under investigation. This model requires a hypothesis or quantitative research question be posed and tested using statistical techniques. The use of statistical techniques and analyses is directly linked to the research design and the methods used to collect the data. Quantitative research uses experimental, correlational and survey designs. Underpinning these research designs is the use of probability sampling, which involves the random selection of participants from the target population (Teddle & Tashakkori 2009). Both descriptive and inferential statistical techniques are used to analyse the data. The purpose of descriptive analysis is to provide an overview of and describe the relationship between the variables. Inferential statistics provide a way of *"..making inferences from samples to populations."* More specifically inferential statistics involves the testing of difference between group means or the relationship between variables and the trustworthiness of those differences. (Teddle & Tashakkori 2009).

### **3.6.2. Qualitative Research**

Qualitative research aligns within a constructionist epistemology and using narrative data employs inductive reasoning that is, a process of generating theory from data, rather than testing theory as in the case of deductive approaches. Qualitative research is predominantly, but not always exploratory using a variety of methodologies such as ethnography, grounded theory and case study. Unlike quantitative research, qualitative research

most commonly uses purposive sampling. Purposive sampling is a type of sampling where:

*"...particular settings, persons, or events are deliberately selected for the important information that they can provide that cannot be gotten from as well from any other choices."*

(Maxwell, 1998 pg 235)

There are a number of characteristics that might differentiate participants including, age, gender, race, illness type and so on with their inclusion being dependent upon the aims of a particular study (Clark & Creswell 2011).

Commonly the analysis of qualitative data involves the identification of themes, categories and/or patterns which are then examined to reach an understanding of the research questions.

### **3.6.3. The 'Paradigm Wars'**

The 'paradigm war' (Creswell & Plano Clark 2011) was initiated by the rise of qualitative research and the criticism of quantitative research and its positivist stance as being limited in producing beneficial research (Guba & Lincoln 1994). Paradigms are belief systems or epistemologies that guide research (Teddlie & Tashakkori 2009). It was argued that since research paradigms are linked to particular research methods and the paradigms rise from differing theoretical perspectives they could not be combined or mixed and were incommensurable (Kuhn 1962). However arguments that highlighted the differences also served to illuminate the strengths and weaknesses in both quantitative and qualitative research and it began to be argued (Denzin 1978) that in combination they could address both exploratory and confirmatory questions simultaneously, provide 'better (stronger) inferences'. It is from this position that allowed the emergence of divergent views (Teddlie & Tashakkori 2009) that mixed methods research arose.

### 3.6.4. Mixed Methods Research

The term 'mixed methods' was first coined by *Teddlie & Tashakkori* in 'The Handbook of Mixed Methods in Social and Behavioural Research' (2010) and has been widely used ever since across many disciplines.

Mixed methods are increasingly used in health research with the proportion of commissioned MM studies rising from 17 per cent in the 1990's to 30 percent in the early 2000s. (O'Cathain, Murphy, & Nicholl, 2007) as it claims to address the complexity of this setting.

*"Within health services research, a mixed methods approach is justified on pragmatic rather than ideological grounds, to help researchers to engage with the complexity of health, health care, and the environment in which studies take place"*

(O'Cathain et al. 2007).

Despite this popularity a clear definition of the approach remains to be agreed, Johnson, Onwuegbuzie & Turner (2007) analysed many different definitions of MM research and suggested the following;

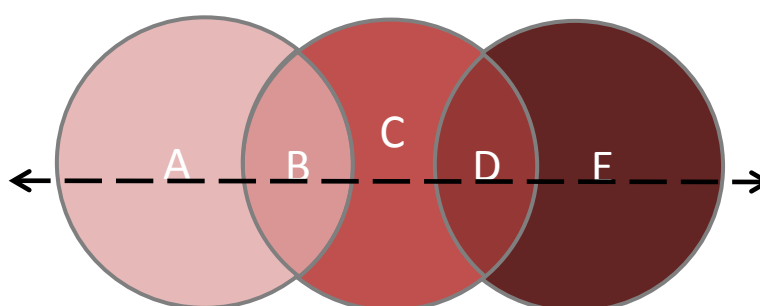
*"Mixed methods is the type of research in which the researcher or team of researchers combines elements of qualitative and quantitative research approaches, (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purpose of breadth of understanding or corroboration."*

(Johnson et al. 2007pg 123) .

Mixed methods has also been variously referred to as 'an important methodological approach' (O'Cathain, Murphy, Nicholl (2007), 'a research paradigm or research approach' Johnson et al. (2007) whilst Teddlie and Tashakkori state it is not a methodology and refer to MM research as the 'third methodological community' (Teddlie & Tashakkori 2009).

Mixed methodologists argue that the research question drives the research process and that whatever methodological approaches are required to answer that question should be used (Teddlie & Tashakkori 2009). Johnson et al. (2007) describe it as lying in the centre of a continuum as illustrated in Figure 3.3 overleaf.

**Figure 3.3: The QUAL-MM-QUAN Research Continuum**



A = Totally Qualitative research  
B = Primarily Qualitative research with some Quantitative  
C = Totally integrated MM research  
D = Primarily Quantitative research with some Qualitative  
E = Totally Quantitative research

Adapted from Teddlie & Tashakkori 2009

Mixed methods research involves the collection, analysis and, pivotally an integration of findings with inferences drawn from both qualitative and quantitative data from a single study or programme of enquiry with a common research question (Tashakkori & Creswell 2007).

### **3.7. Mixed Methods Research - the philosophical stance**

The two prominent theoretical perspectives underpinning MM research are pragmatism and critical realism.

#### **3.7.1. Pragmatism**

There are many forms of pragmatism which derive from the work of Dewey, James and Mead (Cherryholmes 1992). Pragmatism is defined as;

*"... a deconstructive paradigm that debunks concepts such as 'truth' and 'reality' and focuses instead on 'what works' as the truth regarding the research questions under investigation. Pragmatism rejects the either /or choice associated with the paradigm wars, advocates for the use of mixed methods in research, and acknowledges that the values of the researcher plays a large role in the interpretation of the results"*

(Teddlie & Tashakkori 2003a p 713 cited in 2009)

Pragmatists view the research question to be of utmost importance over and above the methods used or the underlying paradigm of those methods.

(Morgan 2007; Teddlie & Tashakkori 2009). This lack of affinity to a single paradigm allows the researcher to benefit from the strengths of both quantitative and qualitative approaches. Pragmatism is concerned with 'what works' and the solutions to problems and emphasises the use of all available methods to understand the problem. Pragmatism is thus understood as a practical and applied research philosophy that supports mixed or multiple methods of social science inquiry (Maxcy, 2003). Pragmatism takes a neutral view of ontology and epistemology. Its originators were concerned with the practical consequences of beliefs – if a belief had no practical consequence then it was meaningless and of no use. From this point of view it could be argued that the debate between objectivists and constructivists is meaningless – it does not matter whether a theory is objectively true or socially constructed – what matters are the consequences of believing it.

Although pragmatism is commonly the theoretical perspective aligned to MM research (Teddlie & Tashakkori 2009) is it not the only one. Critical realism has also been associated with MM and this has quite distinct views of ontology and epistemology to pragmatism.

### **3.7.2. Critical Realism**

Critical realism is a philosophical stance which attempts to describe a link between the natural and social worlds (Sayer 2000). Critical realism is viewed as being an integration of a realist ontology i.e. there is a world which exists outside of human consciousness, with a constructionist epistemology, i.e. our understanding of the world is a construction of our experiences and perspectives (Creswell & Clark 2011). Critical realists believe there is a 'real reality' that is, they agree with the objectivist position that entities exist outside human consciousness (Denzin & Lincoln 2011) but this can only be partially understood as our understanding of that external entity is constructed (Teddlie & Tashakkori 2009).

Critical realists acknowledge the strengths of both the positivist and constructionist stance and consider that external realities can only be known in the social world through how they are socially constructed by human agents. This is acknowledged by Sayer when he states:

*"...critical realism seeks to avoid both scientism and 'science envy' on the one hand and radical rejection of science on the other"*

(Sayer 2000 pg 3)

The foundation of critical realism is realism and based on developments of the original work by Bhaskar (1975 cited by Sayer) critical realists are interested in the context and mechanism of findings. (Sayer 2000).

Pragmatists suggest that the practical consequences of a mixed method researcher adopting either pragmatist or critical realist views are moot; as such they might dispute the meaningfulness of the debate at all. Realists would dispute this, particularly in relation to the understanding of complex, open systems. However, in research on fairly straightforward social phenomena, the pragmatists have a point. It is for this reason, a pragmatic view was taken in this study; there was no need for the researcher to take sides in this dispute and so she did not. Critical realism was rejected in this study because the research questions are exploratory and do not require the complex social phenomena i.e. the context or mechanisms underlying the questions to be understood in depth as this was not the aim of this study. (Sayer 2000).

### **3.8. Justification for the use of pragmatic sequential mixed methods design**

Creswell & Plano Clark (2011) have identified six major mixed methods research designs, the convergent parallel design, the explanatory sequential design, the exploratory sequential design, the embedded design, the transformative and the multiphase design.

The choice of a '*pragmatic, sequential mixed methods*' research design for this study is based on the need to both identify unknown factors or important issues, which lends itself to qualitative research methods, and the need to generalise or transfer the findings to a wider population necessitating the use of a more quantitative method. The data are generated and collected sequentially where the findings from the qualitative dataset are used to develop a quantitative tool that is then used to test or examine the extent to which the qualitative findings can be generalised / transferred.

The purpose of this study is to *explore* and *confirm* the information and support needs of older women when faced with a treatment choice for breast cancer. This requires a two-phase, pragmatic, sequential approach as neither a positivist nor constructionist philosophy alone is capable of achieving this.

### **3.9. Benefits and Challenges of Mixed Method Research**

The benefits of MM research have been much discussed in the literature (Green & Caracelli 1997; Creswell & Clark 2011) and these have been synthesised in two now prominent frameworks based on the work of Greene and colleagues (1989) and Bryman (2008). Greene, Caracelli and Graham (1989) identified five broad reasons for the use of MM research, these are triangulation, complementarity, development, initiation and expansion. Bryman (2008) produced a second more detailed framework based on an analysis of researcher practices. (See Table 3.1 for the items within this framework that justify the use of MM for this study).

Mixed methods research does not come without challenges. It requires the researcher is familiar with both qualitative and quantitative research including the methodologies employed and the methods of data collection and analysis (Creswell & Plano Clark 2011). Where a team is undertaking the research this may not be an issue. Consideration needs to be given to available resources since MM research requires significant time to complete all phases of the study.

The greatest challenges identified are, data management, processing and analysis and the potential for data overload (Lieber 2009). Once the data are analysed this is likely to create significant amounts of information which needs to be synthesised and presented in an integrated or combined way demonstrating how the methods complement each other rather than expose their inherent weaknesses (Molina-Azorin 2010).

The following chapter will outline the research procedure; describe the data collection tools, the rationale for their use and the analysis methods before detailing the ethical review process.



**Table 3.1: Justification for the use of Mixed Methods Research for this study.  
(Adapted from Bryman (2008))**

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Triangulation or greater validity: the combination of quantitative and qualitative research to triangulate findings in order that they may be mutually corroborated or provide a fuller picture

Offset: recognition that quantitative and qualitative methods have strengths and weaknesses and combining the two will allow the weaknesses to be offset and the strengths to be drawn upon.

Completeness: the notion that a more comprehensive understanding can be achieved using both quantitative and qualitative methods.

Different Research Questions: quantitative and qualitative research answer different types of research questions.

Explanation: one method is used to explain the findings from the other.

Unexpected results: combining quantitative and qualitative research can help understand unexpected findings arising from one method.

Instrument development: when qualitative research is used to develop a questionnaire and scale items

Credibility: the notion that employing both approaches enhances integrity.

Context: qualitative research is used to provide contextual understanding to either generalizable or broad relationships among variables uncovered through a survey.

Illustration: the use of qualitative data to illustrate quantitative findings.

Utility or improving the usefulness of findings: the notion that combining the two approaches will be more useful to practitioners.

Enhancement: the ability to enhance or augment the findings from qualitative or quantitative approach by the use of the alternative approach.

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## Chapter 4: Methods

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## **4. Chapter 4: Methods**

This chapter details the methods employed in the study. The data collection tools and analysis methods of semi-structured interviews and postal self-completion questionnaires will be described and examined against the objectives of the research. The process of ethics review will be presented first.

### **4.1. Ethical Approval**

Multi-site ethical approval was gained via a proportionate review from NRES London -Surrey Borders Research Ethics Committee (12/LO/1722) as was local research governance at each of the sites (See Appendix 6 & 6A).

Proportionate reviews are for questionnaire and or interview research that does not include highly sensitive areas or where accidental disclosure would not have serious consequence (NHS Health Research Authority)

### **4.2. Ethical Implications**

In keeping with good practice, a number of ethical issues were carefully considered during the development, administration and analysis of the interview and questionnaire elements of the study.

Research involving older people raises potential issues of age-related reduction in physical and cognitive ability, which may affect the ability to consent to participation and to give and receive information (Tinker 2003). Using advice from the Health Research Authority careful consideration was given to how the initial approach was made to invite the women to take part in the study and to the construction of the written information. Women were approached by their treating clinician or a breast care nurse as they were familiar with them and had developed a relationship with them. These HCPs were well placed to identify eligible patients and assess their cognitive ability.

Written material, including invitation letters, participant information sheets and consent forms were developed in line with Health Research Authority guidance (HRA guidance). To address the possible reduction in visual capacity an increased font size and a generous space layout were used to create all research documents. Importantly non-medical, everyday language

was used in participant information and consent sheets and the questionnaire.

Older people are often described as being 'vulnerable'. Vulnerable people are those who are unable to protect themselves from harm or exploitation possibly for reasons of physical or mental illness or age (Lange, Rogers & Dodds 2013). To guard against any unintended pressure or coercion potential participants were given information packs and asked to reply to the researcher direct. In this way there was less chance they would feel any pressure to participate.

Discussing the topic of cancer, whether this be the participant's own cancer or that of a family member or friend, may be distressing. The researcher needs to be mindful of this during the interview. Some participants will be willing to disclose great detail whilst others may be more reluctant and the issue of using probe questions needs to be delicately handled before and during the interview. At the start of the interviews all interviewees were reminded that they did not have to answer questions they were uncomfortable with and that they had the right to withdraw from the study at any time without giving a reason.

Confidentiality of all documentation was also assured by secure storage and handling according to the Data Protection Act 1998 (UK Government 1998). Confidentiality in research means that the participant will not be identified and any data, e.g. quotes from interviews, used in publications will be done anonymously. Protecting confidentiality can raise ethical issues. When a researcher obtains knowledge of malpractice, mistreatment or criminal activity this can present a dilemma of what action to take (Kvale & Brinkman 2009). This situation needs to be considered prior to any interviews being conducted to inform the interviewee as to the action that would or wouldn't be taken.

The women were given a choice of the most convenient and comfortable venue for the interviews to take place, their own home being one option. Entering a participant's home shifts the balance of power and means the researcher has less control over the environment, for example other people

being present or the noise level not being conducive to interviewing. It also requires the researcher to consider a number of health and safety issues. To maintain the safety of the researcher the 'lone working policy' of the researcher's university was followed (Sheffield Hallam University lone working policy).

### **4.3. Phase one - Qualitative Interviews**

The sequential mixed methods design introduced previously, includes an exploratory phase (phase one) which was achieved by the use of interviews to generate data to explore the topic. These data were then used to develop a questionnaire that was used in phase two to test or confirm the findings within a wider population.

The study objectives met by the interviews were:

- To elicit the views of older women towards preference for information and its source and presentation when facing a choice between surgery and PET.
- To elicit the views of older women towards decision-making styles when faced with a choice of surgery or PET.

#### **4.3.1 The Sample**

Purposive sampling was used for this phase of the study.

Purposive sampling is a type of sampling where:

*"... the sample is chosen because they have particular features or characteristics which will enable detailed exploration and understanding of the central themes and questions which the researcher wished to study"*

*(Ritchie, et al. 2014 pg 113).*

Within this study, the interview participants were purposively sampled from the target population of women, over 75 years of age, who had received a choice of surgery or PET for the treatment of primary operable, oestrogen receptor positive, breast cancer, and therefore able to provide the information sought in the study. The sampling frame for the purposive

sample for the qualitative interview phase comprised five NHS breast cancer units within UK hospitals in England and Wales. Where purposive, non-probability sampling is undertaken it is not necessary to calculate a sample size with all women in the sites being eligible. Thirty-eight women participated in an interview, forming the purposive sample for the study.

The aim of qualitative research is to explore issues and in the case of this study the information needs and decision-making style preferences of older women faced with a treatment choice for breast cancer. Adler & Adler (Baker, Edwards & Doidge 2012) recommend that data be gathered until empirical data saturation is reached. They acknowledge that the number will depend on the size of the sample pool, the ease with which the participants can be accessed and the time and resources available to the researcher. In this study an estimate of 35-40 was made.

#### **4.4. Eligibility Criteria**

Women were eligible if:

- they were  $\geq 75$  years, (the lower age at which PET is predominantly used),
- had been diagnosed with invasive breast cancer in the preceding 60 months
- offered an initial treatment choice between PET and surgery (documented in the medical records).

Women were not eligible if

- in the view of their Health Care Practitioner (HPC) they showed signs of significant cognitive impairment,
- they were unable to give informed consent
- they had locally advanced or metastatic breast cancer as they would have a different set of experiences and characteristics.

Women were not excluded on the basis of language. Where an interpreter was required this would be supported with funding from the parent study. However, this strategy was not required.

#### **4.4.1. Recruitment**

The recruitment strategy employed is detailed in the article two in chapter 5. Below is an overview of the sites involved and process of engagement.

During the development of the parent study an invitation to take part in the identification and recruitment of participants had been accepted by many sites. Five of these sites were invited to participate in this PhD study. The sites were approached as it was known they had sufficient numbers of potentially eligible patients, they had expressed interest in the project and the geographical location meant they were accessible to the interviewers.

Prior to the start of this study a certificate of good clinical practice, a research passport and letters of access or honorary research contracts (See Appendix 7 & 8) were obtained in compliance with the Research Governance Framework for Health and Social Care 2005. In line with NHS research guidelines (NIHR 2012) 'set up' meetings were undertaken at each of the five sites participating in the interviews. Set up meetings enhance common understanding of the study protocol, including participant eligibility, data reporting mechanisms, data storage and the roles and responsibilities of each member of the research team.

In accordance with the specific governance approval at each site, patients were approached to participate by either the consultant surgeon or a research nurse during a routine check-up visit to the breast clinics. Each eligible patient received a study pack that contained: a letter of invitation, a participant information sheet, a study reply slip (See Appendix 9, 10 & 11) and a freepost return envelope. The surgeon and/or research nurse answered any immediate questions but the patients were not asked to make a decision immediately but to take the pack home and discuss their involvement with their family and friends if they wished to do so. Using the freepost return envelope the reply slips were sent directly to the researcher who was then able to contact the patient to make arrangements for the interview. No reply was requested should the patient decide not to take part. Informed written consent was taken at the beginning of the interview (See Appendix 12).

Once a positive response was received by the researcher, women were contacted to arrange a convenient date, time and venue to conduct the interview. Women were encouraged to choose a venue in which they felt most comfortable and they were invited to have a friend or relative in attendance during the interview if they so wished. The researcher arranged to call the participant earlier in the day of the interview to check they were well and that it was still convenient for them to take part.

In line with the university 'lone working' policy the researcher left details, with the administrative staff, of the address they were visiting and contact was made with the administrative staff prior to meeting with the participant and immediately following the interview.

At the beginning of the interview the researcher took the opportunity to refresh the participant's understanding of the study, address any questions they may have and ask permission to digitally record the interview. Once it was apparent that the participant was happy to proceed they were asked to give written consent (Appendix 12).

At the end of the interview the participants were thanked for their time and support for the project. They were also offered the opportunity to receive a copy of the research findings on completion of the study.

#### **4.5. Research Interviews**

Research interviews are commonly categorised by the degree of structure or standardisation, ranging from the very structured at one end of the continuum to the unstructured at the other (Robson 2002). Structured interviews commonly have a combination of closed questions often with a pre-coded response choice which create quantitative data and open questions which allow for some elaboration on responses producing qualitative data. (Bowling 2009; Kvale & Brinkmann 2009). These are used to survey populations or when the participant does not have the capacity to complete a self-administered questionnaire. (Tod 2006) Unstructured interviews have only a rudimentary interview guide of the topics to cover and are most often conducted where little is known of the phenomenon and are



led more by the participant than the researcher (Tod 2006). At the centre of this continuum lies the semi-structured interview.

The semi structured interview is commonly used to explore something that is already known about a particular phenomenon but requires further exploration. This format allows a narrative and/or discursive style of interview where the familiar act of talking and conversation are used. Kvale & Brinkmann (2009) state;

*"Conversation is a basic mode of human interaction....Through conversation we get to know other people, learn about their experiences, feelings, attitudes, and the world they live in."*

(Kvale & Brinkmann 2009 pg xvii)

Semi-structured interviews are conducted using a guide that enables topics to be explored within a conversational style of interview. This format also has the flexibility to probe answers and draw on cues to gain more detailed information and discuss issues that previously have not been identified (Kvale & Brinkman 2009; Gray 2013).

A semi-structured interview format was used in this study. The topic guide (see Appendix 13) was developed from the literature findings, with input from members of the North Trent Cancer Network Consumer Research Panel and by identifying key areas to be explored in order to meet the study objectives.

The semi-structured research interview uses conversation that has a structure and aims to produce knowledge (Kvale & Brinkmann 2009). Obtaining data to create knowledge requires that the researcher listens carefully and probes the answers given without influencing the perspective of the participant. Unlike everyday conversation the parties involved are not equal partners because the researcher determines the topic and through follow on questions, directs the flow and focus of the interview by picking up on areas which are of most interest to the researcher. Directing the flow and topic areas is not always easy, particularly with older people (Robertson & Hale 2011).

Semi-structured interviews may have the benefit of being pleasurable to take part in, particularly when the topic is non-contentious (Gray 2013). Reflecting

on events with a stranger (the researcher) may arguably be cathartic (Robertson & Hale 2011). Asking people to commit, in writing, their thoughts and feelings is a much more onerous task so the opportunity to talk about events in a relaxed situation may also be more appealing (Gray 2013) and possibly have the benefit of increasing recruitment.

#### **4.6. Interviewing the older person**

##### **Sensory Impairments**

Research interviews with older people are in many ways no different to interviews undertaken with other groups of people, however there are some specific issues which require consideration (Gubrium & Holstein 2002; Robertson & Hale 2011). Potential age related physical impairments such as visual disturbance and hearing loss need to be considered. Where poor sight is an issue providing a suitable lighting level and appropriate close positioning of the researcher will enable the older person to make out the features and facial expressions more clearly and make them feel more comfortable. Hearing loss requires the researcher speaks clearly and slowly and position themselves to allow the respondent to gain additional information from the facial expressions and lip reading. (Whitbourne et al., 2010).

##### **4.6.1. Cognitive Function and the Research Interview**

Although many cognitive abilities remain in older age, there is an acceptance that there is general slowing of information processing (Salthouse 1996). This slowing process increases with advancing age. Salthouses' 'general slowing hypothesis' (Salthouses 1996) is also used to explain the decline in working memory (short term memory), the part of the memory that makes information temporarily available. The loss of processing speed creates a backlog of cognitive processes that impairs memory (Hasher, Zacks & May 1999). Coupled with this slowing process is the theory that older people have difficulty filtering out information that is not relevant to the task (Whitbourne et al. 2010). To overcome the possibility of overloading and overwhelming the participant consideration needs to be given to the style and pace of the interview.

A conversational style of interview was utilised in order to help the older women interviewed in this study feel more relaxed. Conversation being viewed as a familiar activity is likely to reduce the burden of the interview (Kvale & Brinkmann 2009). During a conversation there is an expectation that information will be exchanged and the researcher needs to consider their stance on this element of the interview. It seems unavoidable to disclose nothing of one's own life but equally full disclosure may not be appropriate (Wegner 2001). Reciprocity may build trust in a relationship and may encourage the respondent to be more expansive in the information they reveal (ibid). Wegner (2001) states that reciprocity is particularly expected by older people during interviews.

#### **4.6.2. Story-telling during the Research Interview**

Older participants tend to require more frequent re-focusing back to the topic than their younger counterparts (Robertson & Hale 2011). Additionally, allowing the older person to tell their stories in their own way may also facilitate richer description and foster mutual respect between the researcher and the researched (Robertson & Hale 2011). Context is important when recollecting events (Errante, 2000) and storytelling can be one way of providing the context. Storytelling may trigger the recall of related issues or events and provide a richer description. Re-telling a story also provides an opportunity for reflection and deeper understanding of a situation or event (Davidson 2004). Interweaving the 'set questions' whilst listening to the story may further stimulate other recollections which may be pertinent to the topic under review.

Answering questions in an indirect fashion, such as story-telling, may result in lengthy interviews which may in turn fatigue an older people (Wegner 2001). However, conversely, older people may benefit from story-telling and reminiscing which might serve a positive function, for example evaluating events or re-living pleasing events giving a sense of self-esteem (Webster, Bohlmeijer, Westerhof 2010).

For all of these reasons a conversational style was adopted during the interviews in this study.

### **4.6.3. The Research Interview Relationship**

Regardless of age, the need to establish and develop an interviewer-interviewee relationship is essential to conducting a productive interview (Tod 2006). The participant needs to feel at ease with the research topic, which comes from a clear understanding of the research and the part they will play during the interview and beyond.

Giving a degree of control as to the location, timing and providing any additional support required during the interview may further engender a sense of ease. Participants in this study were given the freedom to choose when and where the interview was conducted and given the opportunity to have a member of the family or friend present.

### **4.7. Interviews - Data Analysis**

The interview transcripts were analysed using the Framework approach to identify recurrent themes (Ritchie & Lewis 2013). The aim of the study was to explore the information and decision support needs of older women faced with a choice of surgery or PET for the treatment of primary operable breast cancer it was necessary therefore to identify common themes amongst the narratives of this group of women. The Framework approach enables the systematic analysis of large volumes of textual data and permits within and across case and theme comparison and so was ideally suited to analyse the interview data in this study. The advantage of the Framework approach is that it provides a comprehensive, robust and transparent approach to data management and analysis. However, it is extremely time consuming and labour intensive. It requires the researcher to be skilled in the approach and informed, reflexive and critical when developing the themes and analysing and interpreting the data.

Other methods of analysis were considered and could have been used, for example thematic analysis as described by Braun and Clarke (2006) which has similar stages. However, the researcher was familiar with Framework analysis and it was therefore convenient to use, and its flexibility for use across epistemological viewpoints made it congruent with MM research and in this study supported the inductive approach to the data (Gale et al. 2013).

## **Framework Analysis**

There are five steps to Framework analysis: familiarisation; theme development; indexing; charting and finally mapping and interpretation (Ritchie & Lewis 2008)

### **Familiarisation**

Familiarisation is the first step to identifying the themes and involves listening to audio and/or reading the transcripts, any field notes and being aware of the topic guide. Through this process the researcher will become aware of the recurring issues and topics and this leads onto the next step: theme development.

### **Theme development**

Important and recurring themes are highlighted and sub-themes are developed. This stage relies on making judgments about meaning and relevance and the connection between the issues.

### **Indexing**

Based on this framework the researcher returns to the data and begins 'indexing'. Indexing is the process of identifying which sections of the data corresponds to which themes or sub-themes. Ritchie & Lewis (2013) recommend the use of a numerical system of labelling or coding the transcripts. It is important that the thematic framework remains flexible and that data are not forced into a theme. Further themes or sub-themes can be introduced if necessary.

### **Charting**

The fourth stage is charting. Charts are developed based on a theme identified at the theme development stage or by transcript that is based on each transcript in the study. In this study the researcher was interested in common issues surrounding information and support needs for decision-making in breast cancer therefore the charts were theme based. Data related to each of the themes and the associated sub-themes are separated from

the original framework, but crucially the context is not lost. One of the key features of the Framework approach is that all findings should have a transparent trail, therefore the context and any quotes must be identifiable and traceable.

### **Mapping and interpretation**

The final stage is mapping and interpretation and it is here that the links are made within the data and between themes to allow findings to be described and explained. In the descriptive accounts the researcher uses the organised data to identify key dimensions and maps the range of phenomena.

Explanatory accounts seek to explain patterns in the data and why those patterns occur. It is important that the construction of the findings based on the patterns and their explanation are clearly reported to allow to assess their validity and credibility (Ritchie & Lewis 2013)

The thirty-three interviews undertaken in this study created a large amount of data; Framework analysis was well placed to handle such large amounts of data. It also allowed a second researcher to easily examine and scrutinise the theme development providing credibility to the themes and the findings. Agreement about the themes was reached and this gave confidence to the development of the questionnaire for use in phase two of the study.

### **4.8. Phase 2 - Questionnaire Survey**

The purpose of the questionnaire was to quantify and present the level of agreement with the information and support needs identified in the interviews and to assess the level of and satisfaction with involvement in the treatment decision-making process.

The objectives of the questionnaire survey were:

- To quantify the themes and concepts arising from the interviews
- To facilitate transferability of information to the wider population of women over 75 years of age with breast cancer.

In this mixed methods study the questionnaire (See Appendix 14 for full questionnaire) was designed to quantify issues raised in the interviews and thus further illuminate the findings.

#### **4.8.1. Questionnaire Sample**

The sampling frame for the quantitative questionnaire survey phase comprised ten NHS breast cancer units in England and Wales.

All women in this study were  $\geq 75$  years and all had primary operable breast cancer the major difference was the type of treatment they received. In the UK population of women, 75 years and older with breast cancer 60% are treated with surgery and 40% with PET (Morgan et al. 2014a). This can be further broken down by age with those over 85 years of age 60% being likely to receive PET (Morgan et al. 2014a). Based on these figures it was possible to draw up a sampling strategy that would achieve an acceptable measure of representativeness.

#### **4.8.2. Sample Size Calculation**

Probability sampling requires the application of statistical procedures to ensure sufficient numbers, with the correct characteristics, to achieve representativeness in the sample. To increase the chance of trustworthy information a number of decisions need to be made before a sample size calculation can be made. The confidence interval, that is the range between which the total population parameter is expected to lie and the confidence level, the level of confidence that can be placed in the population mean of that parameter need to be decided. A confidence level of 95 percent is deemed acceptable for most studies however a higher level of confidence, usually set at 99 percent, is often required for medical research (Gray 2013)

A sample size calculation for this study was based on a population of 13000 (the number of women over 70 who are diagnosed with breast cancer) and a confidence interval width of  $\pm 5\%$  with a confidence level of 95%, 373 completed questionnaires would be required to give accurate information. With an ambitious return rate of approximately 65% (Ausch 1997) 573 questionnaires would need to be distributed. It was known that this target

would be unrealistic as previous studies in this area had closed prematurely due to poor recruitment (Reed, Wyld, Ellis, Bliss & Leonard 2009). Therefore a more pragmatic approach was taken and recruitment was set at 100. Whilst it is acknowledged that the evidence from an underpowered study provides weaker evidence in this mixed methods study the questionnaire is only a part of the evidence. The strength of the evidence based on this approach can only be determined once the analysis is complete (Gray 2013). Should the data show clear agreement on items within the questionnaire and with items in the interviews then this will provide a level of confidence in the findings. However, should there be gross disagreement then the findings will have little value (Gray 2013).

#### **4.8.3. Eligibility Criteria**

The eligibility criteria were the same as for the interviews.

Women were eligible if;

- they were  $\geq 75$  years, (the lower age at which PET is predominantly used),
- had been diagnosed with invasive breast cancer in the preceding 60 months and
- offered an initial treatment choice between PET and surgery (documented in the medical records).

Women were ineligible if;

- in the view of their Health Care Professional (HPC) they showed signs of significant cognitive impairment,
- they were unable to give informed consent or they had locally advanced or metastatic breast cancer as they would have a different set of experiences and characteristics.

Women were not excluded on the basis of language. Where an interpreter was required this would be supported with funding from the parent study.



## **4.9. Questionnaire Procedure**

### **4.9.1. Recruitment**

All of the five sites involved in the interviews were invited to participate in this part of the study. Five other sites also agreed to recruit patients subject to the necessary ethics and governance regulations being approved.

For those women who had taken part in the interviews and had given consent to be approached for the questionnaire, were sent a slightly different set of paperwork. This simply acknowledged their previous involvement, reminded them of their agreement to take part but also that they were free to withdraw should they wish to.

For those previously not involved the initial invitation, recruitment for the questionnaire was undertaken in a three ways, all of which had been given ethical approval via a non-substantial amendment (See Appendix 15). The patients were either approached in person by the HCPs at a routine check-up appointment, a telephone call made to their home or a direct postal invitation.

### **4.9.2. Administration of Questionnaire**

Study packs including the questionnaire, a combined letter of invitation and participant information sheet (See Appendix 16) and a freepost return envelope were sent to all sites.

Study site contacts were requested to record the age and treatment type of each patient they invited to complete the questionnaire. This was to allow the researcher to more fully understand the response and the non-response rates. This strategy was not completely successful and is discussed further in article 3 in chapter 6.

## **4.10. Questionnaire Development**

Questionnaires are a commonly used method of collecting information about participants' attitudes, knowledge, beliefs and behaviour (Boynton & Greenhalgh 2004).

Initial consideration needs to be given to the information required to answer the research question. What questions need to be included? Every question included should have a purpose and provide information relevant to the study (Oppenheim 1992). Whilst it is tempting to add additional questions because 'they might be useful' this should be avoided. What type of response is required? Should open and/or closed questions be used? Deciding on the questions and the way in which they are asked are crucial to the success of the data collection and are heavily influenced by the topic of the study and the sample population (Tod 2006).

In the same way that interviews are categorised as structured or semi structured, so are questionnaires. Structured questionnaires contain standard questions with a pre-coded response choice frequently used. Unstructured questionnaires are used in exploratory studies and create qualitative data (Bowling 2009). Both categories of questionnaire can be administered via a face to face meeting with a researcher, via telephone or by postal self-administration and each has strengths and weaknesses.

The strength of structured questionnaires is the potential to collect large amounts of unambiguous quantitative data that is easy to analyse (Boynton & Greenhalgh 2004). Including a pre-coded response choice allows the use of a 'tick box', reducing participant burden and allows those with reduced hand dexterity to participate more easily. These are potentially important issues in this study with older women,

However, structured questionnaires can place significant cognitive demands on participants. Participants require comprehension skills to understand the instructions surrounding the questionnaire and the questions, recall and memory skills and the ability to link the question with the retrieved information (Bowling 2009). The wording and type of questions i.e. open or closed questions, and the flow of the questions, need careful consideration. Using familiar language and words to ask the questions will reduce the cognitive burden and facilitate participant response (Oppenheim 1992). Words used in questionnaires can be a source of ambiguity. Oppenheim cites the example of the term 'tea' as one that has different meanings

depending on the culture and geographical location. For some, tea is a drink taken any time of the day, for others it is the meal taken at the end of the day. Still further discrepancy arises as for some the meal taken at the end of the day is referred to as dinner. It is important therefore to make sure the words are within the participants' frame of reference, which can be assessed during the piloting of the questionnaire. Forming questions that are preferably less than 20 words, grammatically correct and free of spelling errors will encourage participation. It is important that all questions asked are done so politely demonstrating respect and an understanding that the participants are giving their time to the study (ibid)

Dividing the questionnaire into sections with questions about a particular aspect of the study grouped together will allow the participant to concentrate more fully and provide a more considered response. Sections of the questionnaire should be introduced by providing an explanation as to why the questions have been included and reassurance that there are no right or wrong answers (ibid)

Providing clear, consistent instructions about how to indicate their answer to the questions, and what to do when they have completed the questionnaire will reduce participant burden and enhance completion and return rates. Seemingly minor details such as neatly placing tick boxes in the same position on the page make the process of completing the questionnaire an easier task (ibid). Providing a freepost envelope in which to return the questionnaire will also enhance the return rate (Dillman, Smyth & Christian 2014).

The final presentation of a self-completion questionnaire is important and possibly more so for postal distribution. A well laid out questionnaire, using colours and high resolution pictures or other graphic, printed on good quality paper gives a sense of importance and value to the study. Without initial visual attraction, a well-designed questionnaire may be disregarded without the participant ever taking the first step to complete it (Bowling 2009).

All postal questionnaires require an accompanying letter from the researcher giving the outline to the study and politely inviting them to take part. The

letter should explain why they have been invited, what will happen to the data and confirm the confidentiality of the information provided and that there will be no detrimental consequences should they choose not to take part.

#### **4.11. Development of the Study Questionnaire**

Each of the items in the above section was considered in the development of the questionnaire for this study. Given the age range of the study population particular attention was paid to the use of language and to the layout and presentation of the questionnaire. Over time the meaning of words change and this may lead to confusion. It is now common for doctors, nurses, physiotherapists etc. to be referred to as 'clinicians' or 'health care professionals' but in this questionnaire 'doctor' and 'nurse' were chosen as these would be more familiar and meaningful to this older population.

It was important to convey to this group of older women that the questionnaire was about them and their views, and so the questions were phrased to emphasise the personal often using statements prefaced with the word 'I'. For example 'I wanted to know....' or 'I was helped....'.

A photograph of a, smiling older woman was placed on the front page to signify relevance and portray a user friendly questionnaire. Since some of the questionnaires would be delivered without warning it was important that the women were clear of from where and whom this was sent. All questionnaires and letters had the study logo and more importantly the header of the recruiting hospital; the hospital where they received their treatment and therefore a place with which they were familiar and trusted.

Although Oppenheim (1992) and Bowling (2009) recommend that the demographic data is collected at the end of the questionnaire, in this study this was collected on the first page. These questions could be considered as 'warm up' questions. They were simple questions which required very little recall or any decision-making as they were factual questions about age, type of treatment, level of education and the ethnic group they belonged to.

Adjusting font size and colours to accommodate any visual impairment and giving consideration to the manual dexterity required for writing will further

enhance response. To reduce writing burden pre-coded responses can be used; however this creates the problem of 'forced' responses. Pre-coded responses may not provide an option that the participant would choose and they are therefore forced into an inappropriate answer that does not truly represent their view. This has implications for the quality of the data.

All of these issues were carefully considered in the development of this study's questionnaire as the participants were older women who had to contend with some or all of these issues.

To obtain the data required, the questionnaire needed to be completed by women 75 years and older with primary operable oestrogen receptor positive breast cancer across the country. Therefore a postal, self-administered questionnaire was the most efficient and cost effective method. Despite some of the potential problems of postal surveys in terms of lower response rates (compared to face to face completion), the inability of the participant to clarify questions and the lack of control over who completes the questionnaire, there are a number of advantages for both the participant and the researcher. In this study, participants were not known to the researcher and the questionnaires were anonymous, reducing the pressure of social desirability i.e. giving answers that present a positive image when this is not the participant's view (Bowling 2009). When completed at home, participants have the luxury of time and flexibility as they are able to complete it in stages and in any order they wish (Bowling 2009).

A concise, clearly written letter of invitation along with the questionnaire and a pre-paid reply envelope were included as these are all known to enhance response rate. (Bowling 2009)

#### **4.12. Attitudinal Measurement Scales**

Assessing the different elements required the use of differing pre-coded response scales. The response options were kept simple with dichotomous 'yes/no' being used to ascertain the usefulness of some of the items listed. It was important to also give the option of 'unsure' to avoid forcing the women to make inappropriate choices. Other sections of the questionnaire required

confirmation of information and so statements were offered and the participant selected the most appropriate.

Embedded within the questionnaire were two validated scales, the modified Control Preference Scale, (CPS) (Sutherland, Llewellyn-Thomas, Lockwood, Tritchler & Till 1989; Degner et al 1997) and the Decision Regret Scale (DRS), (Brehaut et al. 2003). The CPS assesses the 'degree of control an individual wants to assume when decisions are being made about medical treatment' and asks the patient to indicate which of the statements most accurately described the role they preferred to play in the decision-making process and role they actually achieved. The DRS (Brehaut et al 2003) was designed to measure regret after healthcare decisions and uses a Likert scale. Two other questions within the questionnaire were open to a graded response and so the Likert scale was also used for these. (See Appendix 14 Section 5 Questions 3&5).

In attitudinal measurement, i.e. the measurement of people's beliefs, feelings, etc. on a scale of positivity to negativity, the Likert scale is the most commonly used. The scale contains a series of opinion statements in which the participant is asked to state their level of agreement or disagreement with each of those statements. There are generally five points along the scale from favourable / positive responses through to unfavourable or negative responses. For example the response options for the statement 'I regret the choice I made' are 'strongly disagree' 'disagree' 'neither agree nor disagree' 'agree' 'strongly agree'. The Likert scale is easy to use and analyse and provides ordinal level data. A score can be calculated from Likert scales with each response being allocated a value with higher values generally being assigned to favourable evaluation. The major disadvantage of this type of scoring system is that a total score can be derived from different configurations of the responses. This is not an issue for this questionnaire as scores are not required. (Bowling 2009)

#### **4.13. Questionnaire pre-piloting & piloting**

A draft questionnaire was developed based on the findings from the literature review, interviews and the expert opinion of members of the BTAG team.

Members of the BTAG trial management group, including members of the North Trent Cancer Network Consumer Research Panel (NTCNRP) were then invited to comment.

The questionnaire was then piloted with members of the North Trent Cancer Network Consumer Research Panel. Members were asked to comment on the content, length, flow, ease of administration, clarity, comprehensibility and overall acceptability of the questionnaire. Table 4.1 shows the amendments made based on the feedback from the pre-piloting and the piloting.

**Table 4.1: Feedback from the pre-piloting and piloting**

<b>Issue raised</b>	<b>Actions taken</b>
Questionnaire is too long.  Some repetition in questions. The same questions being asked in different ways.	14 questions from section 3 which were felt to be repetitive were removed.
GP missing as a source of information giving.	Added GP to section 2.
Need to include a statement regarding the use of general or local anaesthetic for the operation.	Item added - "if I could be asleep (general anaesthetic) or wake (local anaesthetic injection) for the operation"
Section 3 - it would be useful to understand why women were unsure if they were offered a choice.	Free text box added to section 3.
Text box after the control preference scale in section 3 is not required.	Free text box removed.
Would be useful to allow women to say more about their answer in final question in section 3.	Free text box added.
Section 5 - need to split question which include doctor and nurse together.	Additional response item, "Face to face chat with a nurse" was added.
Videos to show what would happen when they go into hospital are available and might be useful.	Response added to include "I would like to see a video of what happens when you come into hospital for an operation"
Six questions required additional words to clarify the meaning.	Words added



#### **4.14. Psychometrics of the questionnaire**

##### **Content validity**

The content was derived following a review of the literature, findings from the interviews, with input from experts within the BTAG research team and members of the (NTCHRP).

##### **Face validity**

Face validity was confirmed during the piloting of the questionnaire when members of the BTAG research team and members of the (NTCHRP) were asked to identify any missing or irrelevant items.

##### **Criterion or concurrent validity**

It was not possible to assess the criterion validity as this was a bespoke questionnaire and there were no other validated questionnaire against which to examine.

##### **Construct validity**

Construct validity assesses abstract constructs such as pain. This questionnaire did not measure any abstract concepts therefore it was not assessed.

##### **Reliability**

Test-retest reliability was not assessed due to the small numbers involved in the pilot study. There were also concerns about the extra burden placed on the members of the NTCNRP.

The final questionnaire can be found in Appendix13

#### **4.15. Questionnaire Analysis**

Demographic and limited number of clinical characteristics of the responders to the questionnaire were summarised using appropriate descriptive statistics. Five of the six sections of the questionnaire were analysed using descriptive statistics and sixth section in the free text boxes were subjected to framework analysis and included in the convergence coding matrix.

Questionnaire responses were compared according to treatment, modality (i.e. surgery or PET) using chi-squared tests for categorical responses or where not valid Fisher's exact test, and the two-independent samples t-test for continuous responses. The association between age and the preferred media for information support, format, level and type of risk information was also examined, using Fisher's exact test.

#### **4.16. Mixed Methods Analysis**

Integration of data is an essential component of mixed methods research (Creswell, Fetters & Ivankova 2004). To ensure integration of the findings from all components of the study a triangulation protocol was used in this study. The word triangulation can be confusing as it has two meanings. It is used to describe the corroboration between two sets of data i.e. one data set supporting the other. However, the alternative meaning of gaining a more complete picture of the issues under investigation was used in this study (O'Cathain, Murphy & Nicholl 2010). Triangulation also contributes to the validity of the research findings where there are multiple sources of data (Famer et al. 2006). Triangulation takes place at the interpretation stage of the study with the data sets first being analysed separately. Once the findings are known, the researcher then examines them to see where they converge or agree, i.e. complement each other, or where they contradict, also referred to as dissonance or discrepancy.

Integrating the large quantities of data that a mixed methods study produces can be problematic (O'Cathain, Murphy & Nicholl 2010). Making the process of analysis clear to the reader requires a systematic approach to the handling of the data. Farmer and colleagues (2006) describe the use of a 'convergence coding matrix' that clearly demonstrates the integration of the findings from each source of data. This technique requires the researcher to assess where there is 'agreement', 'partial agreement' or 'dissonance' across the findings. Dissonance refers to disagreement in the findings and indicates the need for further exploration but not that there are flaws in the study (O'Cathain, Murphy and Nicholl 2010). This technique also includes a 'silence' code to describe where findings exist about a topic in one set of data but are absent in another.

Convergence coding matrices were developed for each of the research questions and the study objectives.

The following chapter is the second article that forms part of this Article-based PhD and was published in *Psycho-Oncology*. It reports the findings from the interview phase of the study.

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## Chapter 5: Article 2

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## **5. Chapter 5: Article 2**

'The information and decision support needs of older women ( $\geq 75$  yrs) facing treatment choices for breast cancer: a qualitative study'

The aim of this article was to present findings regarding the preference for information when faced with a treatment choice and the preferred decision-making styles of these older women. This article reports the qualitative component of this study to meet study objective 2 'to elicit the information needs and preferences of older women ( $\geq 75$  years) with operable breast cancer to treatment options; surgery (plus adjuvant endocrine therapy) and PET'.

This article builds on the literature review and offers an original contribution to the current knowledge base.

I am the first author on this paper as I led on the development of the participant information packs and topic guide, liaised with the breast clinic staff to facilitate recruitment; I conducted the interviews, developed the analysis framework and wrote the article. My co-authors contributed in advising on the participant information packs, the topic guide, acting as second reviewers in the analysis process (KL) and provided input on the structure and writing of this paper.

## The information and decision support needs of older women (>75 yrs) facing treatment choices for breast cancer: a qualitative study

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### Abstract

**Objective:** Primary Endocrine Therapy (PET) is a good alternative to surgery for breast cancer in older frailer women. Overall survival rates are equivalent although rates of local control are inferior. There is little research regarding the decision support needs of older patients faced with this choice. This qualitative study aimed to explore these among older breast cancer patients offered a choice of treatment, as the basis to develop an appropriate decision support tool.

**Methods:** Semi-structured interviews were undertaken with older women (>75 years) with breast cancer who had been offered a choice of PET or surgery at diagnosis. Women's involvement in their treatment decision and support for the process were explored and analysed using framework analysis.

**Results:** Thirty-three interviews were undertaken (median age 82, range 75–95 years, 22 PET, 11 surgery). Most women, regardless of treatment choice, wanted tailored information about the different treatment options, their impact on independence, the practicalities of treatment and the risk of recurrence and spread. Surgery was the treatment of choice in women wanting optimal disease control; those choosing PET felt that they were 'too old' for surgery and wanted minimal disruption.

**Conclusions:** Older women described making active treatment decisions. However, some knowledge was inaccurate. Women wanted information and decision support from their clinicians along with a specific tailored information booklet to support this process.

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### Background

Breast cancer affects 13 000 UK women over age 70 annually and causes the deaths of 6733 per year [1]. Patients over 70 years of age have seen less than half of the reduction in breast cancer mortality compared to younger women [2].

The standard care for early breast cancer is surgery [3]. However, some older women may be judged too frail or ill to tolerate surgery and may be offered primary endocrine therapy (PET) for oestrogen receptor (ER) positive breast cancer. This is the use of anti-oestrogen tablets, omitting surgery altogether. Approximately 40% of women in the UK, over the age of 70, are treated with PET [4]. Randomised trials have shown that PET has equivalent overall survival rates when compared to surgery (and adjuvant endocrine therapy), although rates of local disease control are inferior and therefore appropriate patient selection is important [5,6].

No guidelines are available to aid clinician or patient choice between surgery and PET in the treatment of older women. The decision is therefore both medically complex and potentially sensitive as it may involve discussion of life expectancy and trade-offs of reduced cancer control in return for reduced surgical morbidity (pain, disfigurement, etc.).

There is some published research regarding the information needs of older women with breast cancer. The most important include the likelihood of cure and the risk of metastatic spread [7–9] regardless of patient age. Additionally older women request age-specific treatment and prognostic information [10,11].

Presenting complex material to people who have limited knowledge and possibly declining cognitive function is a challenge. Poor health literacy, reduced word and numeracy fluency [12], poor comprehension of written information [13], and impaired hearing and eyesight may impact on an older person's ability to access and assimilate information.

This in turn may affect their ability to make an informed treatment decision [14]. Two studies have reported that older women undergoing cancer treatment want information in the form of booklets with brief explanations of the risks and benefits of treatment which include clear diagrams and are free of medical terminology [10,15].

There is limited evidence of the preferences for treatment decision making in older women with breast cancer [16,17]. There is a trend for older patients to prefer their clinician to make the final treatment decision, and this trend increases with age [18,19].

A previous study [20] indicated that older women faced with a choice of surgery or PET for the treatment of breast cancer relied heavily on the health care professionals (HCPs) for treatment information and reported listening for hints from the medical team to detect what treatment was being suggested. The main concerns were disfigurement, the impact on their independence following surgery and a general fear of hospitals and operations. These women demonstrated complete trust in the HCPs recommendations, which is likely to be a product of the paternalistic view this generation have of the health service.

Although just under half of older women (>70 years) in the UK are treated with PET [4] there are few resources to aid in making a choice between surgery or PET. Breast Cancer Care, a charity devoted to patient information, has no guidance on this choice for older women (<http://www.breastcancercare.org.uk/>). Similarly there are no specific NHS leaflets with information for older women faced with a choice of surgery or PET.

The following multicentre UK study aimed to determine the information needs and preferences for this age group of women relating to the choice between surgery and PET. The ultimate aim being to use this evidence to develop decision support for this underserved group.

## Methods

Research ethics approval was obtained from the National Research Ethics Service (12/LO/1722) and research governance approval from 5 UK hospitals. Women were eligible if they were  $\geq 75$  years (the lower age at which PET is predominantly used), had been diagnosed with invasive breast cancer in the preceding 60 months and offered an initial treatment choice between PET and surgery (documented in the medical records). Eligible women were invited to take part in semi-structured interviews either when attending clinics or by letter. An interview topic guide was developed from the literature with input from members of the North Trent Cancer Network Consumer Research Panel [21]. Topics included: sources of information they used, desired or would have preferred, factors that influenced their treatment choice, how and who made the treatment decision and their views on computers/the internet/CDs & DVDs in information gathering.

Informed written consent was obtained from all participants. The interviews were digitally recorded and transcribed verbatim. The Framework approach was used to analyse interview data [22]. Framework analysis involves five steps, familiarisation, theme development, indexing, charting and interpretation analysis and was independently performed by two experienced qualitative researchers (MB/KC) with supplemental analysis by two patient representatives (both former breast cancer patients and members of a recognised patient group [23]). Recruitment ceased once data saturation had occurred.

## Results

Interviews were undertaken between April and December 2013, with 33 purposively selected older women (median age 82, range 75–95 years) with breast cancer who had been offered a choice of PET or surgery at diagnosis. These women were between 3 and 60 months from diagnosis (median, 20 months). Twenty-two women received PET (median age, 83 years, range 76–91), and 11 underwent surgery (median age, 82 years, range 75–94) (9 mastectomy, (Mx) 2 wide local excision, (WLE)). Interview duration ranged from 23 to 85 min (mean 50 min). The Framework analysis categorised the data into three themes:

- Theme 1—The impact of discovering breast cancer
- Theme 2—Treatment decision making
- Theme 3—Information—use, preferred content and format

### Theme 1: The Impact of discovering breast cancer

The women interviewed either had breast cancer identified as a consequence of investigations for other illnesses or had themselves discovered changes to their breast. Some ( $n=17$ ) women talked of being shocked, frightened and worried when discovering a breast lump and immediately sought medical advice.

Other women ( $n=11$ ) appeared less concerned and mentioned breast symptoms only when attending their general practitioner for other reasons. Several women waited until their domestic situation changed, e.g. caring for a husband, before seeking medical advice. The possibility of symptoms being breast cancer was the first thought of some women, and most were fatalistic about this, as illustrated by these two participants:

‘.. I thought, ‘.. I’m going to die with this, so we’ll base it round that’. (85 yrs, PET)

‘I just thought I have cancer and I wasn’t bothered about it because let sleeping dogs lie. The less you know the less you bother about it..’ (90 yrs PET)

## Information and decision needs of older women with breast cancer

Those who had experienced the death of a friend or family from cancer had distressing memories of the illness and the treatment. These experiences significantly contributed to the treatment decisions they made as seen from this extract:

'I just kept saying, 'Do what you've got to do, do what you've got to do'. We lost a daughter-in-law with breast cancer, she was only 26, and that's 30 years ago.. she would have still been alive if they'd have taken it off.' (84 yrs, WLE)

### Theme 2: Treatment decision making

The second theme to emerge was how breast cancer treatment options were considered and decisions made among this group of women. Most ( $n=22$ ) women said that they had been given a choice and were pleased with their discussion and involvement in the decision making process.

However, others said that they did not wish to make a choice themselves as they feared making the 'wrong' decision. Several women felt that treatment should be decided by the doctors who had specialist knowledge of breast cancer.

A small number of women ( $n=5$ ) also reported asking the HCP which treatment option they would recommend. This resulted in either, a direct recommendation, a refusal to recommend or a subtle recommendation within the offer of a choice of two options as can be seen from these extracts:

'..you're a bit gobsmacked [when they give you a choice] you don't know what....' well obviously, he deals with that all day and every day so I just said, 'Well what do you advise?' ..I mean what do you see these people for if not to take their advice?' (81 yrs WLE)

'I said 'well I don't know, what would you do?', very diplomatically she [nurse] said 'well if I was advising my mother I would advise her to have the tablets', which I thought was a nice way of putting it without directly telling they advised so that's what I did.' (80 yrs PET)

When asked who made the final decision most women felt they had ( $n=24$ ). Some had decided based on verbally received information and discussion with the HCP and so this could be seen as a shared decision. Eight women eventually had their decision overtly made for them as four has a medical condition precluding surgery and the other four could not make a decision themselves. Others ( $n=19$ ) made immediate decisions on preconceived ideas of surgery or cancer often related to previous cancer treatment experience of family or friends.

Fourteen women said that they had thought about what treatment they would want or not want prior to receiving a

cancer diagnosis or having a discussion with a HCP. This woman was typical of some:

'... I'd already made my mind up because I knew it was cancer...—you know in my own mind and made my mind up that I was having the breast taken off.' (80 yrs Mx)

It was common for women who said they had made their own decision to want the approval of the HCP for their decision, as this woman said:

'He [Surgeon] seemed pleased with my decision.' (76 yrs, Mx)

After arriving at a decision almost all women stated that they were either 'satisfied' or 'happy' with their treatment choice. Only one woman was dissatisfied with her treatment choice and said that in hindsight she would have chosen mastectomy instead of a WLE because she could have avoided travelling for radiotherapy.

It was evident that most women chose PET to avoid surgery. The reasons for this being, their age, feeling physically or mentally unable to withstand surgery, fear of surgery or anaesthesia, impact on independence and for a small number the belief that surgery would stimulate other illnesses. As these women said:

'I was extremely tired,... and I knew I couldn't cope with surgery. I thought if there was any alternative, I would like to go for that.' (80 yrs, PET) ..

I decided the years I've got left... I'm not messing about going into hospital...' (95 yrs, PET)

Women talked openly about not being afraid of death. There was an implied assumption and acceptance amongst this group that having PET might result in them dying sooner than if they had chosen surgery with many stating that they would have chosen surgery had they been younger. Women who chose PET said it had no negative impact on their lives as most of them already took regular medication so having an extra tablet was not viewed as problematic.

The words 'get rid of it' were frequently associated with women's reasons for choosing surgery. This woman's comment was typical of surgery patients:

'my reaction immediately was 'get rid of it'...cut it off' (79 yrs, Mx)

Some women chose mastectomy and not WLE to avoid further treatment particularly radiotherapy. As one said:

'Right, I said, 'let's get rid of it, at my age,' so I went for a full (mastectomy). But if I [h]adn't have had a [mastectomy] I'd have to have had radiotherapy...' (75 yrs, Mx)



One patient chose surgery as she was not convinced that PET would be effective.

Several women felt that they were 'steered' towards a particular treatment, i.e. younger women towards surgery and older women towards PET. However, seven women had chosen not to take what they perceived to be the doctors' recommendation.

All the women interviewed stated that the information they received at diagnosis was given verbally by the clinician and for most this was supplemented by a general breast cancer treatment booklet and discussion with a breast care nurse (BCN). Some ( $n=14$ ) felt they had received enough information, written or verbal, to make a decision. Whilst some reported receiving 'lots of information' in booklet form, others did not recall being given any. The women were divided in whether they read the information. Some decided they would not read it as it was frightening or they trusted the doctors and therefore had no reason to read it. A small number said they read everything ( $n=7$ ). Only two women at the younger end of the age range sought further information, one bought a book about breast cancer and another used the internet.

In addition to reading the information given, being able to discuss treatment options with the HCPs was appreciated. Those women who were asked during the interview if they received enough written information would respond by saying they would have liked more discussion. It was rare to ask for more written information.

When asked by the researcher most women found it difficult to articulate what information they needed to make a treatment decision. It was only with significant prompting and further questioning that they were able to identify items.

### Theme 3: Information—use, preferred content and format

Most women, regardless of treatment choice, wanted details about the different treatment options and most importantly their impact on physical function, self-care and the practicalities of treatment, e.g. travel arrangements for appointments, prescription collection and post-op care.

Women wanted targeted information that was personal to them and presented in an uncomplicated jargon free style, as these women said:

'I didn't want to go and talk about somebody else's operation or care because that wasn't mine. I wanted to know about myself' (87 yrs, PET)

'You see if they get big words and things like that... well you lose interest don't you?' (76 yrs, Mx)

Some women felt that they did not need additional information other than that received verbally from the

HCPs. There was little desire for large volumes of information. As this woman said:

'.. why would you need all the other information? It's only extra worrying.' (81 yrs, PET)

There was a general consensus that an information booklet comprising the advantages and disadvantages of each treatment option would have been a helpful adjunct to the understanding the options following the consultation.

During the interviews women were shown various formats of breast cancer information (booklets, option grids, DVDs, CDs and internet). Written information in the form of a booklet and an option grid were the preferred formats.

Option grids are one page tools that summarise information and compare different treatment options in a 'frequently asked questions' format, presented in everyday language [24]. The women liked the succinct content and presentation style of these grids:

'.. when you've read about six pages you put it down.... and as you get older them six pages you never get past because you keep reading the same ones. By the next day you've forgotten what it's saying. Yeah, that's good that because it gives you all your questions?' (94 yrs, Mx) ... I like this [option grid]. I think it is very clear.' (79 yrs, Mx)

Of the women interviewed 10 stated they had access to the internet but only 5 said they used it, and this was primarily for shopping or communicating with family and friends. One woman attempted to acquire additional information about treatment options. The large volume and lack of confidence in the credibility of the health information sites were cited as barriers.

When asked about finding breast cancer information this woman said:

'I've got it, [internet] but I don't bother about it very much.....'No, it would be the last thing I'd do [go to the internet]. (80 yrs, PET)

There were also issues around having and retaining the ability to use computers and navigating the internet:

'I'm on the internet and I do emails... but I'm not very good at it. (75 yrs, Mx)

The CD/DVD format was not favoured by most of the women because they did not own a CD/DVD player or lacked confidence to use.

Women were shown examples of bar charts, pictograms, frequency and percentage displays and asked whether they felt these helped their understanding of the risks and benefits of treatment options. All said they did not add to their understanding and for some they were confusing or frightening.

Photographs of women post-operatively were disliked; however, simple diagrams showing post-operative scars were felt to be informative.

### Discussion

In line with previous studies [10,11] there was a general consensus regarding the information women required when considering different treatment options for breast cancer. Information of greatest importance was the impact of treatment on self-care and physical function. Additionally information on the timelines for treatment events, e.g. dates of surgery, length of hospital stay and the practicalities of treatment, e.g. would they need care after surgery, where would they get their medication, were of high importance.

The current literature is contradictory with regard to the amount of information older women desire to facilitate treatment decisions. Some studies report that older people want less information [25], others that their information needs are similar to younger women [26]. This study found the level and amount of information desired were variable but tended towards limited amounts which was received verbally and supported by written text. In line with the findings of Jing-Wen Jong *et al.* [10] this study found that women who reported having *discussed* the information they received were also likely to state that they played an active or shared role in treatment decision making. The opportunity to discuss treatment options was also associated with women expressing high levels of satisfaction with the quality of their care.

Previous studies point to older patients being more passive in decision making [4,20,27] with a tendency to delegate responsibility to their doctors, family and friends [28–30]. Many of the women in this study stated that they made the final treatment decision but also reported the need for reassurance or approval for their decision from the HCPs. It is possible that their view of the decision making process represents the lack of an imposed treatment by the doctor but may still reflect the preference of the doctors or other HCP [31]. The impact of patients' choice on surgical rates in older women was investigated by Lavelle *et al.* [32] who conclude that actively opting out of surgery is unlikely to be the reason fewer older women undergo surgery. This study found that older women wish to be active decision makers with women frequently reporting making an instant decision about their treatment choice either before a confirmed diagnosis or immediately after. Making a decision quickly was something that many women either felt was expected by the HCP or was a personal need to have a plan to deal with the threat and uncertainty of breast cancer [33].

Information is a pre-requisite for informed decision making [9,34,35]. Although there is a large amount of

literature to inform younger women faced with treatment choices in early breast cancer there is little that addresses the specific needs of older women. All women interviewed said that they had received enough information, and in line with other studies did not seek further information [7,30] but for some the written information was sometimes overwhelming [31] with much of the content not of interest to them. Faced with large amounts of unfamiliar and complex information or where decisions require high levels of cognitive processing (e.g. trade-offs), short-cuts in decision making are made [36]. To reduce the cognitive load a familiar, concrete item becomes the focus of the decision making at the expense of possibly more beneficial items being included in the decision. In this study women focussed heavily on the practicalities of treatment, e.g. the need to travel for radiotherapy, who would care for them after surgery, the need to care for a husband and ignored important factors such as the benefits of the other options.

To capitalise on the experiential style of decision making used by this group of women [36–38], it is necessary to identify the most effective format, content and presentation of information. Making information more familiar and accessible by using clear, jargon-free language with the addition of uncomplicated diagrams will enhance the women's ability to make informed choices.

Simply reducing the amount of information given, making the unfamiliar more inviting and 'tailoring' the information to the individual can help to increase patient understanding and aid in decision making. Hawkins *et al.* [19] identified the need for more specific information for older people with cancer and suggest that risk should be tailored to the individual as general statistics do not provide the desired information. However, identifying the most effective way to describe risk and benefit is difficult since the literature is conflicting. Graham *et al.* [38] support the use of words with quantification, whilst Fausset & Rogers [13] suggest percentages best communicate risk and benefit, particularly for people with a lower numeracy level, a category into which many older people are said to fall [39]. In this study there is some evidence that words are preferred to numbers, but the women were largely uninterested in this type of information. For most women statistics and/or graphs were not regarded as helpful, meaningful or of interest and occasionally thought to be confusing and frightening.

It is acknowledged that a retrospective study, particularly one involving older people, will always be subject to inaccurate recall of events and details. However despite this there is confidence in the data collected as many of the items raised were common amongst the women. The time lapse and the significance of the event also add strength to the findings. The seriousness of breast cancer will make this a prominent issue in their lives and one which they appear

to think of often. The time lapse also provides time to reflect on and evaluate the handling of the cancer and how it has affected their life since leading to more measured responses.

## Conclusions

The findings indicate that women want clear, succinct, tailored information in a format that is familiar and easy to use. Booklets, free of medical terminology, with careful

use of graphical representations and simple diagrams are required. Most importantly women want the opportunity to discuss the information with an HCP.

This qualitative study has provided a rich description of the information needs of older women faced with a choice of surgery or PET for breast cancer and provides the foundation for further studies. The information will provide the basis for the design of decision support tools for older women faced with this choice in the future.

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## Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web-site.

### **5.1. Reflective review of Article 2**

This section presents a reflective review of article 2 post-publication and provides additional detail that it was not possible to include in the publication due to the scope of the author's guidelines of the journal.

#### **Critical commentary**

The article was reviewed using the NICE Quality appraisal checklist - qualitative studies (2012) (See Appendix 5 for the details of the review).

The article was shown to be of good quality. Less strong areas included the limited level of detail of the recruitment procedure, the lack of justification for the research methods chosen and no examination of the relationship between the participant and the researcher. These omissions are addressed below but were largely due to the limited word count and the focus of the journal.

#### **Recruitment**

Women were approached by clinical / research staff in the breast clinics. These staff reported that they had discussed the study with a number of women and given them a study pack including a reply form, but the number of and which women were not recorded. Therefore, it was not possible to know how many were women approached or to send reminders about the study. Therefore only details about the participants who actually volunteered were available.

It is unfortunate the number of women approached and their demographics were not available as this would have provided information about the sample and the women who decided not to volunteer. Tetley, Grant & Davies (2009) highlights how older people are often excluded from research activities. It is only in recent times that older people have been invited to participate in studies, and there appears to be a nervousness and suspicion surrounding the word 'research'. This was evidenced in some of the interviews where women confessed to being worried about what was expected of them or that they what they had to say was not helpful. There is still work to do to make research more transparent and appealing to older women.

## **Rationale for the choice of data collection method**

The rationale for the choice of interviews stems from the qualitative methodology used in this study. Qualitative research aims to provide a detailed description of the topic under exploration from the perspective of the participants. This method of data collection ensures the concepts and/or theories are grounded in data.

Semi-structured interviews are ideally suited to fulfil these aims. The conversational style interviews used in this study allows the participant to tell their story using the familiar act of talking, and the researcher attempts to make the interview a comfortable and non-pressurised event. Story telling during interviews also triggers memories and provides a richer description of the topic (Davidson 2004). A more detailed examination of interviewing as a method of data collection was given in chapter four of this thesis.

## **Acknowledging the position of the researcher**

Detailing the role of the researcher within a qualitative study is difficult to achieve within the permissible word count of the journal *Psycho-Oncology*.

An important aspect of rigor in qualitative interviews is that the researcher acknowledges and makes public his or her perspectives or 'biases' so that their influence on the interpretations of the data can be judged (Frank 1997). This process is termed reflexivity that has been described as

*"..... an integral process in qualitative research whereby researchers reflect continuously on how their own actions, values and perceptions impact upon the research setting and can affect data collection and analysis"*

(Gerrish & Lacey, 2006 pg 346).

The making public of the researcher's reflexive position is done through providing an account that reflects on the process of the data generation and analysis. Throughout the interviews I was very conscious of how my demeanour and attitude could affect the interviews. It is key that researchers are organised and prepared for the interview (Legard et al. 2013) and I feel

that this was the case. Each interview added to the next in terms of how to raise questions and probe issues raised without 'grilling' the participant.

The qualitative approach to uncover the multi-layered realities of the social world made it important for me not to be rigid in my approach to interviewing. This meant there was sometimes a tension between being flexible with the questioning and straying away from the point. I am aware this did happen on occasions, but I also found that this often triggered memories and allowed the participant to provide greater insight. Allowing the women to speak 'off track' provided space to talk to someone who was interested in their illness and let them enjoy it as a social occasion. As the interviews progressed I learned to say less, control my natural instinct to convey agreement or overly encourage a statement. I did however use information, anonymously, from other interviews or create imaginary scenarios to encourage thinking about a topic, particularly when the interview was stalling. Despite some, from a more positivist perspective, considering such practice inappropriate, it is seen as a legitimate way to conduct qualitative semi-structured interviews (Kvale 2007).

As a HCP it is a natural reaction to try to help or provide guidance about a problem a woman might raise (Tod 2006). Women in the interview would sometimes raise a problem with the prosthesis or with the side effects of the drugs or the lack of movement they have in the shoulder, and I naturally wanted to offer support or direct them to appropriate services. It is recommended that roles are strictly separated and I continued throughout trying to remain within the researcher role (Tod 2006). However, it is important to show genuine interest and a degree of reciprocity of information to develop a good interview relationship, and I felt my open, flexible approach assisted in achieving these things.

I acknowledge that my gender, maturity and extensive experience as a HCP and as a researcher were a factor in interviewing the women in this study, and feel that they were advantageous (Stevens, Abrams, Brazier, Fitzpatrick & Lilford 2001) I have a great deal of experience of talking to patients in the hospital setting and from previous research with older people. I feel my age conveyed a sense of credibility and of someone with experience of the world,

and this, including being a woman, allowed an easy rapport to develop with these older women who arguably could feel more comfortable talking on this topic with someone of the same sex. Gaining an understanding of breast cancer services and attending clinics where women were given a diagnosis and the treatment options discussed gave me very valuable insight into the experience of the women and gave me confidence to conduct the interviews.

The interview findings reported in this chapter informed the development of the questionnaire and the also contributed to two further papers, '*The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer*' and '*Understanding older women's decision-making and coping in the context of breast cancer treatment*'.

The following chapter is the third article that forms part of this Article-based PhD and was published in *Psycho-Oncology*. It reports the findings from the questionnaire phase of the study.



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## Chapter 6: Article 3

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## 6. Chapter 6: Article 3

Burton, M., Kilner, K., Wyld, L., Lifford, K. J., Gordon, F., Allison, A., ... & Collins, K. A. (2017). Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer. *Psycho-Oncology*.



The aim of this article was to present results from the quantitative component of this study that further established older women's preferences regarding receiving information about breast cancer treatment options (surgery or PET) and quantified issues raised in the interview study. Other results reported a quantification of women's preferences regarding the presentation of information; and established their preferred DM styles.

This article builds on the literature review and qualitative study offering an original contribution to the current knowledge base.

I am the first author on this paper as I was a major contributor to the development of the questionnaire, to the participant information packs and I liaised with the breast clinic staff to facilitate recruitment. With support from statisticians I cleaned and analysed the questionnaires and wrote the paper. My co-authors contributed in advising on the questionnaire development and analysis, by acting as second reviewers in the analysis process (KK) and provided input on the structure and writing of this paper.

## PAPER

# Information needs and decision-making preferences of older women offered a choice between surgery and primary endocrine therapy for early breast cancer

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## Abstract

**Objectives:** To establish older women's (>75 years) information preferences regarding 2 breast cancer treatment options: surgery plus adjuvant endocrine therapy versus primary endocrine therapy. To quantify women's preferences for the mode of information presentation and decision-making (DM) style.

**Methods:** This was a UK multicentre survey of women, ≥75 years, who had been offered a choice between PET and surgery at diagnosis of breast cancer. A questionnaire was developed including 2 validated scales of decision regret and DM preferences.

**Results:** Questionnaires were sent to 247 women, and 101 were returned (response rate 41%). The median age of participants was 82 (range 75 to 99), with 58 having had surgery and 37 having PET. Practical details about the impact, safety, and efficacy of treatment were of most interest to participants. Of least interest were cosmetic outcomes after surgery. Information provided verbally by doctors and nurses, supported by booklets, was preferred. There was little interest in technology-based sources of information. There was equal preference for a patient- or doctor-centred DM style and lower preference for a shared DM style. The majority (74%) experienced their preferred DM style. Levels of decision regret were low (15.73, scale 0–100).

**Conclusions:** Women strongly preferred face to face information. Written formats were also helpful but not computer-based resources. Information that was found helpful to women in the DM process was identified. The study demonstrates many women achieved their preferred DM style, with a preference for involvement, and expressed low levels of decision regret.

## KEYWORDS

breast cancer, decision making, elderly, information needs, primary endocrine therapy

## 1 | INTRODUCTION

A third of new breast cancer diagnoses occur in women aged over 70 years in the UK. Across all age ranges, survival rates have improved with a fall in mortality of 37% since 1971.<sup>1</sup> However, improvement in survival rates in older women (>70 years of age) is lower than in younger women.<sup>2</sup> Older women are less likely to receive standard treatment; with rates of primary surgery, adjuvant radiotherapy, and chemotherapy all lower.<sup>2–4</sup>

Current UK guidelines<sup>5</sup> state that primary endocrine therapy (PET) should only be offered if “significant comorbidity precludes surgery”

and that age alone should not affect the decision.<sup>5</sup> However, PET continues to be widely used in the UK as an alternative to surgery with PET used in up to 40% of women over 70, compared with less than 6% in women under 70.<sup>6</sup> Increasing age, being deemed too frail or unfit for surgery are cited as reasons for older women receiving nonstandard treatment such as PET.<sup>3,4</sup> Patient choice is also identified as a factor in women receiving PET instead of standard surgical treatment. Oncologic outcomes with PET are acceptable, but rates of local control are inferior to surgery, and there may be a small reduction in breast cancer specific survival.<sup>7,8</sup> This needs to be balanced against short-term morbidity associated with surgery. Weighing such “trade-offs” is

complex, requiring adequate information about each option and its consequences.<sup>9</sup>

There is little research investigating information needs of older women or their preferred level of involvement in decision making (DM) about treatment options.<sup>10</sup> Currently, there are no resources to support women faced with a choice between surgery plus adjuvant endocrine therapy (hereafter referred to as "surgery") and PET for early breast cancer. This study (nested within a current NIHR study "Bridging the Age Gap"<sup>11</sup>) aimed to identify the information needs and preferences among women age  $\geq 75$  offered a choice between PET and surgery at diagnosis for breast cancer. Previously reported qualitative findings<sup>9,12</sup> were used to develop the content of a questionnaire and to illuminate its analysis. The main aim of the questionnaire was to further establish older women's preferences regarding receiving information about breast cancer treatment options (surgery or PET) and quantify issues raised in the interview study.<sup>9</sup> A secondary aim was to quantify women's preferences regarding the presentation of information and establish their preferred DM styles.

## 2 | STUDY DESIGN

This was a retrospective, cross-sectional, survey of women aged  $\geq 75$  years who had been offered a choice between PET and surgery at diagnosis for breast cancer within the previous 5 years. Those with locally advanced or metastatic breast cancer or who lacked cognitive capacity to consent were excluded.

Questionnaire development<sup>13</sup> was based on findings from a literature review,<sup>14</sup> expert opinion within the research team, the input of a local patient group,<sup>15</sup> and previous qualitative interviews.<sup>9</sup> The questionnaire collected data on the information women "had" found helpful during their treatment DM, on information they "would ideally prefer," its preferred format and source, and on the women's preferred and actual DM styles. There were a total of 57 questions split into 5 sections.

1. Patient demographics (4 items).
2. Information needs prior to treatment decision (30 items).
3. The process of treatment DM, including the Control Preferences Scale<sup>16</sup> (7 items).
4. Optimal DM, including the Decision Regret Scale<sup>17</sup> (10 items).
5. Preferred format, media and presentation of information (9 items).

A combination of categorical responses and Likert scales were used for most of the questions. In addition, there were 4 open response questions.

The questionnaire was piloted by the full study team that included 5 members of a local cancer patient support group and subsequently adapted according to their feedback to maximise content and face validity, clarity, comprehensibility, acceptability, and presentation.<sup>18</sup> Because of the absence of related validated questionnaires, criterion validity was not assessed. As the questionnaire did not measure any abstract concepts, such as pain, construct validity was not assessed.

## 2.1 | Sample size

Eligibility criteria included women diagnosed with breast cancer within the previous 5 years who had a treatment choice documented in their medical notes. The study population was drawn from 10 breast cancer units. This was a convenience sample from units that were stratified on the basis of high and low rates of surgery and PET. Each unit has a yearly average of 300 diagnosed women. Of these, approximately 25% will be over 75 years, and 85% of these will have ER+ cancers, equating to 64 eligible women per unit per year, or 3200 women in total. On the basis of this population size, a random sample of 344 enables estimation of proportions to within a maximum of  $\pm 5\%$  with 95% confidence.

## 3 | ETHICS APPROVAL

National Research Ethics Committee approval and local research governance approval was obtained.

## 4 | RECRUITMENT

Eligible women were identified by health care professionals (HCPs) in 10 NHS breast units across England and Wales. Women were offered a pack, including a letter inviting participation, an information sheet, a questionnaire, and a freepost envelope for return. Consent was implied by the return of the questionnaire. Study recruitment commenced November 2013 and ended January 31, 2015.

## 5 | DATA ANALYSIS

Statistical analysis was completed using SPSS V23 and the "R" Stats Package. Analysis was primarily descriptive. Categorical data were presented as frequencies and percentages. Fisher Exact test was used to identify associations between preferences and age, treatment received, and level of education. (Only associations with age are reported in this paper.) In line with convention, the 5 statements in the patients' preferred and achieved style DM tool were collapsed into 3 categories; doctor-centred (passive), shared (collaborative), and patient-centred (active) DM. The decision regret scale score was calculated using the developer's formula<sup>18</sup> (see Table 1). Data were entered by a single person and then checked and cleaned by a second.

## 6 | RESULTS

Two hundred and forty-seven women were offered a questionnaire, and 101 were returned (41% response rate). Twenty-nine (29%) were in the 75 to 79 age group, 32 (32%) in the 80 to 84 age group, 22 (22%) in the 85 to 89 age group, 17 (17%) in the 90+ age group, and 1 unknown (median age 82 y, range 75–99 y). Fifty-eight (57%) women received surgery and endocrine therapy, 37 (37%) received PET, and 6 (6%) unknown. Seventy-six (75%) women left school at or before age 16, 5 (5%) left school at 18, 19 (19%) attended college or university, and 1 unknown.

TABLE 1 Questionnaire options for DM styles

	Preferred Decision-Making Style	Actual Decision-Making Style	DM Classification
1	I prefer to make the final decision about which treatment I have	I made the final selection about which treatment I had	Patient-centred DM
2	I prefer to make the final selection of my treatment after seriously considering my doctor/nurse's opinion	I made the final selection of my treatment after I had seriously considered my doctor/nurse's opinion	
3	I prefer that my doctor/nurse and I share the responsibility for deciding which treatment is best for me	My doctor/nurse and I shared the responsibility for deciding which treatment was best for me	Shared DM
4	I prefer that my doctor/nurse makes the final decision about which treatment will be used, but seriously consider my opinion	My doctor/nurse made the final decision about which treatment was used, but seriously considered my opinion	Doctor-centred DM
5	I prefer to leave all the decisions regarding my treatment to my doctor/nurse	My doctor/nurse made all the decisions regarding my treatment	

## 6.1 | Information needs to support decision making

Women were asked to identify information that had been helpful in making a treatment decision (Figures 1A,B). Across all ages, information about the need for further treatment and how long tablets should be taken for were most frequently cited, 58/73 (79%) and 58/74 (78%), respectively. Items scoring lowest across all ages related to cosmetic outcomes, specifically, how the scar would look after surgery, 7/60 (12%), and whether they would look different after surgery, 11/60 (18%). Less than half (28/63, 44%) of the women had found information about posttreatment independence helpful. The helpfulness of information about cure rates with PET increased with age (Fisher Exact  $P = .005$ ). In the 75 to 79 age group, 6/17 (35%) found the information helpful, 5/21 (24%) in those 80 to 84, 12/17 (71%) in those 85 to 89, and 9/11 (82%) in those 90+.

## 6.2 | Source and format of preferred information

### 6.2.1 | Actual information sources used by women to make treatment decisions

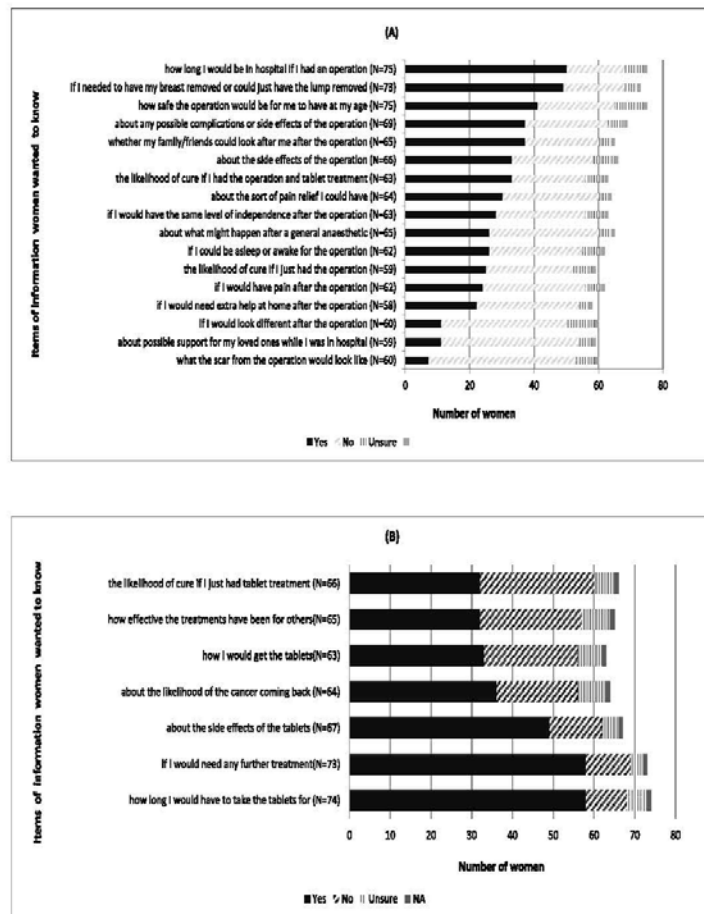
Additional to the information given verbally by doctors and nurses, leaflets and booklets provided by the hospital were considered helpful forms of information (57/101, 56%) by most women. Discussion with the general practitioner (43/101, 43%) and family and friends (37/101, 37%) was also helpful. Only 6/101 (6%) reported using the Internet. Sources that required reading information, ie, leaflets, booklets, magazines, and online materials, showed a decreasing preference with age (Fisher Exact  $P = .007$ ). When asked if enough information to make a treatment decision was provided, 79/91 (86%) said that it was, whilst a small number, 13/91 (14%) all under age 90, would have liked more.

### 6.2.2 | Ideal information sources

Face to face discussion with the doctors in the breast clinic was the preferred information source (81/100, 81%) followed by a nurse (37/101, 37%) then a booklet or leaflet (33/101, 33%). Of least interest were DVDs or videos (6/100, 6%) and Internet-based information (2/100, 2%). Only 5/100 (5%) did not want any information. Level of access to the Internet was generally poor with only 27/93 (29%) patients owning their own computer and having Internet access. A total of 23/93 (25%) had no access to the Internet, 21/93 (23%) could access the Internet via others, and 22/93 (24%) said that they did not want to use the Internet. When asked about the likelihood of future use of Internet-based information, 57/88 (65%) responded that they were "very unlikely" or "somewhat unlikely" to use it for information related to breast cancer whilst 21/88 (23%) stated that they were "likely" or "somewhat likely" to use it. Ten (11%) were unsure. However, of the 17 surgery-related items, a median of 3 (range 0-14) was deemed to be useful. Of the 7 tablet-related items, a median of 3 (0-7) was deemed helpful.

### 6.2.3 | Ideal information formats

The preferred format of written information regarding treatment risks and benefits across all ages was a statement in words (eg, "breast cancer is common in women in the UK") (51/101), followed by proportion, eg, "1 in 8 women in the UK will get breast cancer." There was little



**FIGURE 1** A, Information women found helpful when deciding between PET and surgery (surgery information). B, Information women found helpful when deciding between PET and surgery (tablet information)

interest in visual displays with only 11/101 preferring a pictogram, 10/101 a pie chart, and 9/101 a bar chart.

### 6.3 | Preferred support during the decision-making process

One eligibility criterion for the study was the women having received a documented treatment choice. However, more than half recalled being offered only 1 option 52/93 (56%) either only surgery or only PET, and only 40% (37/93) recalled being offered a choice.

Preference for a patient-centred (36/93, 39%) and a doctor-centred (35/93, 38%) DM style was fairly evenly split, with fewer preferring a shared DM style 22/96, (24%). There was a significant association between ideal and actual DM style (Fisher Exact  $P < .001$ ) with 69/93 (74.2%) achieving their preferred DM style (Table 2). There was also a strong association between patient-centred actual DM and PET and between doctor-centred DM and surgery (Fisher Exact  $P > .001$ ).

Most women stated that ideally, their doctor (76/82, 93%) or breast care nurse (45/55, 82%) would be the person to discuss their treatment decision with. A number of women (41/46, 89%) also felt leaflets would be helpful in making their treatment decision. There was a negative association with age for preference for written leaflets

(Fisher's Exact  $P > .007$ ). Friends and family were reported to be helpful for 34/47 women (72%).

#### 6.3.1 | Decision regret

The mean score of the Decision Regret Scale was 14.48 (scale 0-100, SD 18.60, range 0-100) demonstrating a low level of regret.

## 7 | DISCUSSION

This study has identified the information and DM support needs of older women with breast cancer facing a choice between surgery or PET.

**TABLE 2** Congruence between women's preferred and actual decision-making style

No. of Patients Preferred DM Style	Actual DM Style			Total
	Doctor-Centred	Shared	Patient-Centred	
Doctor-centred	31	1	3	35
Shared	7	9	6	22
Patient-centred	4	3	29	36
Total	42	13	38	93

The strong preference was for face to face discussion with a doctor (most preferred) or nurse when making a treatment decision. Booklets or leaflets were considered the most useful after the face to face consultations. These findings reflect our previous qualitative findings.<sup>9</sup> In line with the findings from Husain and colleagues, it is feasible that the women were not only gaining information from the face to face discussions but also looking for any obvious or subtle clues as to what treatments they felt the doctor was "recommending." The women were reluctant to access breast cancer-related information via technology, which is in contrast to younger women who increasingly seek information via the Internet.<sup>19</sup> Previous studies in this age group have identified feeling too old, fear of technology, lack of skills, no interest in technology, and no access to the Internet<sup>20,21</sup> as being potential reasons for this.

Presenting numerical information visually, eg, pie charts, was substantially less preferred than using words, reinforcing the findings of our qualitative study. Visual displays are particularly beneficial to people with lower numeracy skills provided that they are able to understand graphical representations.<sup>22</sup> Older people found visual displays less helpful and sometimes confusing for those with low levels of both numeracy and graph literacy.<sup>22</sup> The evidence of a link between declining numeracy, lower literacy<sup>23</sup> and increasing age, and the desire to conserve time and energy<sup>24</sup> may explain the strong preference for the more familiar use of words. This strong preference is of some concern, as it may lead to inaccurate risk perception.<sup>25</sup>

The most surprising finding was the limited preference for information regarding the effect of treatment on the women's independence level. This is in contrast to other studies, including our previous interview study,<sup>9</sup> that have shown the impact on independence and quality of life were key considerations.<sup>16,26</sup> However, over a third of respondents (38%) did not answer the 2 questionnaire items related to these, which could partly explain this finding. It is possible that this is as a result of the wording of the questions, which states "... after my operation," that led women who received PET to dismiss this question as at the time of completion that it seemed irrelevant to them.

The amount of information older women require to make a treatment decision is variable. Some older patients find the type and amount of medical information overwhelming<sup>27</sup> and are reported to express fewer information needs<sup>28,29</sup> whilst others want as much information as possible.<sup>20</sup>

Also reported is variance in the role women wish to play in DM. Some studies report that older women are often passive in the DM process, relying on HCPs to make treatment decisions,<sup>30,31</sup> whilst other studies report that older women want a more active role.<sup>12,32-34</sup>

Four studies examine DM where women are faced with a choice of PET or surgery followed by endocrine therapy.<sup>9,10,12,35</sup> Husain et al<sup>10</sup> reported heavy reliance on expert medical advice when making a treatment choice. In more recent studies,<sup>9,12</sup> women were not only eager to demonstrate their involvement and how "they" made the decision but were also keen to gain approval of their choice demonstrated by statements such as "the doctor seemed pleased with my choice."<sup>9</sup> Morgan and Burton et al<sup>35</sup> explored the balance of input of clinicians and patients into the DM process and reported that whilst there was variability in the DM styles, many older women achieved their treatment preferences.

Ensuring that women receive the preferred level and amount of information as well as involvement when making treatment decisions can be a challenge for clinicians. Decision support tools of varying length and detail may therefore help patients reach their preferred level of information and involvement in decision making.<sup>12</sup> The findings from this study will contribute to the development of decision support interventions specifically for women  $\geq 75$  years, faced with a treatment choice of surgery or PET.

A number of women reported not being offered a choice of treatments. This could be a problem of recall or the lack of clarity about what constitutes being offered a choice, which has been previously reported.<sup>36</sup> During the consultation, it may be that 2 treatments were discussed which HCPs deemed to be an offer but that there was an emphasis on one and the other was merely mentioned.<sup>12</sup> It could also mean that having made up their mind about the treatment that they wanted prior to the consultation, women simply filtered out information that they felt was irrelevant.

Where more communication between surgeons and women occurs, choice is perceived to be greater.<sup>37</sup> However, when asked about their involvement in treatment DM, the findings from both our interview and questionnaire studies found women consistently reporting involvement.<sup>9,12</sup> It would seem that women are differentiating between the offer of a choice of treatment and involvement in treatment DM. This could indicate that there is a need for HCPs to make the offer of a choice much more overtly.

## 7.1 | Study limitations

The declining cognitive ability and memory function of older people<sup>38</sup> may impact on reliability of findings in a retrospective questionnaire of this kind. However, the diagnosis and treatment for breast cancer is a significant event, and as such is arguably likely to produce strong memories. Time after the event is also a useful period of reflection and provides a space for making sense of the situation. However, it is acknowledged that for some of the women, the period since breast cancer treatment was significant (up to 5 years) and the details of information received and used, and the DM process, may be difficult to recall.

The achieved sample size was low for statistical representation of the population, and the low completion rate further impacted the validity of the results, so the findings should be used with caution. However, despite the sample size not achieving its target, the study provided evidence supporting our interview findings.<sup>9</sup> Previous studies with this population of women have closed early because of inadequate recruitment.<sup>39</sup> Recruitment to this study was reliant on HCPs in NHS breast units with the questionnaires being anonymously completed. The researchers, therefore, had no access to patient details to enable reminders to be sent to nonresponders. Although the questionnaire was rigorously developed, it would seem that for some of this older population, completion proved to be a challenging process. We can only speculate that the length of the questionnaire and/or the content were issues that contributed to the amount of missing data. The present study has provided a great deal of information about the appropriateness of postal, self-completion questionnaires with women who report a lack of interest in reading.

## 8 | CONCLUSION

The findings of this study demonstrate that most women achieved their preferred decision-making style and expressed low levels of decision regret. They also challenge the notion that older women prefer a passive role in DM. The findings highlight that the preferred way to receive information is via face to face communication, supplemented by uncomplicated written information, and there is a reluctance to engage with technology to obtain information. The development of decision support tools for women with older women facing a treatment choice of surgery or PET may enhance the quality and consistency of the information provided and encourage participation (to individuals' preferred level) in the DM process.

### 8.1 | Clinical implications

Items of information were identified that women found useful in making their decision that will be of value to HCPs in supporting women through the DM process as well as informative in the development of information and breast cancer decision support tools for older women.

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### CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

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### **6.1. Reflective review of Article 3**

This section presents a reflective review of article 3 post-publication and provides additional detail that it was not possible to include in the publication due to the scope of the author's guidelines of the journal.

### **6.2. Critical commentary**

Despite careful consideration at all stages of the questionnaire development and administration the non-completion i.e. where the participant fails to answer all items of the questionnaire, was disappointingly high with all questions missing at least one response. Section 2, the list entitled 'I wanted to know...' was most affected with 35% of responses missing. This figure is in line with that of Brazier and colleagues (1996) who reported 31.9% of missing data in one section of the SF-36. Non-completion is a feature commonly recorded in health surveys that target older people (Hayes, Morris, Wolfe & Morgan 1995; Brazier, Jones & Kind 1993).

However, others have reported high response and completion rates when surveying older people (English Longitudinal Survey of Ageing, ELSA). ELSA is a nationally representative panel survey of community-dwelling people aged 50 years and older in England. Running since 2002 this survey has amassed objective and subjective data relating to health and disability, biological markers of disease, economic circumstance, social participation, networks and well-being (ELSA). The core participants across the waves of ELSA are those who responded to the Health Survey for England in 1998 through to 2011. The survey uses both self-completed questionnaires and face to face computer assisted personal interviews (CAPI). Over the seven waves of data collection they have achieved response rates, ranging across ages, from 63 - 85% and completion rates (item non-response rates) of between < 0.1 - 2.6%. (Technical report ELSA Wave 6).

There are a number of features that are likely to have contributed to these impressive response and completion rates. Response rates are known to be high when people have responded to an initial survey, in this instance the HSE, because they are more likely to respond to subsequent requests (Dillman 2014). Establishing trust in a survey and the researchers further

enhances the likelihood of response and this is particularly so for government or university backed research (Dillman 2014). Similarly the offer of an incentive further impacts the response rate (Dillman 2014). The ELSA study was able to offer a £20 gift voucher, something that was not possible in this PhD.

The ELSA high completion rates are impressive. It is reasonable to assume that the use of assistance in the form of a computer assisted personal interview has significantly impacted the completion rates. This method ensures the participant is able to seek clarification from the researcher about questions they don't understand and that questions are not inadvertently missed. There are obvious costs associated with this method of data collection, however they are not excessive and would be something to be taken into consideration for future projects.

It was recognised early in the study that the random sample of 344 women required to enable estimates of proportion to within a maximum of  $\pm 5\%$  would not be possible due to the timescale of the study. It was therefore decided that 100 questionnaires would be the target response. The recruiting breast cancer units received a total of 247 questionnaires based on their estimation of the number they would be able to recruit. Subsequently 101 were returned which, if we presume that all of the 247 questionnaires were distributed to patients, equates to a 41% response rate. It is suggested that a response rate of 70% is necessary for a questionnaire to be representative (Stevens et al. 2001) others suggest a higher rate of 80 - 90% (Kerlinger & Lee 2000) but it is also known that response to health surveys are often much lower (Asch, Jedrzejewski & Christakis 1997).

The ELSA study also used a self-completion questionnaire (unassisted) in wave 7 to examine the sexual activity of older people and again the rate of return of 67% was good with an item non-response of between  $<0.1 - 2.6\%$ . The mean age of these participants is 66.7 years, which is significantly younger than the participants in this PhD study (mean age 82). They report the responders to be slightly older, less likely to be married or cohabiting, and in poorer health (Hinchliff, Tetley, Lee & Nazroo 2017). This is contrary

to the findings of others who found that in both general and health care populations, non-responders tend to be older, less well educated, with poor levels of literacy, of lower socioeconomic status and in poorer health (Czaja & Blair 2005; Müller-Nordhorn, Roll & Willich 2004; Smeeth et al. 2001; Lim & Fisher 1999; Hayes et al. 1995; Brazier, Jones & Kind 1993 Cartwright 1986).

The low response rate is now considered in the light of the relevant key themes relating to patients' views on completing questionnaires identified by Moore, Jones & Radley, (2012)

During their development of the QQ10, an instrument designed to assess the face validity, feasibility and utility of questionnaires, the authors identified ten key themes relating to patients' views on completing questionnaires (Moore, Jones & Radley, 2012). These were split into six *value* items and four *burden* items. (See Figure 6.1)

**Figure 6.1: Key themes from the development of the QQ10**

<i>Value items</i>	<i>Burden items</i>
<p>Helped communication</p> <p>Relevant</p> <p>Easy to use</p> <p>Comprehensive</p> <p>Willing to repeat</p> <p>Enjoyable</p>	<p>Overlong</p> <p>Embarrassing</p> <p>Overcomplicated</p> <p>Upsetting</p>

Although the QQ10 development (See Appendix 17 for the full QQ10) was undertaken in a group of women with a mean age of 53, it is possible the themes identified are also important to older women. The patients' perceived value, relevance, ease of use and level of burden of the questionnaire are likely to impact on the completion and return rates, (Lohr & Zebrack. 2009; Moore, Jones & Radley 2012), which may have affected the completion rates in this survey.

### **Perceived value**

People often agree to participate in surveys knowing that they will not personally benefit but feel their input may benefit others (Dillman, et al 2014 ; Blau 1964). At the point at which the women agreed to participate in this study they had no real notion of what was expected of them. Once they received the questionnaire the scale of the task may have been too great and so they 'did their best' to complete. It may be that the mental challenge outweighed the desire to contribute to the study.

### **Relevance**

From the interviews it was clear that women were only interested in information and discussion about their own condition and treatment. It is feasible that the women invited to take part felt that some of the questions were irrelevant as there were many questions unrelated to their own situation. Women who chose PET were asked to consider questions about surgery and vice versa. For some women although they were given a choice of treatment, they may never have considered the alternative option seriously and therefore the questions were irrelevant. In essence, they were being asked questions about a subject with which they were unfamiliar.

### **Cognitive function**

A number of the returned questionnaires were incomplete, i.e. women had missed questions or deliberately chosen the ones they wished to answer.

There is a common perception, backed by some evidence (McArdle, Fisher & Kadlec (2007) that age related cognitive decline is a linear process. Using data from the well designed and executed longitudinal ELSA study, Tampubolon (2015) demonstrated this is not the case. Since cognitive functioning is a multivariate concept and there is no accepted single measure, episodic memory was chosen as the dependent variable in the ELSA and McArdle, Fisher & Kadlec (2007) study. Episodic memory (the sum of delayed and immediate recall) a key feature in the day-to-day activities of older people and in decision making and is therefore an appropriate representation.

The ELSA data from British adults, 50-89 years of age, demonstrated that cognitive function was curvilinear in nature with the peak appearing in the early 60s (Tampubolon 2015). This contradicts most studies that put the peak variously in the 20s, 30s and 40s (Singh-Manoux et al 2012; Salthouse 2009; Schaie, Willis & Caskie 2004). When the ELSA study findings were examined across cohorts, pre and post-world war II (WWII), those in the pre WWII cohort did show a linear decline. It was also noted that there were significant individual variations within the cohorts i.e. some with linear decline whilst others maintaining their function.

Physical function, occupational class, wealth, marital status and education social networks and interactions of various kinds were also seen to affect cognitive function in the ELSA study. Those who were more physically able, in the managerial / professional classes, had received higher education, were in the top wealth bracket, married and had regular social contacts had higher cognitive function. Ill health, i.e. chronic disease such as arthritis, cardiovascular disease, diabetes and depression impacted negatively on cognitive function.

Since the median age of the respondents to the questionnaire in this PhD was 82 (range 75 to 99) it is reasonable to assume that at least some were experiencing some decline in cognitive function and that this had a bearing on the response and completion rates. Presenting the questionnaire, that may be considered lengthy, and asking women to remember detailed information about an event that happened up to five years previously may have been too ambitious. The impact of length of a questionnaire was found to be unclear (Iglesias & Togerson 2000; Rolstad, Adler & Ryden 2011). Although the content was broken down into clear sections, the wording carefully chosen and the provision of instructions for completion very detailed, it is possible that the women found it too complicated. Women were asked to remember the information they received and its usefulness and also what information they would have preferred. This level of cognitive processing may have been too great for some women and these women then filtered out the information they felt was irrelevant or difficult to answer and answered only the questions they perceived to be pertinent.

## **Sensitive questions**

Surveys containing embarrassing questions are known to reduce uptake and completion (Moore, Jones & Radley 2012). The women asked to take part in this survey were asked to relive a potentially upsetting time in their life and this may have impacted the completion rate.

Surveys are complex. They rely on a large number of elements positively interacting to ensure a valuable level of uptake, completion and return. Should one or more of these elements be missing it is likely to influence the quality of the data collected (Stevens et al. 2001).

### **6.3. Summary**

The development and administration of the questionnaire was rigorously undertaken but despite this the completion rate was disappointing. Although telephone support to complete the questionnaire was offered none of the women chose to contact the researcher. It is clear that many of the women struggled to complete this questionnaire and on reflection it may be that much closer support in the form of a structured telephone interview would have enhanced the completion rate (Musselwhite, Cuff, McGregor & King (2007).

Further examination of the self-completion questionnaire method of data collection will be addressed in the discussion.

The following chapter is the fourth and final article that forms part of this Article-based PhD.

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## Chapter 7: Article 4

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## 7. Chapter 7: Article 4

Morgan, J. L., Burton, M., Collins, K., Lifford, K. J., Robinson, T. G., Cheung, K. L., Audisio, R., Reed, M.W & Wyld, L. and on behalf of the Bridging the Age Gap Trial Management Team (2015). The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer. *Psycho-Oncology*, 24(12), 1761-1766.

### **Aim of the article**

The aim of this article was to present results and findings regarding the preferred decision-making styles including the influence of the HCP on the process. This article reports the qualitative component of this study to meet study objective 4 'to determine the influence of the health care professional in treatment decision-making in older women with operable breast cancer'.

The influence of the HCP, particularly the doctor, in treatment decision-making was made very clear during the interview and the questionnaire phases of this PhD. Some women reported being given the choice of treatment and supported by HCPs to make a decision, whilst others reported either not being offered a choice or simply informed it was up to them to decide despite asking for a recommendation. It seemed that there were very different perspectives on the issue of treatment decision-making. Another researcher within the wider Age Gap study was investigating the regional variation in treatment patterns of older women with breast cancer. This element included an exploration of the factors that HCPs take into account when assessing the treatment options and their views on patient choice. The opportunity was therefore taken to explore the interaction and concordance between HCPs and older women in the decision-making process and their views regarding the process and this is reported elsewhere (Morgan et al., 2017).

This article builds on the qualitative component of the study and draws on results and findings derived from a complementary study within the main BTAG study and offers an original contribution to the current knowledge base.

This article presents both a combined analysis of two components of the parent BTAG study; a questionnaire to older women undergoing consultation about breast cancer treatment options that established their DM preferences; and qualitative interviews with HCPs (both of which focused on DM preferences in this setting) and secondly the qualitative patient interviews undertaken as part of this PhD study.

The issue of HCP influence on DM has been explored in younger women with breast cancer but little is known about the experience of older women. Integrating these three components allowed a fuller picture of the process and drivers of DM to be developed.

I am the joint first author on this paper as I was the major contributor to the development of the qualitative interviews of older women and in the mixing of the findings from all three components of data collection. I was a contributor to the structure and writing of the article.

## The balance of clinician and patient input into treatment decision-making in older women with operable breast cancer

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### Abstract

**Objective:** Primary endocrine therapy (PET) is an alternative to surgery for oestrogen receptor positive operable breast cancer in some older women. However the decision to offer PET involves complex trade-offs and is influenced by both patient choice and healthcare professional (HCP) preference. This study aimed to compare the views of patients and HCPs about this decision and explore decision-making (DM) preferences and whether these are taken into account during consultations.

**Methods:** This multicentre, UK, mixed methods study had three components: (a) questionnaires to older women undergoing counseling about breast cancer treatment options which assessed their DM preferences and realities; (b) qualitative interviews with older women with operable breast cancer offered a choice of either surgery or PET and (c) qualitative interviews with HCPs (both of which focused on DM preferences in this setting).

**Results:** Thirty-three patients and 34 HCPs were interviewed. A range of opinions about patient involvement in DM were identified. Patients indicated varying preferences for DM involvement which were variably taken into account by HCPs. These qualitative findings were broadly supported by the questionnaire results. Most patients (536/729; 73.5%) achieved their preferred DM style; however, the remainder felt that their DM preferences had not been taken into consideration.

**Conclusions:** These results suggest that whilst many older women achieve their desired level of DM engagement, some do not, raising the possibility that they may be making choices which are not concordant with their treatment preferences.

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### Background

Breast cancer in the older population represents a significant problem, with around one third of all new diagnoses occurring in the over 70s in the UK [1]. The 'standard' treatment for breast cancer is surgery, but as age increases, so does co-morbidity and frailty, resulting in reduced tolerance to surgery and other breast cancer therapies [2]. Additionally, life expectancy decreases with age [3] and co-morbidity increases [4] so that other-cause mortality outweighs breast cancer mortality, thereby decreasing the potential benefit of surgery [5,6]. Consequently, older women with operable breast cancer may be offered alternative treatments, such as Primary Endocrine Therapy (PET) where women with oestrogen receptor positive (ER+) breast cancers are treated with endocrine therapy alone. PET is an effective treatment for some older women, with a Cochrane review demonstrating no difference in overall survival when compared to surgery [7]. However local control rates are superior in surgically treated patients, with

disease progression sometimes necessitating a change of management in patients treated with PET [8–10].

There is wide variation in PET use in the UK, rates ranging from 12% to 40% in different regions [11]. Whilst some of this may be because of case mix variation, studies have shown that this does not account for all of the variation [12,13] and patient preference for non-surgical therapy is often reported as a major factor in determining PET treatment in older patients [14–16]. However, other studies suggest that patient choice alone is unlikely to be the only cause of lower UK surgery rates [17], with clinician preference and how treatment options are presented also being significant in determining treatment [18].

Shared DM is increasingly considered to be relevant in preference sensitive health care decisions with patients and HCPs working together to make health care decisions that are based on clinical evidence and patients' informed preferences [19–21]. However there is evidence to suggest that not all older patients want to engage in shared DM, instead preferring to simply receive information [22] and accept a doctor-led DM process [23–26].

Currently little is known about the influence of HCP opinion on DM in older women with operable breast cancer. This study aimed to explore the interaction between HCPs and older patients in the DM process, as well as the concordance between HCP and patient views regarding the process of DM about treatment of operable breast cancer.

## Methods

### Study design

This study is a convergent mixed methods study with three components, where data were collected concurrently and findings were integrated following independent analysis:

1. Questionnaires about DM style administered to a large cohort of older women recruited as part of a multicentre UK cohort study of older women with breast cancer (the Bridging the Age Gap in Breast Cancer study).
2. Interviews with older women previously diagnosed with operable, ER+ breast cancer, to explore their DM preferences about the choice between surgery or PET
3. Interviews with HCPs involved in the care of older women with breast cancer to explore their views about older women's involvement in DM

This type of study design was chosen so the qualitative interviews would provide a more in-depth insight into the quantitative findings obtained from the cohort study.

#### 1. DM preferences questionnaire.

This was a prospective observational cohort study of women aged over 70 years diagnosed with operable primary breast cancer in 43 UK units since February 2013. Recruitment for this trial is ongoing, and results presented here represent an interim analysis of the first 729 patients with available data. Data were collected on patient and tumour characteristics, treatment type, as well as the patients' preferred and actual DM styles for their breast cancer treatment using a widely used validated instrument [27,28] (Table 1). The DM preferences questionnaire was applied within 4 weeks of diagnosis and prior to treatment. DM styles were then classified into three categories: Patient-centred, Shared and Doctor-centred (Table 1).

#### 2. Patient interviews.

Semi-structured interviews were undertaken with patients across five of the UK breast units recruiting to the Age Gap cohort study to explore opinions on treatment DM styles and preferences between April and December 2013. Eligibility criteria were: age 75 or over with operable breast cancer, diagnosed within the previous 5 years and offered a documented choice of either surgery or PET at initial diagnosis. Interviews and analysis were undertaken by one of two experienced qualitative researchers (MB/KL). The interview schedule focused on DM preferences and experiences of the DM process. Interviews were digitally recorded and transcribed verbatim. Recruitment ceased once data saturation had occurred.

#### 3. HCP interviews.

Interviews were undertaken with HCPs (surgeons, nurse specialists or geriatricians working with older breast cancer patients) recruited across 14 of the UK breast units recruiting to the cohort study to explore their opinions on treatment DM styles. Interviews were conducted between January and November 2013, by JM, and participants were purposively selected from regions with high and low PET rates according to UK national audit data [11]. Interviews were digitally recorded and transcribed verbatim. Recruitment ceased once data saturation had occurred.

### Data analysis

#### Questionnaires

Statistical analyses were performed using IBM SPSS statistical package, version 21. Concordance between preferred and actual DM preferences was assessed using Kappa, and associations between age, treatment and DM style were identified using Chi-squared tests. Statistical significance was taken at  $p < 0.05$ .

#### Interviews

Framework analysis [29], involving five steps of familiarisation, theme development, indexing, charting and interpretation, was used. Analysis of patient interviews was undertaken by MB with 10% of transcripts double-

**Table 1.** Questionnaire options for preferred and actual DM styles [27,28]

	Preferred DM style	Actual DM style	DM classification
1	I prefer to leave all decisions regarding my treatment to my doctor	My doctor made all the decisions regarding my treatment	Doctor-centred DM
2	I prefer that my doctor makes the final decision about which treatment will be used, but seriously considers my opinion	My doctor made the final decision about which treatment was used, but seriously considered my opinion	
3	I prefer that my doctor and I share responsibility for deciding which treatment is best for me	My doctor and I shared the responsibility for deciding which treatment was best for me	Shared DM
4	I prefer to make the final selection of my treatment after seriously considering my doctor's opinion	I made the final selection of my treatment after I had seriously considered my doctor's opinion	Patient-centred DM
5	I prefer to make the final selection about which treatment I will have	I made the final selection about which treatment I had	

coded by KL and supplemental feedback undertaken by lay patient representatives.

Analysis of HCP interviews was conducted by JM with 10% of transcripts double-coded by MB. Initial DM themes from both sets of interviews were compared and contrasted by two researchers (JM/MB).

### Ethics and research governance

The study protocols were approved by the UK National Research Ethics Committee and institutional approvals were granted at each site (12/LO/1808, 12/LO/1722 & SMBRER243). All patients and HCPs gave written informed consent.

## Results

### Questionnaires

Data on DM styles and treatment were available for 729 patients (age range 70–96 years; median 77 years), of whom 594 had undergone surgery and 135 had been treated with PET.

Both preferred and actual DM styles were associated with final treatment type, with surgery being associated with more doctor-centred treatment decisions and PET with more patient-centred decisions ( $p < 0.001$  and  $p = 0.002$  respectively; Figure 1). There was moderate agreement between patients' preferred and actual DM style (Kappa = 0.60,  $p < 0.001$ ) with 536/729 (73.5%) achieving their preferred DM style (Table 2). Increasing age was also associated with more patient-centred DM styles, both preferred and actual ( $p < 0.001$ ).

### Interviews

Patient interviews were undertaken with 33 older women with breast cancer (median age 83, range 75–94 years), who were a median of 20 months (range 3 to 60) from diagnosis. Twenty-two women received PET, and 11 received surgery. Interview duration was a median of 57 (range 23 to 85) minutes.

Healthcare professional interviews were undertaken with 34 HCPs (20 surgeons, 13 breast care nurses (BCNs) and 1 geriatrician). Twenty-one (62%) were from high PET rate

**Table 2.** Comparison between patients' preferred and actual decision style

Preferred decision style	Actual DM style			Total
	Doctor centred	Shared	Patient centred	
Doctor centred	198	28	21	247
Shared	61	178	45	284
Patient centred	16	22	160	198
Total	275	228	226	729

Agreement = 73.5%; Kappa = 0.60,  $p < 0.001$ ; agreed values in bold.

units, with the remaining 13 (38%) from low PET rate units. Interview duration was a median of 33 (range 16 to 55) minutes.

Combined interview analysis categorised the data into three themes pertaining to the treatment DM of older women with operable breast cancer:

1. Patient involvement in DM
2. Influence of HCP on DM
3. DM processes

### Theme 1: patient involvement in DM

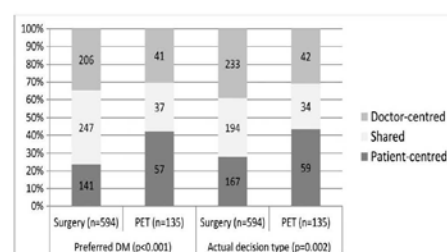
Healthcare professionals varied on their opinions regarding the DM styles of older women, some believing that older patients preferred a more doctor-centred approach whilst others felt they utilised a more patient-centred DM approach. Patients also tended to fit into one of these categories (Table 3, Subtheme 1b). Patients who had a more patient-centred approach described having already made their mind up about treatment before discussing options with their HCP. Overall, most patients ( $n = 29$ ) were satisfied with their involvement in the DM process.

Patients' preconceived ideas about themselves, breast cancer and cancer treatments were identified by both HCPs and patients as factors that influenced their treatment preference. Particular issues raised included the belief that they were too old for treatment (particularly surgery), the notion that quality of life was prioritised over quantity and the impact of previous experiences of cancer, either themselves or of family and friends (Table 3, Subtheme 1a).

### Theme 2: influence of HCP on DM

Both HCPs and patients felt that the HCP had a significant influence over patient DM when offered a treatment choice (Table 3, Subtheme 2a). Indeed, some women ( $n = 8$ ) described situations where the HCP tried to change their mind regarding their treatment choice (Table 3, Subtheme 2a). Not all HCPs ( $n = 5$ ) felt that patients should be offered a choice of surgery or PET, and this was mirrored by some patients ( $n = 7$ ) who felt that they had not been given a choice of treatment options (Table 3, Subtheme 2b).

Several patients ( $n = 12$ ) stated that they wanted a recommendation from their HCP about treatment. Willingness to recommend varied, with most ( $n = 25$ ) quite happy to advise



**Figure 1.** Patients' preferred and actual decision style according to treatment received

**Table 3.** Representative quotes from interviews comparing HCP and patients views

	HCP views	Patient views
Theme 1: Patient involvement in DM		
Subtheme 1a: patients' preconceived ideas	<p>'Some ladies will say at 70 I'm too old to have an operation' (Female Nurse; High PET unit)</p> <p>'The older woman who lives independently, they'd rather die than lose their independence... their priorities are very different... It's not about survival... thorough treatment of their breast cancer may be something that they're not actually interested in' (Female Surgeon; High PET unit)</p> <p>'Usually when people hold such strong, seemingly irrational, views it's usually because of an experience that they have had or an experience that a member of family or close friend has had' (Male Geriatrician; High PET unit)</p>	<p>'Well I am too old, 91 to go to a big operation like that' (91 yrs; PET)</p> <p>'I was feeling okay and I thought if my quality of life is like this at the moment, if I can keep it like this for a couple more years, well, that's okay with me, so that was my decision' (81 yrs; PET)</p> <p>'Do what you've got to do,' we lost a daughter-in-law with breast cancer, she was only 26, and that's 30 years ago... Cancer is the most frightening word' (82 yrs; Surgery)</p>
Subtheme 1b: DM styles	<p>'A lot of women in that age group have their own opinions and they can't be changed' (Male Surgeon; Low PET unit)</p> <p>'Some women really don't want to make that decision, they think it's the sort of thing that a doctor should do' (Female Surgeon; High PET unit)</p>	<p>'I'd already made my mind up because I knew it was cancer—you know in my own mind and made my mind up that I was having the breast taken off' (81 yrs; Surgery)</p> <p>'[Dr] deals with that all day and every day so I just said "Well what do you advise?" And I mean because he knew about it, I just took his advice' (81 yrs; Surgery)</p>
Theme 2: Influence of HCP on DM		
Subtheme 2a: Impact of HCP view on DM	<p>'It's the way you... sell something and personal opinion comes into it... a surgeon might think they know best and patients obviously listen to their doctor' (Female Nurse; Low PET unit)</p>	<p>'I think she [Dr] played a big part, because she put it so clearly that it was easy to make a decision' (89 yrs; PET)</p> <p>'I said "well I'm not taking tablets, I'm going to have my breast off"... he [Dr] said "but I'm very reluctant" he said "you're 94 year old"' (94 yrs; Surgery).</p>
Subtheme 2b: Offering a choice	<p>'The literature suggests... they should be offered an operation and so that's what I offer them. So I don't give them a choice between surgery and PET' (Male Surgeon; Low PET unit)</p>	<p>P: I wasn't given a choice, no.</p> <p>I: No, would you have liked a choice?</p> <p>P: I think I would really. I don't know what I would of chosen though thinking about it.' (80 yrs; PET)</p>
Subtheme 2c: Making recommendations	<p>'If they ask me well what do I think, I will tell them... "You choose what is right for you, not what is right for me... I don't know how I will choose if I was sitting where you're sitting so it really is your choice"' (Female Surgeon; High PET unit)</p> <p>'I certainly tell them which is the preferable option' (Male Surgeon; High PET unit)</p>	<p>'My son said to him... "If it was your wife what would you recommend her to do" and he said "I can't answer that... it's your mother's decision. She has to decide for herself"' (75 yrs; Surgery)</p> <p>'What would happen if I don't have treatment? And... the doctor actually did say to me, "your other option is to have nothing done... but I wouldn't recommend that..."' (81 yrs; PET)</p>
Theme 3: Processes of DM		
Subtheme 3a: Timing of DM	<p>'Giving them time to think through it, the pros and cons, is very important' (Female Surgeon; Low PET unit)</p>	<p>'Get rid of it. And see you don't have time, because you want it done there and then. So you don't have a lot of time to think about it' (81 yrs; PET)</p>
Subtheme 3b: HCP involved in DM process	<p>'She [nurse] does all the decision-making with them. They go into a room with her, I just tell them what it is and what the options are and over to the Breast Care Nurse.' (Male Surgeon; Low PET unit)</p>	<p>'It was when the nurse took us into a separate room away from Dr [name] we thrashed this out' (85 yrs; PET)</p>
Subtheme 3c: Information requirements	<p>'A lot of the older population, I feel, don't want information' (Female Nurse; High PET unit)</p>	<p>'They weren't very forthcoming with information' (75 yrs; PET)</p> <p>'why would you need all the other information? It's only extra worrying' (81 yrs; PET)</p>

patients and others (n=5) feeling very uncomfortable about making recommendations (Table 3, Subtheme 2c).

### Theme 3: DM processes

Giving patient's time to reach a treatment decision was viewed as important by HCPs. However, some patients (n=5) felt that they had been expected to make a decision quickly, despite HCPs encouraging them to take time to consider their options. Others (n=12) described an internal desire to get the DM process 'over with' (Table 3, Subtheme 3a). Both groups felt that the BCNs played a major role in helping patients decide (Table 3, Subtheme 3b).

Interestingly, there was a notion from HCPs that older patients generally did not require or want as much information regarding treatment compared to younger women, and this corresponded to some patients' who felt overwhelmed by the volume of information they were given. A small number of patients (n=4) felt that the HCPs did not want to give them information (Table 3, Subtheme 3c).

### Discussion

Despite the evidence suggesting older patients prefer a more passive, doctor-centred role in treatment DM [23–26],

this study identified a range of preferred DM styles among older women with operable breast cancer and demonstrated the complex relationship between patients and their HCPs in the DM process. Vogel and colleagues explored the concordance between HCP and patient preference for DM in breast cancer patients and found that HCP perceptions were often inconsistent with patient preference [22]. Within this study, almost three-quarters of patients achieved their preferred DM style, suggesting that HCPs were utilising a more individualised approach to treatment DM. However, a quarter of patients did not achieve their preferred DM style, raising the possibility that they may be making choices which are not concordant with their treatment preferences.

Treatment received was related to patient DM style, where women choosing PET generally had a more patient-centric DM experience compared to women treated with surgery. This suggests that a significant proportion of women treated with PET chose this treatment as a means of avoiding surgery. This is in line with other similar studies where patient choice is commonly stated as a reason why patients receive PET [14,16,30]. Interestingly, increasing age was also associated with more patient-centred DM styles, with those at the younger end of the age spectrum having more doctor-centred and shared DM styles. This may partly explain the increasing rates of PET in the oldest old, with HCPs perhaps feeling more inclined to stress the importance of surgery in the younger cohort, thus resulting in the perception of a doctor-centred decision. Additionally, some patients treated with PET may have been considered too frail to be offered surgery and so their treatment choice may have been PET vs. no treatment which could partly explain why they felt a patient-centred DM had been used. The findings of the present study are in contrast to findings by Lavelle and colleagues [17] who reported that lower rates of surgical treatment are unlikely to be because of patient choice. This may represent a difference in study population, with the study by Lavelle and colleagues recruiting patients mainly from one region in England in comparison to this study in which patients were recruited from a wider area.

Hamaker and colleagues [18] suggested that although patient preference or refusal of surgery were often stated as possible reasons for variation in treatment, it may actually reflect clinician preference influencing communication of treatment options and how these are presented to the patient. The present study found that not all patients are offered a choice of treatment and a significant proportion of treatment decisions were doctor-centred (Table 3). This may reflect current guidelines suggesting PET should not be used unless patients are deemed unfit for surgery, have significantly reduced life expectancy or refuse surgery [31,32]. However, it is recognised that for some patients, quality of life is more important than quantity [33], and it may be appropriate to offer PET as an alternative to surgical treatment, allowing the patient to decide their preferred treatment option. This principle also fits with the current

drive for more shared DM in healthcare, which requires treatment alternatives to be discussed with patients.

For those offered choice, a small number of patients wanted a recommendation from their HCP, and Schonberg and colleagues found this to be the most influential factor affecting older women's breast cancer treatment decisions [25]. However not all HCPs are comfortable recommending a treatment plan, choosing instead to encourage the patient to decide. Encouraging an active role in DM when patients prefer a more passive role may increase anxiety and cause distress [34,35].

Healthcare professionals did not feel that older patients wanted as much information as their younger counterparts, however, for patients this varied, with some appreciating more detailed information on treatment choices. This is in keeping with Elkin and colleagues who found that despite some older people not wishing to take an active role in the DM process, they still wanted to receive information about the treatment options available [36]. Even when patients do not wish to take an active role in decisions they may seek information as a method of coping with and taking control of breast cancer [37,38].

Although most HCPs unsurprisingly felt that patients needed adequate time to consider their treatment options and make decisions, this was in complete contrast to the patients' perception who tended to feel internal pressure to make a decision quickly, this being in line with previous studies [39,40]. Additionally, some patients felt pressured to take a decision quickly as they believed it was expected by the HCPs.

It is acknowledged that retrospective interview studies, particularly involving older people, may be subject to inaccurate recall of events and details. However many themes were common findings between women and HCPs, giving confidence in the data. Combined with the prospectively collected questionnaire data, the mixed methods approach allows the questionnaire data to expand on the qualitative findings, giving a broader overview of this problem.

Our findings support an individualised approach to treatment DM for older women with operable breast cancer, including the discussion of alternative treatment options, which may come with the caveat that one option is considered superior. A decision aid which includes more information on the treatment options and outcomes in this population may be helpful to both patients and HCPs to improve concordance in the DM process. This study also highlights the need for further research on the DM process and its relationship to decision regret in this setting.

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## Reflective Review of Article 4

This section presents a reflective review of article 4 post-publication and provides additional detail that it was not possible to include in the publication due to the scope of the author's guidelines of the journal.

The reporting of MM research is frequently criticised for not providing sufficient detail of the process and method of integration of data (Farmer et al. 2006; O'Cathain, Murphy & Nicholl 2008). This reflective review will therefore give further details of the theme development and outline the method of integration used.

### **7.1. Summary of the decision preference questionnaire findings**

The decision preference questionnaire findings were able to provide evidence of the strong links between the decision-making style and the final treatment and of the involvement of the HCP in the decision-making process.

The questionnaire showed that patients who preferred a patient-centred style were more likely to choose PET and those who preferred a doctor-centred style were more likely to choose surgery. Moderate agreement was found between the patients' actual and preferred decision-making style with 73.5% achieving their preferred decision-making style. Whilst this can be seen as a good level of agreement it means that 26.5% do not achieve their preferred style. The findings from both the HCP and patient interviews allowed these findings to be further explored and understood.

### **7.2. Analysis and integration of the interviews**

A triangulation protocol was used and the data demonstrated using the convergence coding matrix as suggested by Farmer and colleagues (2006).

Separate analysis of each set of interviews (i.e. the HCP and patient interviews) were undertaken by the authors (JM the HCP interviews and MB the patient interviews). Each then familiarised themselves with the findings from the other set of interviews. Based on the topic guides, the data and the focus of the study, three themes and eight sub-themes were developed and

the data categorised accordingly. Quotes from both sets of interviews were identified which represented the sub-themes. Although not displayed in the paper there was an assessment of the agreement, partial agreement or dissonance of views. A fuller description of the integration is given in chapter 4 & 8. Table 7.1 shows the findings displayed using the convergence coding matrix.

Generally there were high levels of agreement which supports the findings of the questionnaire but there were also areas of partial agreement and disagreement. Areas of partial agreement and dissonance help to better understand of the discordance between the patient's preferred and actual decision-making styles seen in this PhD study.

The following chapter will integrate the findings from each component of this PhD study. The findings will be discussed in the light of current literature and it will conclude with practice recommendations and further research

**Table 7.1: Representative quotes from interviews comparing HCP and patients views**

Theme 1: Patient involvement in DM	HCP views	Patient views	Convergence Coding Matrix
Subtheme 1a: patients' preconceived ideas	<i>"Some ladies will say at 70 'I'm too old to have an operation' ".</i> (Female Nurse; High PET unit)	<i>"Well I am too old, 91 to go to a big operation like that."</i> (91 yrs; PET)	<b>Agreement(A)</b>
	<i>"The older woman who lives independently, they'd rather die than lose their independence... their priorities are very different...It's not about survival... thorough treatment of their breast cancer may be something that they're not actually interested."</i> in.' (Female Surgeon; High PET unit)	<i>"I was feeling okay and I thought if my quality of life is like this at the moment, if I can keep it like this for a couple more years, well, that's okay with me, so that was my decision."</i> (81 yrs; PET)	<b>A</b>
	<i>"Usually when people hold such strong, seemingly irrational, views it's usually because of an experience that they have had or an experience that a member of family or close friend has had."</i> (Male Geriatrician; High PET unit)	<i>"Do what you've got to do,' we lost a daughter-in-law with breast cancer, she was only 26, and that's 30 years ago...Cancer is the most frightening word"</i> (82 yrs; Surgery)	<b>A</b>

Subtheme 1b: DM styles	<i>"A lot of women in that age group have their own opinions and they can't be changed"</i> (Male Surgeon; Low PET unit)	<i>"I'd already made my mind up because I knew it was cancer—you know in my own mind and made my mind up that I was having the breast taken off "</i> (81 yrs; Surgery) <b>A</b>
	<i>"Some women really don't want to make that decision, they think it's the sort of thing that a doctor should do"</i> (Female Surgeon; High PET unit)	<i>"..[Dr] deals with that all day and every day so I just said 'Well what do you advise? And I mean because he knew about it, I just took his advice.'" (81 yrs; Surgery) <b>A</b></i>

Theme 2: Influence of HCP on DM			
Subtheme 2a: Impact of HCP view on DM	<p><i>"...it's the way you... sell something and personal opinion comes into it... a surgeon might think they know best and patients obviously listen to their doctor" (Female Nurse; Low PET unit)</i></p>	<p><i>"I think she [Dr] played a big part, because she put it so clearly that it was easy to make a decision" (89 yrs; PET)</i></p> <p><i>"I said 'well I'm not taking tablets, I'm going to have my breast off'... he [Dr] said 'but I'm very reluctant' he said 'you're 94 year old.'" (94 yrs; Surgery).</i></p>	Partial Agreement (PA)
Subtheme 2b: Offering a choice	<p><i>"The literature suggests... they should be offered an operation and so that's what I offer them. So I don't give them a choice between surgery and PET" (Male Surgeon; Low PET unit)</i></p>	<p><i>'P: "I wasn't given a choice, no. I: No, would you have liked a choice? P: I think I would really. I don't know what I would of chosen though thinking about it." (80 yrs; PET)</i></p>	Dissonance(D)

<p>Subtheme 2c: Making recommendations</p>	<p><i>"If they ask me well what do I think, I will tell them... 'You choose what is right for you, not what is right for me... I don't know how I will choose if I was sitting where you're sitting so it really is your choice.'" (Female Surgeon; High PET unit)</i></p> <p><i>"I certainly tell them which is the preferable option" (Male Surgeon; High PET unit)</i></p>	<p><i>"My son said to him... 'if it was your wife what would you recommend her to do' and he said 'I can't answer that...it's your mother's decision. She has to decide for herself.'" (75 yrs; Surgery)</i></p> <p><i>"What would happen if I don't have treatment? And... the doctor actually did say to me, 'your other option is to have nothing done...but I wouldn't recommend that..." (81 yrs; PET)</i></p>	<p>A</p>
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Theme 3: Processes of DM			
Subtheme 3a: Timing of DM	<i>"Giving them time to think through it, the pros and cons, is very important"</i> (Female Surgeon; Low PET unit)	<i>"Get rid of it. And see you don't have time, because you want it done there and then. So you don't have a lot of time to think about it."</i> (81 yrs; PET)	D
Subtheme 3b: HCP involved in DM process	<i>"She [nurse] does all the decision-making with them. They go into a room with her, I just tell them what it is and what the options are and over to the Breast Care Nurse."</i> (Male Surgeon; Low PET unit)	<i>"It was when the nurse took us into a separate room away from Dr [name] we thrashed this out"</i> (85 yrs; PET)	A
Subtheme 3c: Information requirements	<i>"A lot of the older population, I feel, don't want information"</i> (Female Nurse; High PET unit)	<i>"They weren't very forthcoming with information"</i> (75 yrs; PET)  <i>"...why would you need all the other information? It's only extra worrying"</i> (81 yrs; PET)	D

**Key:**

A = agreement PA = partial agreement D = dissonance

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## Chapter 8: Summary of Findings

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## **8. Chapter 8: Summary of Mixed Methods Findings**

The integration of findings derived from multiple data sources is considered a hallmark of mixed method research studies (Creswell, Fetter & Ivankova, 2004). This chapter reports the integration of the findings from the literature review, the semi-structured interviews and the questionnaire utilised in this study. A triangulation protocol was used and the data displayed in a convergence coding matrix (Farmer et al, 2006) with the aim of gaining a more complete picture through addressing the research questions.

### **Research Questions**

1. "What are the preferences for information, its sources, format and presentation for older women faced with a treatment choice for operable breast cancer?"
2. "What are the preferred decision-making styles in older women faced with a treatment choice for operable breast cancer?"

### **8.1. Study aim and objectives**

#### **Aim:**

To establish the information preferences and decision-making styles of older women faced with a choice of surgery and adjuvant endocrine therapy or PET.

#### **Objectives:**

1. To establish the evidence relating to information and decision-making preferences in older women ( $\geq 75$  years) with primary operable breast cancer with a specific focus on the use of surgery or PET.
2. To elicit the views of older women towards preference for information and its source and presentation when facing a choice between surgery and PET.
3. To elicit the views of older women towards decision-making styles when faced with a choice of surgery or PET.
4. To determine the influence of the health care professional in treatment decision-making in older women with operable breast cancer.

Using a convergence coding matrix, as described by Farmer and colleagues (2006), the findings from each of the study components were triangulated and presented under three meta-themes. The meta-themes were developed from the findings of the interviews and used as a framework to consider the results and findings of all data sets. The Meta-themes are:

1. Receiving a choice
2. Shaping the decision
3. Making the decision

Each meta-theme was sub-divided into themes to address key findings. (See Tables 8.1, 8.2, 8.3 for each meta-theme matrix.)

For each theme there was an assessment of where, across the findings from each component, there was 'agreement' A; 'partial agreement' PA; 'dissonance' (disagreement) D; or 'silence' S (where findings exist about a topic in one set of data but are absent in another).

**Table 8.1: Integration of findings to address research question 2**

<b>Meta-theme: Receiving a Choice</b>					
	<b>Literature Review</b> * based on literature in the review article.	<b>Qualitative (Interviews)</b>	<b>Quantitative (Questionnaires)</b>	<b>Convergence code</b>	<b>PhD Objective addressed</b>
<b>Themes</b>					
<b>The offer of treatment choice.</b>	Previous studies only examine the choice between WLE & mastectomy in - not focussed on older women.	Most women reported being offered a choice of treatment. Some remember the choice as being between mastectomy and wide local excision.	Only 37/93 women remember being offered a choice between Surgery & ET and PET	<b>Dissonance (D)</b>	<b>3</b>
<b>Older age and the offer of treatment choice.</b>	Fewer choices were given with increasing age. All women >80 said they were not given a choice.	Some of the older women said they were offered a choice and others said they were offered a choice with direction as to the best option. Others interpreted the doctor/nurses comments to decide which treatment they felt they were being	12/15 women aged 90+ and 12/22 women 85-89 were offered a choice of surgery or PET. Compared to those 75-79 and 80-84yrs who were offered choice 6/25 and 7/27 respectively.	<b>Partial Agreement (PA)</b>	<b>3</b>

Meta-theme: Receiving a Choice					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
		recommended. Others said they were offered a choice of mastectomy or WLE. There was little difference in the median age of those offered a choice and those offered no choice - 81(range 73-95) and 82 yrs (range 73 98) respectively. Two women age 76 &98 were unsure whether they had been offered a choice.	The latter two groups were more often offered surgery.		

Meta-theme: Receiving a Choice					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
Reactions to being offered a choice of treatment.	A study of younger (median age 44.5yrs, range 23-88) Chinese women with breast cancer highlights the difficulty and worry that the women suffered when asked to make a treatment decision without the Drs guidance, albeit they had received information from the Dr. Older women worried about having to make a decision. Women said they needed time to make a decision and some felt they were rushed into a decision. In studies of	Most women appreciated being given a choice of treatment. For some women being given a choice caused anxiety as they worried they would make the wrong choice. A small number were surprised to be given a choice as they expected the doctor to know the best treatment for them.	This was not directly addressed in the questionnaire. A couple of women use the free text section to express their belief that women should 'listen to the doctor' whilst another four expressed the need for reassurance during the decision-making process.	Agreement (A)	3

Meta-theme: Receiving a Choice					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
	younger women some appreciated it whilst others found it traumatic and anxiety provoking.				

**Table 8.2: Integration of findings to address research question 1**

<b>Meta-theme: Shaping the decision</b>					
	<b>Literature Review</b> * based on literature in the review article.	<b>Qualitative (Interviews)</b>	<b>Quantitative (Questionnaires)</b>	<b>Convergence Code</b>	<b>PhD Objective addressed</b>
<b>Themes</b>					
<b>Preferred source and method of receiving treatment information.</b>	Older patients prefer information to be given to them verbally by their treating clinician.	Information given verbally by the doctor in the breast clinic was the most preferred and trusted method of information. Only two women sought further information.	A face to face chat with the doctor in the breast unit was the most preferred way to receive information. Followed by a chat with a nurse. Booklets were the third most preferred	<b>A</b>	<b>1,2</b>
<b>Information needs to facilitate decision-making</b>	At diagnosis information about the chance of a cure and the spread of the disease were the most commonly requested, regardless of age. Medical information about the	Women wanted information that was personal to them. They wanted Information about the need for further treatment e.g. radiotherapy, chemotherapy; the risk of recurrence or spread and the	Ranked 1 <sup>st</sup> for information needs: whether there was a need for further treatment and how long tablets would need to be taken for. Other items	<b>A</b>	<b>1,2</b>

Meta-theme: Shaping the decision					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence Code	PhD Objective addressed
	disease, the nature of breast cancer, symptoms, diagnostic tests, treatment options and prognosis were also important for older women (>70 yrs). Older women wanted information on the impact of treatment on their functional independence, self-care, quality of life, social life and on the practical aspects of treatment e.g.travel.	implications for daughters. Practical consideration e.g. impact of treatment on independence, transport for further treatment, dates and times of appointments, length of stay post surgery, and prescription collection.	were; how long they would be in hospital; whether it was necessary to have a mastectomy or was a WLE possible; the side effects of the tablets and the operation; how safe the operation was at 'my age'; the side effects or complications of the operation; whether it was possible for family & friends to care for the women after the operation; the likelihood of the cancer recurring; the likelihood of cure		



Meta-theme: Shaping the decision					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence Code	PhD Objective addressed
			after surgery and how the tablets would be obtained.		
<b>Views on information materials e.g. booklets, leaflets, DVDs, CDs, in shaping the treatment decision.</b>	Simple booklets with short explanations of risks and benefits of treatment, free of medical language and with clear diagrams were requested by older women undergoing adjuvant therapy. Personal cancer stories within the information were viewed as being in helping to understand and cope with the disease and its treatment.	Clear, uncomplicated, jargon free booklets containing relevant information were the preferred option. Very little interest in acquiring information from DVDs, CDs or the internet.	Booklets were the preferred source. DVD/videos, internet based material and CD were helpful to 6 or fewer women. 5 women did not want any information.	<b>A</b>	<b>1,2</b>

Meta-theme: Shaping the decision					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence Code	PhD Objective addressed
<b>Preferred presentation to ease understanding of information.</b>	Older women with breast cancer preferred words to quantify or describe risk. Younger and more educated people had a greater preference for numerical expression.	With two exceptions all the women said they did not find graphs, charts or percentages helpful. They preferred information in words.	51/101 women preferred a statement in words e.g. 'Breast cancer is a common cancer in women'. Followed by a number e.g. '1 in 8 women in the UK will get breast cancer'. Very few women (11 or fewer) preferred a pictogram, graph, a chart, percentages or fractions.	<b>A</b>	<b>1,2</b>
<b>Amount of information preferred to make a decision about treatment.</b>	Cancer patients regardless of age have high information needs. The amount required by older people is variable. Some	There were a range of opinions on the amount of information preferred. Some felt they had enough others felt overwhelmed and a very small	The majority of women felt they had all the information they needed to decide on treatment.	<b>A</b>	<b>1,2</b>

Meta-theme: Shaping the decision					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence Code	PhD Objective addressed
	want as much information as possible whilst others have fewer information needs.	number would have liked more information. All said they had enough information.			
<b>The role of previous experience of serious illness and own perceptions of cancer in shaping the decision.</b>	Personal experience of others' cancer is a factor which impacts on knowledge of cancer treatments. Prior experience or perception of cancer was a barrier to treatment.	Almost all the women interviewed cited previous experience of cancer in a family of friend which influenced their decision-making. This was sometimes cited as a reason for not wanting surgery, but for others it was a reason to choose surgery.	This topic was not addressed in the questionnaire	<b>Silence(S)</b>	<b>3</b>

Meta-theme: Shaping the decision					
	Literature Review * based on literature in the review article.	Qualitative (Interviews)	Quantitative (Questionnaires)	Convergence Code	PhD Objective addressed
<b>The role of family and friends, and others play in shaping the decision.</b>	The role of family varied. Some families have little or no influence on DM whilst others are heavily involved with some making decisions on behalf of the women due to dementia, cognitive impairment or cultural reasons. Family and friends were also a source of information for some women.	Approximately half of the women interviewed said they talked to family & friends and three talked to their GP. Daughters were heavily involved in DM. There were a small number of women who only told their family after they had made their decision. Others didn't speak to anyone other than breast cancer staff.	15 or fewer women spoke to their family & friends or to their GP. 2 spoke to no one.	<b>A</b>	<b>3</b>

**Table 8.3: Integration of findings to address research question 2**

<b>Meta-theme: Making the Decision</b>					
	<b>Literature Review*</b> * based on literature in the review article.	<b>Qualitative</b> (Intdecision-makinger views)	<b>Quantitative</b> (Questionnaires)	<b>Convergence</b> code	<b>PhD</b> <b>Objective</b> <b>addressed</b>
<b>Themes</b>					
<b>Making the final treatment decision.</b>	Across all age groups women with breast cancer want to be involved in the treatment decision. One systematic review reported a wide range of DM styles. Between 15.5-64.63%.experienced active DM, 21-63.5% experienced SDM, & 8.1-60.7% experienced passive DM. With increasing age women are reported to want less involvement than younger women but this is variable.	Most women stated they made their own decision. Some made a 'snap' decision before diagnosis or immediately on diagnosis. Some women decided against surgery without knowing that PET was an alternative treatment. A small number of women chose a treatment against what the Dr/nurse was encouraging them to choose. Some were happy for the Dr to make the	21/98 stated they made the final treatment decision. A further 23/98 said they made the decision after considering the Dr or nurses' opinion. 15/98 shared the decision, 15/98 allowed the doctor to make the decision after to listening to her opinion and 24/98 stated the Dr or nurse made the final treatment decision.	<b>A</b>	<b>4</b>

Meta-theme: Making the Decision					
	Literature Review* * based on literature in the review article.	Qualitative (Intdecision-makinger views)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
	One study of older women with breast cancer reported women more likely to take an active / sole role in the final treatment decision.	decision.			
<b>The role of the Dr or nurse in the discussing the treatment decision.</b>	Decision-making was influenced by the doctor and most women trusted the Dr to make the decision.	The doctor or nurse had a major role in discussing the treatment decision. Women were frequently of the opinion that they should be guided by the doctor or nurse as they had the experience to make the decision.	53/101 had input from the Dr or nurse in making the treatment decision.	<b>A</b>	<b>3&amp;4</b>

Meta-theme: Making the Decision					
	Literature Review* * based on literature in the review article.	Qualitative (Intdecision-makinger views)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
Preferred decision-making style.	This varies considerably across all ages of women with breast cancer. Between 13-40.4% preferred an active style of decision-making, 21-63.5% a shared role, 12.2-66% preferred a passive role.	This item was not specifically addressed but comments about 'knowing their own mind' and I made the decision immediately, and for some this was without consideration of possible alternatives, were made by some of the women interviewed. Women frequently stated they wanted to discuss the option intimating a shared decision-making preference. The oldest women were very active decision makers with some choosing without input from the Dr/nurse.	16/96 would prefer to make their own decision. 20/96 would prefer to make the decision after considering the doctor or nurses' opinion. 23/98 prefer to share the responsibility; 16/96 preferred the doctor made the final decision after considering her opinion; 21/96 said they would prefer the doctor or nurse to make the final decision. Women who had an operation were more likely to want	A	3&4

Meta-theme: Making the Decision					
	Literature Review* * based on literature in the review article.	Qualitative (Intdecision-makinger views)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
			(ideally) to experience SDM whereas women who chose PET preferred an ADM role. Fisher Exact p=.015. Women who had an operation were more likely to experience SDM whereas women who chose PET experienced an ADM role. Fisher Exact p=.008		
<b>Satisfaction with treatment decision.</b>	Regardless of age there is a high level of satisfaction with the decision-making process and the treatment decision.	Only one woman said she would have chosen a different treatment.	83/89 women said they agreed or strongly agreed they had made the right decision. 5	<b>A</b>	<b>3</b>



Meta-theme: Making the Decision					
	Literature Review* * based on literature in the review article.	Qualitative (Intdecision-makinger views)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
			women either 'strongly disagreed' or 'disagreed' they would choose the same treatment again.		
<b>Influencing factors in the treatment decision.</b>	Few studies have examined the factors influencing treatment decision-making in women ≥70 yrs but there are a number of studies that have examined post-menopausal women. Age, education level, independence, treatment preference, family involvement and doctor communication are all known to influence the decision.	Some women saw themselves as too old for surgery, whilst others felt the doctors were implying they were too old. Fear of surgery and the impact on independence it would have post-operatively were also cited as a reason not to choose surgery. Others wanted to rid themselves of cancer so chose surgery. One	No association was found between level of education and type of treatment received, or between the person they preferred to help them decide and the treatment received. There was a strong association between age and the treatment received. (Fisher's Exact p =.000)	<b>A</b>	<b>3</b>

Meta-theme: Making the Decision					
	Literature Review* * based on literature in the review article.	Qualitative (Intdecision-makinger views)	Quantitative (Questionnaires)	Convergence code	PhD Objective addressed
	Women saw older age as a reason to rule out some adjuvant therapy.	woman was unconvinced of the efficacy of PET and therefore chose surgery. Personal experience of illness and lay information about cancer treatments also influenced their decision.	Women under the median age of 82 were more likely to receive surgery and those above more likely to receive PET.		

## **8.2. Mixed methods findings**

The following sections provide a summary discussion that draws together the integrated findings presented in the convergence coding matrix.

Interpretation of the qualitative findings had resulted in the generation of three major themes.

These meta themes were then expanded on 'mixing' the data to include sub-themes, as presented in the convergence coding matrix above, to draw together findings meeting the study objectives and questions as a whole. The three meta themes represent a trajectory that represents older women's preferences for information to aid decision-making and their decision-making styles when faced with a choice of surgery and adjuvant endocrine therapy or PET. The findings illustrate older women's reactions to being offered a decision, how the decision they make is shaped and the processes involved in making the decision.

### **8.2.1. Receiving a choice**

There was little evidence in the literature review concerning specifically older women being offered a choice of treatment. The survey results show less than half the women remembering being offered a choice between surgery and ET with PET. However, the interview data suggest that whilst most women interviewed remember being offered a choice, they do not all recall the choice being between surgery and ET with PT. There was agreement between the literature and the quantitative (questionnaire) findings for this theme but there was dissonance with these datasets and the qualitative (interviews) findings. Examining the relationship between age and treatment offered across the datasets showed agreement between the literature and the quantitative data but not with the qualitative data. The literature and the quantitative data show a tendency towards fewer older women being offered a choice, however women in the interviews felt they had been offered a choice. Further interrogation of the qualitative data highlighted a possible difference in interpretation between the women and HCP of the meaning of 'choice'.

There was full agreement across the datasets for the theme concerning reactions to the offer of a choice, with most women appreciating the offer. However, it was clear that across the data sets that some women found the offer of choice a cause of anxiety and it seems that these older women, whilst pleased to be having a choice, wished to have time and support to consider the options available, but many did not want to delay a decision being made. The data sets all suggest that older women being offered a choice may prefer, or expect, to be guided by the HCP. Some women in the interviews felt they had 'no choice' as either their co-morbidities dictated PET or that they must have surgery to rid themselves of cancer. It is possible that the choice made by the women was a reflection of the doctor's preference (Hamaker et al. 2013). Some of the oldest women in the interviews had already made up their mind what treatment they did not want and for some the offer of PET was a bonus as they had simply decided against surgery prior to any discussions with their HCP.

### **8.2.2.        Shaping the decision**

The findings indicate that older women's treatment decisions are shaped by how they receive information and from whom; the amount and type of information they need; the format of that information and how it assists understanding. Also important is the women's own illness experience and perceptions of the meaning of cancer and the role of significant others including HCPs as well as family.

There was agreement across the themes '*Preferred source and method of receiving treatment information*', '*Views on information materials in shaping the treatment decision*', '*Preferred presentation to aid easy to understand information*', '*Amount of information preferred to make a decision about treatment*' and '*The role of family and friends, and others play in shaping the decision*'.

There was strong agreement across the data sets that older women prefer to receive verbal information from a trusted HPC. Much of the information women needed to shape their decision-making was similar to that which younger women might also require, and included issues around prognosis;

the nature of the disease; investigations and treatment and its duration; possible side effects. More specifically associated with older women were functional sequelae of treatment including impacts on independence and thus burden on family; age-related safety of treatments and the convenience and practical management of engaging in the different treatments offered.

Although verbal information was most strongly preferred, when considering other information sources, there was agreement across the data sets that booklets were preferred and these materials should be simply and clearly stated and be free from medical jargon. Personal cancer stories were considered helpful. Whilst simple diagrams were considered to be of assistance, graphs, charts, fractions or percentage statements were found to be unhelpful with the use of more narrative approaches strongly preferred. There was little interest found across the data sets in electronic forms of information presentation such as DVDs CDs or the internet. It was found across all data sets that women wanted information, but the amount appeared very variable, possibly reflecting an individualised, personal need.

There was agreement between the literature and the findings from the interviews for '*The role of previous experience of serious illness and own perceptions of cancer*' in shaping the decision. However, there was 'silence' between these two and the questionnaire findings. This could be explained by it not being specifically addressed in the questionnaire but it was not raised in the free text section. The literature review identified that personal experience or knowledge of others having had cancer impacted negatively on older women's treatment decisions. The interview data agreed that this factor impacted on shaping decisions but revealed a more personalised picture dependant on the personal situation being drawn upon.

The role of family and significant others was agreed as variable across all data sets. While some women rely on other people to inform and support the decision-making process, others do not. This is possibly a reflection on individual and family differences in approaches to information sharing and decision-making.

### **8.2.3. Making the decision**

There was agreement across all datasets for the themes, *"Making the final decision"*; *'The role of the doctor or nurse in discussing the final decision'* *'Preferred decision-making style'* *'Satisfaction with treatment decision'*, and *'Influencing factors in the treatment decision'*.

There was agreement across the data sets that older women wish to be involved in deciding the treatment they will have. There was also agreement that the level of involvement for individual women is variable. The interview data indicates some women were happy for their doctor to make the decision, some of these after explaining their perspective to the doctor; others shared the decision with health staff; some made the final decision after considering the doctor's opinion. The interview data revealed a few women making a decision but not being aware of options and others making a decision against the advice of their HCP. Some women described making an immediate treatment decision without consideration of the alternatives. All data sets agree that the HCP has a major role in influencing the final decision and as discussed previously older women expect and prefer input from their HCP. The data sets agree that the majority of women are satisfied with the treatment decision they took. The factors that influence the decision are not entirely clear in the literature review data, but factors such as age (reflecting the discussion in the shaping the decision theme); fear of surgery or the wish to rid themselves of cancer through surgery. The survey data indicates that women over the median age of 82 were less likely to opt for surgery.

### **8.3. Conclusions**

The findings from this mixed methods study provide further evidence of the broad areas of agreement of factors involved in treatment decision-making in older women with primary operable breast cancer. It also demonstrates the highly variable nature of this preference sensitive choice that includes the need to consider and trade-off values and benefits of many personal and clinical factors. The wide range of information requirements and variable preferences for decision-making styles suggest the need for a more tailored

approach to treatment decision-making in older women with operable breast cancer.

The following chapter provides a concluding discussion of the implications of these findings.

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## Chapter 9: Discussion

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## 9. Chapter 9: Discussion

The wider Age Gap project, in which this study is nested, concerns the problem of women over 70 years of age having seen less than half of the reduction in cancer mortality compared to younger women (ONS 2010). This is, in part, due to sub-optimal treatment as a result of concerns about poor treatment tolerance (Wylie & Ravichandran 2013). Older women have not benefitted from the advances in treatment and many do not undergo surgery, being offered instead anti-oestrogen tablets (Bouchardy et al. 2003; Money Penny 2004; Wyld, et al. 2004; Lavelle et al. 2007; Bastiaannet, et al. 2010; Lavelle et al. 2012; Morgan, Wyld, Collins & Reed 2014a).

Both ageism, the stereotypes and prejudices held about older people on the grounds of their age (Butler 1969) and sexism, the belief in traditional gender role stereotypes and in the inherent inequality between men and women, are generally accepted to exist within society (Minichiello 2000, Chrisler, Barney & Palatino 2016). North and Fiske (2012) further categorise sexism as 'hostile' (belief that women should conform to traditional less powerful roles) and 'benevolent' (wishing to protect). Chrisler, Barney & Palatino (2016) suggest that women often experience benevolent sexism combined with ageism in healthcare. This can lead to women receiving less aggressive medical treatment than men with a similar condition (Travis, Howerton, & Szymanski, 2012). A review by Lievesley, Hayes, Jones, Clark & Crosby (2009) also asserts there is evidence to suggest that ageism and age discrimination (behaviour where older people are treated unequally (directly or indirectly) on grounds of their age) (Ray, Sharp and Abrams, 2006) are frequently found in healthcare settings.

It could be argued that a combination of ageism and sexism is a feature in the assessment and treatment of breast cancer in older women. The most obvious of these is the cut off for routine breast screening. Despite a third of all breast cancers occurring in women over the age of 70 routine screening stops at 73, and women are subsequently expected to request further mammograms. In a series of studies undertaken by Lavelle and colleagues (Lavelle et al. 2007a; Lavelle et al. 2007b; Lavelle et al. 2012; Lavelle et al.

2014) there is clear evidence of sub-optimal treatment with increasing age. It is acknowledged that comorbidities increase with age; however even after adjusting for this; age is still a predictor of surgery, the recommended treatment, not occurring. The predominant reasons cited by surgeons for not performing surgery are the patients are unfit for surgery, the presence of comorbidities, patient preference and old age (Morgan et al. 2017, Sowerbutts et al. 2015). It is patient preference that this PhD aims to investigate further since it not clear why patients are choosing not to opt for surgery. Information is a pre-requisite to decision-making and little is known about the information needs and treatment decision making preferences of older women.

This PhD study aimed to establish the information needs and decision-making preferences of older women with primary operable breast cancer when faced with a choice of surgery or primary endocrine therapy (PET).

The justification for this study was the lack of evidence of the information and decision support needs of increasing numbers of older women ( $\geq 75$  years) who are diagnosed with a primary operable breast cancer and receive a choice of treatment options. Seventy-five is considered by HCPs to be the age at which it becomes clinically acceptable to introduce PET as an alternative treatment option (Mustacchi, Latteier, Milani, Bates & Houghton 1998). (There are exceptions to this particularly where a younger patient has significant comorbidities in which case PET may be a suitable option.)

Using a sequential mixed methods design, comprising a literature review, semi-structured interviews and a questionnaire each phase of the research built on the previous with the findings from each integrated to answer the research questions.

“What are the preferences for information, its sources, format and presentation for older women faced with a treatment choice for operable breast cancer?”

“What are the preferred decision-making styles in older women faced with a treatment choice for operable breast cancer?”

### 9.1. Summary of Findings

The key findings from this study were:

1. Older women with breast cancer are less likely to be given the option of making a decision about their treatment options. However, older women wish to be given a choice in the treatment options available to them, however they do not want to be simply given information and left to make the decision themselves. Although they wish to be given time to think about the decision to make, and consider it important that they are supported and guided in making a choice by their HCP, many do not want to delay a decision being made and some make an immediate decision without wishing to discuss alternatives.
2. Treatment decisions are shaped by information available to the women. Some of this information is drawn from previous personal illness or cancer experience or that of others known to them, and the impact on the decision is dependent on how that information is perceived. Older women prefer to receive information, which is pertinent to their situation, from their HCP in a face to face setting. Information in the form of booklets is preferred to electronic formats including DVDs; CDs or the internet. Booklets, the preferred option after consultation with an HPC, should be simply stated without jargon or statistical presentations. Case scenarios are seen as acceptable in booklets; this is interesting considering the role of previous experience impacting on treatment decisions and may provide the opportunity to provide realistic positive information acceptable to older women.
3. Older women wish to be involved in their treatment decisions. However, there is agreement across all data sets that decision-making style in terms of whether they prefer to make their treatment decision actively and independently; sharing the decision with their HPC or taking a passive role is variable. The majority of women are satisfied with the treatment decision they took. Their considerations of their own age is a factor in making their decision, and women over the median age of 82 were less likely to opt for surgery.

## 9.2. Limitations of the study

The studies included in the literature review were heterogeneous in terms of the design, focus, and country of study and therefore limit the comparability of the findings. The lack of studies dedicated to older women also weakens the evidence directly applicable to this group of women. However, the mixed method approach allowed wider perspectives to strengthen this evidence.

The data from the questionnaire was sub-optimal in terms of the completion rates and missing items. However, it was possible to generate useful results from some areas of the questionnaire. Although the questionnaire was developed in line with best practice this guidance may not be directly applicable to the needs of older women with a serious health issue.

The women who were interviewed were a self-selecting group and as a result it could be that they represent a particular subset of women. Details of all of the women approached were not available and it is impossible to know whether women from other backgrounds and experiences were approached or whether they simply declined the invitation to participate.

The time from diagnosis to interview may have impacted on the memory recall of the details of the women's treatment options offered. The passage of time will have allowed time for reflection and evaluation which may also have altered the views and feelings about the circumstances surrounding the breast cancer diagnosis and treatment offer. However, the commonality of the items raised in the interviews gives confidence in the findings.

It was recognised early in the study that it was not possible to achieve a large enough sample to enable generalisability of questionnaire findings. The lack of generalisability would have been detrimental had the questionnaire been the only means of data collection. As this was a mixed methods study the sub-optimal data did not jeopardise the whole study as it was possible to integrate the data collected from the other two elements.

In an effort to make the questionnaire and the participant information sheet attractive and give the study an identity, a photograph of an older woman was inserted into the documents. Since this was a study with more than one

element it was felt that a photograph of someone with whom the women may identify would encourage continued involvement. However, this proved to not always being the case. When invited to take part in the study some women expressed strong feelings that they did not identify with the image and therefore chose to decline the invitation, impacting on recruitment. These women felt that the photograph of the woman did not reflect them as she looked older than their own self-image. On reflection the photograph used, a smiling, harmless looking woman with ageing skin, conformed to all the stereotypes of an older women when trying to portray a positive ageing image. Trying to find an image that would represent how all women over 75 saw themselves was naïve as it is clear 'one size doesn't fit all'. This was a valuable lesson and something that will be seriously considered in future studies.

### **9.3. Discussion of the findings**

This study was aligned to a pragmatic philosophical position and therefore is concerned with 'what works' (Johnson & Onwuegbuzie 2004). The following discussion of the findings centres on how they may inform future practice in enhancing the care and treatment of older women diagnosed with primary operable breast cancer.

#### **9.3.1. Improving Information Support**

The tendency to prefer brief / simple and/or limited amounts of tailored information was a recurrent theme in the interviews of this study. During the interviews women talked about being 'overwhelmed' by the amount and complexity of information received and would frequently produce numerous documents that they revealed were either skimmed or unread. This finding was echoed by Schonberg et al (2014)

Many studies report cancer patients generally have high information needs (Cassileth et al. 1980; Hack et al. 1994; Davison et al. 1995; Bilodeau & Degner 1996; Blanchard, Labrecque, Ruckdeschel & Blanchard 1996; Galloway et al 1997; Vogel, Bengel & Helmes 2008b). Degner et al (1997) support the findings of this PhD reporting that older women have variable

information needs with a small number preferring a large amount whilst most prefer limited amounts.

A preference for limited information should not be construed as a lack of interest or an inferior approach to decision-making. Restricting the amount of information both verbal and written is a coping strategy some older people use to conserve cognitive resources (Aldwin 2011). There are a number of subtle ways in which women in this study sought to control the level and amount of information they preferred. Both in the literature and in the interviews women expressed a preference for information that was directly relevant to them. Personalising or tailoring information will remove extraneous general material and automatically reduce the amount of information. It will focus only on the information relevant to the women's options which will allow them to use their cognitive resources in the most efficient manner (Aldwin 2011).

Reading is known to be a more exacting activity with increasing age (Salthouse 1996) so decreasing the amount of information will also reduce the resources needed. Declining short term memory was an issue some women said impacted on the usefulness of longer documents with some reporting that by the time they had read a couple of pages they had forgotten the earlier information!

Visual displays of data are introduced into documents to reduce the reading load and provide a short-cut to information but the findings in this study contradict this. Although there is research to support the use of visual displays to explain risk and benefit (Feldman-Stewart 2007) the majority of women in this study reported little or no understanding or were confused by graphs, pictograms and charts.

Findings from this study show older women wish to be given a choice of the treatment options available to them, however they do not want to be simply given information and left to make the decision themselves. The findings from this study indicate that older women prefer to be involved in the treatment decision but they also have a desire for very focused, limited in amount information on which to make that decision.

In all three elements of this study women preferred to 'discuss' the information before making a treatment decision suggesting they wanted to ask questions and retrieve information relevant to themselves and their situation. Conversation is an activity constant throughout life and therefore a well-rehearsed skill that is generally not lost with age. Preferring verbal information is another way of reducing the amount and depth of information and therefore the cognitive load. A conversation with a doctor or nurse specialising in breast cancer is seen to be an optimum route to high quality information (Bilodeau, & Degner 1996) in comparison to the potential barriers surrounding written documents. Given the trust and respect most women have for the doctors and nurses, accessing information via a conversation seems to be an effective coping strategy.

### **9.3.2. Supporting decision-making**

It is reported in this study that involvement in treatment decision-making was preferred by older women with breast cancer. This finding is supported by Harder, Ballinger, Langridge, Ring & Fallowfield (2013). Previously older women have been reported to prefer a more passive role in treatment decision-making (Brom et al. 2014). This was not supported by this study as the findings from the Control Preference Scale (CPS) (Degner, Sloan & Ventakesh 1997) that was integrated into the questionnaire in this study showed an equal distribution for preference of an 'active' (patient-centred) or 'passive' (doctor-centred) decision-making style with fewer women preferring a 'shared' decision-making style. Brom et al (2014) reported a disparate range of results among younger women. This pattern of preference suggests women  $\geq 75$  years with primary operable breast cancer are not predominantly 'passive' decision makers compared to other cohorts. However, making any meaningful comparison with previous studies should be treated with caution as this is also the first study to examine the preferred role in DM in women  $\geq 75$  years faced with a choice of treatment for primary operable breast cancer.

It is claimed that a preference for high levels of information does not always indicate a desire for greater involvement in decision-making (Cassileth et al. 1980; Strull, Lo & Charles 1984; Sutherland et al. 1989; Hack et al. 1994;

Cox et al. 2005; Fallowfield 2008). However, the findings from this study suggest that women make immediate decisions often based on limited and/or lay information. It emerged in the interview data that whilst the older women described making seemingly quick decisions, based on their holding lay information about cancer treatments and outcomes that could be inaccurate or outdated. It could also be based on the women being experts of their own experience; their decision being based on knowing their own bodies, their levels of resilience and deep understanding of what they themselves valued and believed to be the best option for them.

The theory of 'unbounded rationality' proposes that to make a rational decision all information must be known, that time is unlimited and computation is unlimited (Simon 1955). These conditions are unrealistic in situations of uncertainty such as health but this does not mean that all human decision-making is 'irrational' (Marewki, Gaissmaier, Gigerenzer 2010). Based on the concept of 'bounded rationality' Gigerenzer and Goldstein (1996) propose the 'fast and frugal heuristic' model, also referred to as the 'rule of thumb', in which they argue, based on the later work of Simon (1978), that information processing systems need to 'satisfice' and not 'optimise' in order to make decisions with limited time, knowledge or computational capacity (cognitive capacity). Simon (1978) rejects the idea of 'unbounded rationality' that decisions made under uncertain conditions are made by examining all possible items of information and calculating their possible outcome and choosing the alternative that scores highest. Results of research comparing the use of the fast and frugal model versus more classical norms of rational decision-making show the number of correct decisions made to be either the same, or in some cases more, using the fast and frugal model (Gigerenzer and Goldstein 1996). During their research a 'less is more' effect was detected. There was a point at which more information eventually caused a decrease in correct decisions being made.

The fast and frugal model supports the notion that providing a preferred amount and level of information can lead to decisions that are no less valid than using a greater volume of information (Gigerenzer and Goldstein 1996; Reyna 2008; Marewki, Gaissmaier, Gigerenzer 2010). In fact, it is argued that



the ability to make valid decisions on key pieces of information which, give the gist of the situation, is an innate feature of human beings (Gigerenzer and Goldstein 1996).

Computation that can be interpreted as cognitive capacity, plays a part in the decision-making process. With increasing age cognitive abilities change often making it difficult to understand more complex information such as the options of treatment for breast cancer. Providing large quantities of information is likely to be counterproductive in informing women of the options as they become overwhelmed and cease to engage in the process and ultimately make less rational decisions (Marewski, Gaissmaier, Gigerenzer 2010).

The third element proposed to be essential in decision-making is time. Time is relative to the situation. Faced with an immediate threat which requires a decision then the timespan is extremely short. In this study women were concerned about the amount of time they should take in making a decision about the treatment for what they perceive as a life threatening illness. Many wanted to make, or made, an instant decision despite being reassured that they could take time to consider their options. In line with other studies (Schonberg et al. 2014; Ekdal, Andersson & Friedrichsen 2010; Husain 2008) some women made their decision on pre-conceived ideas about the treatment and quickly rejected or accepted treatments offered to them. Others immediately deferred the decision to the HCPs they trusted and believed had greater knowledge and experience to make this decision. Deferring to HCPs to make treatment decisions is supported by Husain (2008) who also found women to be guided either by looking for cues as to what the HCP was recommending or by a direct request to make a final decision. Making decisions quickly is no less valid than using a protracted deliberative and resource intensive approach (Marewski, Gaissmaier, Gigerenzer 2010) and is a way of using limited personal resources (Aldwin 2011).

Although it could be inferred that women are choosing an effective coping strategy in deferring to others, it may also be that they are faced with barriers

that preclude participation in treatment decision-making. Not recognising that they were being offered a choice, poor understanding of the information given or feeling they were unable to ask questions about the options presented to them have been recognised as barriers to patient involvement in decision-making (Joseph-Williams, Elwyn and Edwards 2014).

#### **9.4. Conclusions**

This mixed methods study has explored the information needs and decision-making preferences of older women faced with a treatment option of surgery or PET for primary operable breast cancer. New understandings have been generated around the processes of decision-making undertaken by older women and how they can be supported. This study indicates that this group of women are not passive decision makers and make quick based on, at times, limited information. They appreciate being offered a choice of treatment and wish to discuss their options face to face with a HCP from whom they take cues and hold in high regard. This group of women are not inclined to access digital information and prefer clearly stated simply framed information formats.

The findings from this study show there is diversity across the information and decision support preferred by older women with breast cancer and faced with a treatment choice of surgery or PET. The majority wish to be involved in the decision-making process whilst a few prefer to defer total responsibility of the final decision to HCPs, most commonly the doctor. With very few exceptions the women trusted the information and the views of the doctor but still preferred to discuss the treatment options. There were women who did not understand why they were given a choice or feel they had the knowledge and experience to make such a decision.

It may be appropriate that when considering treatment options HCPs are mindful that those deferring responsibility are in the minority and they may need encouragement to understand that they can make a valid contribution to the discussion and the decision if they prefer. For those who find the possibility of decision-making too exacting the HCP should perhaps view this as an efficient coping mechanism and provide support.

Giving time and space to women who have little knowledge and a reluctance to participate in decision-making may seem resource intensive. However, the benefits of appropriate decisions being made outweigh the disadvantages and have been clearly demonstrated in the literature.

## **Recommendations**

It has been reported that younger women prefer to receive extensive information about their breast cancer diagnosis and treatment. Evidence from this study suggests the information needs of older women are different and the information offered should be limited in terms of amount and complexity. This study identified information and decision support preferences that could be used in the development of dedicated decision support tools. Such support for decision-making has been shown to be of benefit (Bennett et al 2011). This work has already provided the foundational basis for the development of the decision-making tools in the form of a booklet and brief decision aid dedicated to the information needs of older women with a choice between PET and surgery.

This study identified the need to tailor decision support tools and provide treatment decision support information to meet individual needs and this has been undertaken in the online decision support tool of the wider Age Gap study.

Digital sources are currently unpopular with this group of women and should not be considered a main source for information. Brief jargon-free booklets should be provided avoiding charts and/or graphs. Statistics should be stated simply using words, for example '*Breast cancer is common in women in the UK.*

Women should be given opportunities for face to face discussions with a HCP about their individual situation. They should be part of decision-making that aligns with their preferred decision-making style, this could include being sensitive to requests for help in coming to a decision.

Some women arrive at a decision very quickly and seemingly without due consideration of the options. Practitioners should invest time in exploring women's rationale for making their decisions.

Training in the use of decision support tools should be planned and implemented for HCPs.

The development of a more comprehensive booklet to address the issues surrounding the treatment option of surgery or PET paying close attention to the language and the presentation would satisfy the needs of those who want more detailed information following consultation.

### **Recommendations for further work**

Older women are frequently excluded from research particularly large scale survey approaches. This study demonstrated some of the difficulties in the administration of self-completion questionnaires. Further work is required in the development of data collection tools appropriate for an older, frail population.

The interviews in this study established information needs and decision-making preferences, but it was not within the scope of the work to explore the underlying reasons that the women held for the decisions they came to, and the speed with which they were made. This important issue requires further research.

**Word count: 54,846**

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## *Appendices*

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***Appendix 1: Executive Summary of the parent study 'Bridging the Age Gap in Breast Cancer'***

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## **Executive Summary**

The UK population is ageing with average life expectancy increasing from 50 years, 100 years ago to over 80 today. The level of fitness of older people is also increasing with many still healthy and fully independent in their 70s and 80s. Health technologies are also rapidly advancing with improvements in the survivability of health interventions such as surgery making them safe even for many people who would have been considered too frail 20 years ago.

Despite this, there is still a perception that once a person crosses the age threshold of 65 or 70 years they are classed as 'elderly' and often subjected to age bias in their medical care. These decisions are often non evidence based as little research has been done on older people to define optimal practice. In addition, research done in the fairly recent past may no longer be valid today due to the rapid changes in technology and the rapidly improving health status and life expectancy of our population.

In the field of breast cancer, age related practice variance is widespread. The gold standard of care for early breast cancer is surgical removal of the primary cancer, sentinel node biopsy of the axillary nodes and adjuvant therapies which may include chemotherapy, trastuzumab, anti-oestrogens and radiotherapy. There is consistent evidence that older women are often denied surgery, chemotherapy, radiotherapy and trastuzumab based on the premise that there is no evidence of efficacy. It is known that cancer specific outcomes in older women with breast cancer are significantly worse than those in younger women and can no longer be simply attributed to competing causes of death.

In the case of surgery, up to 40% of older women do not get surgery for their breast cancer, with treatment being with anti-oestrogen tablets alone, known as primary endocrine therapy (PET). This type of treatment was shown to be effective in several trials in the 1980s, with the trials showing no survival disadvantage although rates of local control were sub-optimal. Life expectancy has moved on by almost 10 years since then and fitness levels have improved and surgical and anaesthetic techniques are much safer and

yet many clinicians continue to use non-surgical strategies in a significant proportion of women over 70.

Undoubtedly there are some older women for whom surgery is associated with significant risks and many older women have a preference for minimalist treatment for a variety of reasons. It is therefore appropriate to use anti-oestrogens in this way in some older women. The problem we have is that there is no guidance on the characteristics of older women which suggest they will do better with surgery or PET.

In a similar vein, chemotherapy is part of the gold standard of care for many women with aggressive, oestrogen receptor (ER) negative and/or Her 2 positive, breast cancer. However the rate of chemotherapy usage in older women is very low, with a lack of research evidence to support its use and concerns about its safety in older women. Older women with these more aggressive cancers are often denied this treatment. Clearly there will be some women for whom chemotherapy will be inappropriate and others for whom benefit may be gained.

The BTAG study will use state of the art statistical and modelling techniques to determine the age, comorbidity, frailty and disease characteristics of women over 70 with early breast cancer to provide guidance on 2 primary questions:

1. What are the personal and cancer characteristics of women who can be safely advised that surgery is unlikely to confer any advantage for them?
2. What are the personal and cancer characteristics of women who should be advised to have adjuvant chemotherapy after surgery?

A preliminary disease and outcome statistical model will be derived using pre-existing data from the UK primary breast cancer registry held by the West Midlands Cancer Intelligence Unit (WMCIU) and the NHS Hospital Episode Statistics data. These data have certain recognised areas of weakness, in particular relating to the completeness of and quality of comorbidity data. In addition, staging and co-morbidity data may be less

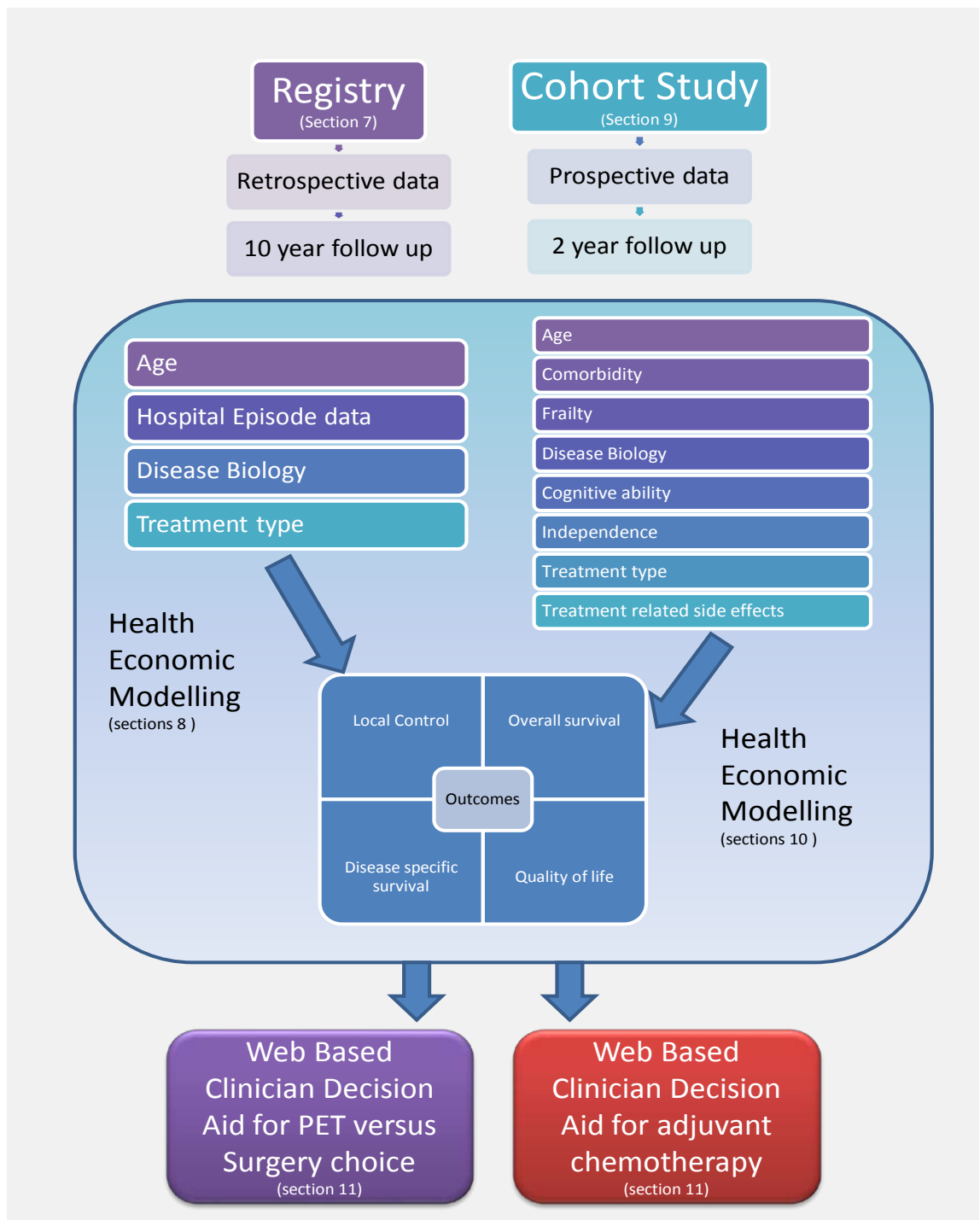


accurate in women treated non surgically as there will be no post-operative pathology data returns. To overcome these limitations a UK wide data collection exercise to gather detailed data on older women, their primary disease, health status and treatment details and medium term outcomes will be performed. Initial 2 year direct follow up via direct data collection for the study will be supplemented by longer term follow-up via cancer registry returns for up to 10 years of follow up.

The study will also explore the underlying reasons for practice variance across the UK by analysis of variance between UK breast units. These new data will be used to revise and validate the preliminary statistical model. The statistical models will also be used to develop a health economic model to estimate long-term health outcomes and costs for different intervention strategies.

The final stage of the project will be to use the model to develop a web-based algorithm to support clinicians in decision-making related to older women with breast cancer which will be responsive to their personal and cancer characteristics.

## Study Algorithm



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## *Appendix 2: Literature Search Strategy*

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## **Literature review Search Strategy**

This review addressed the research aim:

To establish the information needs and preferences of older women with early breast cancer when faced with a choice of surgery or primary endocrine therapy (PET).

The type of review undertaken was 'Systematic search and review'

Eligibility criteria

Studies were selected according to the criteria listed below.

### **Study design**

A study was eligible for inclusion in the review if it reported primary data using either qualitative, quantitative or mixed methods. Review papers were not eligible for inclusion in the review, but were used to cross-check for relevant primary studies. Editorials and opinion pieces were excluded.

### **Population**

Eligible studies needed to focus on older women, defined as:  $\geq 65$  years of age with a primary diagnosis of early operable breast cancer. Studies which included studies which had a proportion of participants  $\geq 65$  years of age and those with mixed cancer cohorts were included. Studies addressing metastatic breast cancer or male breast cancer were excluded.

### **Intervention**

Studies were eligible for inclusion if the intervention reported was surgery or PET.

### **Comparator**

Studies were not required to include a comparator to be eligible for inclusion.

### **Outcomes**

A study was eligible for inclusion if it reported the information needs of older patients, the media or format of information and patient experience of the decision-making process.

### **Setting**

Studies were eligible for inclusion irrespective of their setting.

### **Information sources**

The bibliographic databases as follows were searched from their inception to present: CINAHL (EBSCO), Cochrane Library (Wiley), MEDLINE (EBSCO), PsycINFO (ProQuest), Scopus (Elsevier), Web of Science (Thomson Reuters).

Author, citation and reference searches were undertaken on papers included in the review.

### **Search strategy**

The search strategy comprised four facets and used terms related to: (1) older people, and (2) terms to describe breast cancer, and (3) terms to describe surgery or primary endocrine therapy, and (4) terms related to health literacy. The full search strategy as written up for MEDLINE is included in Appendix 1. The searches were undertaken in January 2013. The searches were updated in February 2017.

All search terms were looked for in the title and abstract fields and controlled vocabulary terms were used where available. The Boolean operators AND and OR were used, alongside truncation, phrase searching and proximity operators. Only papers published from 1980 onwards and in the English language were sought.

**RefWorks**, a bibliographic management tool, was used to organise the literature yielded for this review and to remove duplicate bibliographic records.

### **Selection process**

Using the stated eligibility criteria, all literature was assessed by one reviewer (MB) for inclusion in the review. In the first instance this took place at title and abstract level. Following the initial screen of titles, a second reviewer (KC) checked the inclusions for appropriateness and accuracy. This was followed by a screening of the full-text of all remaining papers to determine their eligibility. During the screening process, the reviewer was not blinded to the author/s or journal title.

### **Data collection process**

All papers included in the review were subjected to a structured information abstraction process. Data was extracted by one reviewer (MB) using the data extraction form

### **Data synthesis**

The data were synthesised using a thematic approach. The themes were pre-derived based on each element of the research aim.

### **Results**

The literature searches yielded 3190 results in the original search and 1367 in the re-run. After the removal of duplicates and screening for relevancy 275 and 111 papers respectively were included in this review.

### **Search strategy for older women, breast cancer, PET / Surgery and information needs**

All searches have been written up for MEDLINE using the EBSCO interface.

Explanation of search terms used: / = MeSH Heading; exp = exploded MeSH Heading; \* = denotes any character/s; ti = title word; ab = abstract word; pt = publication type; N = adjacency of words; N3 = adjacency within 3 words; "" = phrase search

English language filters were applied where available.

1. "older people\*".ti,ab.
2. "older women\*".ti,ab.
3. "older woman\*".ti,ab.

4. geriatric\*.ti,ab.
5. elderly.ti,ab.
6. "older old".ti,ab.
7. sevent\*.ti,ab
8. aged.ti,ab.
9. frail elderly/
10. geriatrics/
11. aged/
12. aged, 80 and over/
13. or/1-12
  
14. "breast cancer\*".ti,ab.
15. "breast neoplasm\*".ti,ab.
16. "breast carcinoma\*".ti,ab.
17. breast neoplasms/
18. carcinoma, ductal, breast/
19. or/14-18
  
20. surgeon\*.ti,ab.
21. "primary endocrine therap\*".ti,ab.
22. pet.ti,ab.
23. general surgery/
24. mastectomy/
25. mastectomy, segmental/
26. or/20-25
  
27. choice\*.ti,ab.
28. preference\*.ti,ab.
29. communicat\*.ti,ab.
30. decision N3 mak\*.ti,ab.
31. role\*.ti,ab.
32. educat\*.ti,ab.
33. knowledg\*.ti,ab.
34. understand\*.ti,ab.
35. pathway\*.ti,ab.
36. "patient choice\*".ti,ab.
37. "patientparticipat\*".ti,ab.
38. comprehen\*.ti,ab.
39. health N3 litera\*.ti,ab.
40. handout\*.ti,ab.
41. hand-out\*.ti,ab.
42. factsheet\*.ti,ab.
43. fact-sheet\*.ti,ab.

- 44. information\* N3 sheet\*.ti,ab.
- 45. leaflet\*.ti,ab.
- 46. pamphlet\*.ti,ab.
- 47. patientpreference/
- 48. communication/
- 49. consumer participation/
- 50. decision-making/
- 51. health services accessibility/
- 52. communication barriers/
- 53. or/27-52
- 54. 13 and 19 and 26 and 53



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### *Appendix 3: Table of New Articles*

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Table to show details of new articles

Author & Article Title Country of study	Aim of the study	Sample & age	Key findings
FRONGILLO, M., FEIBELMANN, S., BELKORA, J., LEE, C. and SEPUCHA, K., 2013. Is there shared decision-making when the provider makes a recommendation? Patient education and counseling, 90(1), pp. 69-73.  USA	Hypotheses: <ul style="list-style-type: none"> <li>when providers made a treatment recommendation, patients would report less Involvement in the interaction compared to no recommendation was made</li> <li>that patients who received a lumpectomy recommendation would have lower involvement scores compared to those who received other recommendations</li> </ul>	440 patients completed the surgery survey (response rate 58%).Patients were on average 56.9 years old (SD 11.3),	This study found an association between the type of treatment recommendation regarding breast cancer surgical decisions and the amount of shared decision-making in the interaction.  Patients are not getting a balanced view of the options, or being asked their preferences, particularly when providers recommend a lumpectomy. Providers are not discussing the option to have a mastectomy or eliciting patients' treatment preferences often enough to ensure shared decision-making in these interactions.

Author & Article Title Country of study	Aim of the study	Sample & age	Key findings
LIVAUDAIS, J.C., FRANCO, R., FEI, K. and BICKELL, N.A., 2013. Breast Cancer Treatment Decision-Making: Are We Asking Too Much of Patients? Journal of General Internal Medicine, 28(5), pp. 630-636.  USA	Explored the associations between breast cancer patients' perceived degree of responsibility for treatment decision-making and a) knowledge of the benefit of surgical and adjuvant treatments discussed with the physician and b) regret of decisions after 6 months.	368 women aged 28–89	Too much perceived responsibility for breast cancer treatment decisions was associated with poor baseline treatment knowledge and 6-month decision regret. Health literacy problems were common, suggesting that health care professionals find alternative ways to communicate with low health literacy patients, enabling them to assume the desired amount of decision-making responsibility, thereby reducing decision regret.

Author & Article Title Country of study	Aim of the study	Sample & age	Key findings
<p>O'BRIEN, M.A., CHARLES, C., WHELAN, T.J., ELLIS, P.M., GAFNI, A. and LOVRICS, P., 2013. Women's perceptions of their involvement in treatment decision-making for early stage breast cancer. Supportive Care in Cancer, 21(6), pp. 1717-1723.</p> <p>Canada</p>	<p>This study aimed to describe the perceptions of women with early stage breast cancer regarding their involvement in treatment decision-making (TDM).</p>	<p>Nineteen women (median age, 61 years; range, 40–74 years) with early stage breast cancer considering surgery (n = 6) or adjuvant therapy (n = 13) participated in semi-structured interviews.</p>	<p>Women described being involved in various stages of TDM and interacting with informal networks and specialists. Women's descriptions suggest that</p> <p>(1) the concept of involvement in TDM may have a broader meaning for patients than strictly their decisional role</p> <p>(2) inclusion of significant others in TDM contributes to the patient's sense of involvement.</p> <p>Raises questions about what involvement means to these patients and suggest that the focus on patient involvement in TDM within the clinic setting may be too narrow to capture the meaning of involvement from the patient's perspective.</p>

Author & Article Title Country of study	Aim of the study	Sample & age	Key findings
<p>SOWERBUTTS, A.M., GRIFFITHS, J., TODD, C. and LAVELLE, K., 2015. Why are older women not having surgery for breast cancer? A qualitative study. Psycho-oncology, 24(9), pp. 1036-1042.</p> <p>UK</p>	<p>This study explores reasons why older women are not having surgery.</p>	<p>28 women, 76–99 years (mean 86 years) participated in semi-structured interviews.</p>	<p>Group 1 - Patients who declined' absolutely ruled out surgery. These patients were not interested in maximising their survival and rejected surgery citing their age or concerns about impact of treatment on their level of functioning.</p> <p>Group 2 - Patient considered surgery but chose to have PET most specifying if PET failed then they could have the operation. Patients viewed this as offering them two options of treatment. Group 3 - Surgeon decided these patients were started by the surgeon on PET. These patients had comorbidities and in most cases the surgeon asserted that the comorbidities were incompatible with surgery.</p>

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## *Appendix 4: NICE Qualitative Appraisal Checklists*

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## NICE Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Crooks, D. L. (2001). Older women with breast cancer: New understandings through grounded theory research. <i>Health Care for Women International</i> , 22(1-2), 99-114.	
<b>Guidance topic:</b> This article reported the use of grounded theory in understanding breast cancer in older women.	Key research question/aim: To study how older women live with breast cancer, integrate cancer into their lives and understand their experiences.	
<b>Checklist completed by:</b>	MB	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example:  Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?  Could a quantitative approach better have addressed the research question?	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  The author went to great lengths to explain why a qualitative methodology was used.
<b>2. Is the study clear in what it seeks to do?</b>  For example:  Is the purpose of the study discussed – aims/objectives/research question/s?  Is there adequate/appropriate reference to the literature?  Are underpinning values/assumptions/theory discussed?	<u><b>Clear</b></u>  Unclear  Mixed	Comments:  The context of the study and the reason for it are discussed with reference to relevant literature. The aim of the study is not overtly stated but as part of the context and literature review.  Values and theories are discussed.
<b>Study design</b>		
<b>3. How defensible/rigorous is the research design/methodology?</b>	<u><b>Defensible</b></u>  Indefensible	Comments:  This article was an exploration of the use of grounded theory and therefore

<p>For example:</p> <p>Is the design appropriate to the research question?</p> <p>Is a rationale given for using a qualitative approach?</p> <p>Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</p> <p>Is the selection of cases/sampling strategy theoretically justified?</p>	<p>Not sure</p>	<p>included significant discussion of the methodology and data collection.</p> <p>No justification was given of the sample</p>
<b>Data collection</b>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <p>Are the data collection methods clearly described?</p> <p>Were the appropriate data collected to address the research question?</p> <p>Was the data collection and record keeping systematic?</p>	<p>Appropriately</p> <p>Inappropriately</p> <p>Not sure/<u><b>inadequately reported</b></u></p>	<p>Comments:</p> <p>The author does not report details of where the interviews took place. The topics addressed were only identified in the findings section. Record keeping was not addressed</p>
<b>Trustworthiness</b>		
<p><b>5. Is the role of the researcher clearly described?</b></p> <p>For example:</p> <p>Has the relationship between the researcher and the participants been adequately considered?</p> <p>Does the paper describe how the research was explained and presented to the participants?</p>	<p>Clearly described</p> <p><u><b>Unclear</b></u></p> <p>Not described</p>	<p>Comments:</p> <p>The researcher appears to be a nurse undertaking a PhD. She describes the bond she developed with the participants. The process of recruitment not described.</p>
<p><b>6. Is the context clearly described?</b></p> <p>For example:</p>	<p>Clear</p> <p><u><b>Unclear</b></u></p>	<p>Comments:</p> <p>Minimum amount of information given</p>



<p>Are the characteristics of the participants and settings clearly defined?</p> <p>Were observations made in a sufficient variety of circumstances</p> <p>Was context bias considered</p>	<p>Not sure</p>	<p>about the participants.</p> <p>As this was purely a grounded theory study only interviews would be used.</p>
<p><b>7. Were the methods reliable?</b></p> <p>For example:</p> <p>Was data collected by more than 1 method?</p> <p>Is there justification for triangulation, or for not triangulating?</p> <p>Do the methods investigate what they claim to?</p>	<p><b><u>Reliable</u></b></p> <p>Unreliable</p> <p>Not sure</p>	<p>Comments:</p> <p>The method is appropriate and fulfils the study aims.</p>
<b>Analysis</b>		
<p><b>8. Is the data analysis sufficiently rigorous?</b></p> <p>For example:</p> <p>Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</p> <p>How systematic is the analysis, is the procedure reliable/dependable?</p> <p>Is it clear how the themes and concepts were derived from the data?</p>	<p>Rigorous</p> <p><b><u>Not rigorous</u></b></p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Very limited information on how themes were derived or their analysis. No one else reported to be involved.</p>
<p><b>9. Is the data 'rich'?</b></p> <p>For example:</p> <p>How well are the contexts of the data described?</p> <p>Has the diversity of perspective and content been explored?</p> <p>How well has the detail and depth been demonstrated?</p>	<p><b><u>Rich</u></b></p> <p>Poor</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Detailed reporting of the findings.</p>

Are responses compared and contrasted across groups/sites?		
<b>10. Is the analysis reliable?</b>  For example:  Did more than 1 researcher theme and code transcripts/data?  If so, how were differences resolved?  Did participants feed back on the transcripts/data if possible and relevant?  Were negative/discrepant results addressed or ignored?	Reliable  Unreliable  Not sure/ <b><u>not reported</u></b>	Comments:  None of these items were addressed
<b>11. Are the findings convincing?</b>  For example:  Are the findings clearly presented?  Are the findings internally coherent?  Are extracts from the original data included?  Are the data appropriately referenced?  Is the reporting clear and coherent?	<b><u>Convincing</u></b>  Not convincing  Not sure	Comments:  Details of the findings were reported and examined in the light of the literature. No quotes were given.
<b>12. Are the findings relevant to the aims of the study?</b>	<b><u>Relevant</u></b>  Irrelevant  Partially relevant	Comments:  The aims of the study were addressed
<b>13. Conclusions</b>  For example:  How clear are the links between data, interpretation and conclusions?  Are the conclusions plausible and coherent?  Have alternative explanations been explored and discounted?	<b><u>Adequate</u></b>  Inadequate  Not sure	Comments:  Limited acknowledgement of the limitations. Limited discussion and exploration. More could have been done with the findings.  In line with the aim of the article the conclusions were largely around the use of grounded theory.

<p>Does this enhance understanding of the research topic?</p> <p>Are the implications of the research clearly defined?</p> <p>Is there adequate discussion of any limitations encountered?</p>		
<b>Ethics</b>		
<p><b>14. How clear and coherent is the reporting of ethics?</b></p> <p>For example:</p> <p>Have ethical issues been taken into consideration?</p> <p>Are they adequately discussed e.g. do they address consent and anonymity?</p> <p>Have the consequences of the research been considered i.e. raising expectations, changing behaviour?</p> <p>Was the study approved by an ethics committee?</p>	<p>Appropriate</p> <p>Inappropriate</p> <p><b><u>Not sure/not reported</u></b></p>	<p>Comments:</p> <p>Although no direct statement about receiving a favourable ethical approval was made reference was made to 'doctoral committee' raising concerns about the burden of the interviews which she defended.</p>
<b>Overall assessment</b>		
<p>As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)</p>	<p>++</p> <p><b>+</b></p> <p>–</p>	<p>Comments:</p>

## Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Ciambrone, D. (2006). Treatment decision-making among older women with breast cancer. <i>Journal of women &amp; aging</i> , 18(4), 31-47.	
<b>Guidance topic:</b> Rx DM among older women BrCa	<b>Key research question/aim:</b> To identify factors associated with older women's breast cancer treatment decisions, their adherence to breast cancer surveillance and to ascertain how the women's primary support persons influence those decisions.	
<b>Checklist completed by:</b>	<b>MB</b>	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example: <ul style="list-style-type: none"> <li>Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?</li> <li>Could a quantitative approach better have addressed the research question?</li> </ul>	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  This was an exploratory study and therefore a qualitative approach was the most appropriate.
<b>2. Is the study clear in what it seeks to do?</b>  For example: <ul style="list-style-type: none"> <li>Is the purpose of the study discussed – aims/objectives/research question/s?</li> <li>Is there adequate/appropriate reference to the literature?</li> <li>Are underpinning values/assumptions/theory discussed?</li> </ul>	<u><b>Clear</b></u>  Unclear  Mixed	Comments:  The case to undertake this study was clearly made with reference to the literature.  The aims of the study are stated early in the paper.  The underlying theories around the sub-optimal treatment women received are raised and discussed.
<b>Study design</b>		

<p><b>3. How defensible/rigorous is the research design/methodology?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Is the design appropriate to the research question?</li> <li>• Is a rationale given for using a qualitative approach?</li> <li>• Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</li> <li>• Is the selection of cases/sampling strategy theoretically justified?</li> </ul>	<p><u><b>Defensible</b></u></p> <p>Indefensible</p> <p>Not sure</p>	<p>Comments:</p> <p>Implied justification for sample. No rationale for the use of qual approach - but based on my knowledge this is appropriate.</p>
<p><b>Data collection</b></p>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Are the data collection methods clearly described?</li> <li>• Were the appropriate data collected to address the research question?</li> <li>• Was the data collection and record keeping systematic?</li> </ul>	<p><u><b>Appropriately</b></u></p> <p>Inappropriately</p> <p>Not sure/inadequately reported</p>	<p>Comments:</p> <p>There were no details about where interviews took place or whether there was a choice of venue.</p> <p>Did not collect data on surveillance as this was not an issue for this group of women.</p>
<p><b>Trustworthiness</b></p>		
<p><b>5. Is the role of the researcher clearly described?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Has the relationship between the researcher and the participants been adequately considered?</li> <li>• Does the paper describe how the research was explained and presented to the participants?</li> </ul>	<p>Clearly described</p> <p>Unclear</p> <p><u><b>Not described</b></u></p>	<p>Comments:</p> <p>Nothing about researcher-participant relationship.</p> <p>Description given of the process of recruitment and this seems to be at a distance from the researcher.</p>

<p><b>6. Is the context clearly described?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Are the characteristics of the participants and settings clearly defined?</li> <li>• Were observations made in a sufficient variety of circumstances</li> <li>• Was context bias considered</li> </ul>	<p>Clear</p> <p><b><u>Unclear</u></b></p> <p>Not sure</p>	<p>Comments:</p> <p>Details of the where and how the women were recruited. Some details given of the women's characteristics and the recruitment rate.</p>
<p><b>7. Were the methods reliable?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Was data collected by more than 1 method?</li> <li>• Is there justification for triangulation, or for not triangulating?</li> <li>• Do the methods investigate what they claim to?</li> </ul>	<p>Reliable</p> <p>Unreliable</p> <p><b><u>Not sure</u></b></p>	<p>Comments:</p> <p>No information as to why only one method of data collection was undertaken and therefore no triangulation.</p>
<p><b>Analysis</b></p>		
<p><b>8. Is the data analysis sufficiently rigorous?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</li> <li>• How systematic is the analysis, is the procedure reliable/dependable?</li> <li>• Is it clear how the themes and concepts were derived from the data?</li> </ul>	<p>Rigorous</p> <p>Not rigorous</p> <p><b><u>Not sure/not reported</u></b></p>	<p>Comments:</p> <p>Very limited information on how themes were arrived at. No one else reported to be involved.</p> <p>Process of analysis was described.</p>
<p><b>9. Is the data 'rich'?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• How well are the contexts of the</li> </ul>	<p><b><u>Rich</u></b></p> <p>Poor</p> <p>Not sure/not</p>	<p>Comments:</p> <p>Detailed reporting of the findings with quotes.</p> <p>Difficult to explore the perspectives as</p>

<p>data described?</p> <ul style="list-style-type: none"> <li>Has the diversity of perspective and content been explored?</li> <li>How well has the detail and depth been demonstrated?</li> <li>Are responses compared and contrasted across groups/sites?</li> </ul>	<p>reported</p>	<p>the women are from a similar background.</p>
<p><b>10. Is the analysis reliable?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>Did more than 1 researcher theme and code transcripts/data?</li> <li>If so, how were differences resolved?</li> <li>Did participants feed back on the transcripts/data if possible and relevant?</li> <li>Were negative/discrepant results addressed or ignored?</li> </ul>	<p>Reliable</p> <p><u><b>Unreliable</b></u></p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>None of these items were addressed</p>
<p><b>11. Are the findings convincing?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>Are the findings clearly presented?</li> <li>Are the findings internally coherent?</li> <li>Are extracts from the original data included?</li> <li>Are the data appropriately referenced?</li> <li>Is the reporting clear and coherent?</li> </ul>	<p><u><b>Convincing</b></u></p> <p>Not convincing</p> <p>Not sure</p>	<p>Comments:</p> <p>All items addressed</p>
<p><b>12. Are the findings relevant to the aims of the study?</b></p>	<p><u><b>Relevant</b></u></p> <p>Irrelevant</p> <p>Partially relevant</p>	<p>Comments:</p>

<p><b>13. Conclusions</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• How clear are the links between data, interpretation and conclusions?</li> <li>• Are the conclusions plausible and coherent?</li> <li>• Have alternative explanations been explored and discounted?</li> <li>• Does this enhance understanding of the research topic?</li> <li>• Are the implications of the research clearly defined?</li> </ul> <p><b>Is there adequate discussion of any limitations encountered?</b></p>	<p><u><b>Adequate</b></u></p> <p>Inadequate</p> <p>Not sure</p>	<p>Comments:</p> <p>Limited acknowledgement of the limitations. Limited discussion and exploration. More could have been done with the findings.</p> <p>However does 'Ring true' when in the context of my own research.</p>
<p><b>Ethics</b></p>		
<p><b>14. How clear and coherent is the reporting of ethics?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>• Have ethical issues been taken into consideration?</li> <li>• Are they adequately discussed e.g. do they address consent and anonymity?</li> <li>• Have the consequences of the research been considered i.e. raising expectations, changing behaviour?</li> <li>• Was the study approved by an ethics committee?</li> </ul>	<p>Appropriate</p> <p>Inappropriate</p> <p><u><b>Not sure/not reported</b></u></p>	<p>Comments:</p> <p>No reference to any ethics approval or issues</p>
<p><b>Overall assessment</b></p>		
<p><b>As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)</b></p>	<p>++</p> <p>±</p>	<p>Comments:</p>



## Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Kreling, B., Figueiredo, M. I., Sheppard, V. L., & Mandelblatt, J. S. (2006). A qualitative study of factors affecting chemotherapy use in older women with breast cancer: barriers, promoters, and implications for intervention. <i>Psycho-Oncology</i> , 15(12), 1065-1076.	
<b>Guidance topic:</b> Barriers to older women with BrCa affecting chemo uptake.	Key research question/aim: To understand factors involved in older women's use or non-use of indicated adjuvant non-hormonal chemotherapy.	
<b>Checklist completed by:</b>	MB	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example:  Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?  Could a quantitative approach better have addressed the research question?	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  The qualitative approach was appropriate.
<b>2. Is the study clear in what it seeks to do?</b>  For example:  Is the purpose of the study discussed – aims/objectives/research question/s?  Is there adequate/appropriate reference to the literature?  Are underpinning values/assumptions/theory discussed?	<u><b>Clear</b></u>  Unclear  Mixed	Comments:  Each of these items was addressed.
<b>Study design</b>		

<p><b>3. How defensible/rigorous is the research design/methodology?</b></p> <p>For example:</p> <p>Is the design appropriate to the research question?</p> <p>Is a rationale given for using a qualitative approach?</p> <p>Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</p> <p>Is the selection of cases/sampling strategy theoretically justified?</p>	<p><b><u>Defensible</u></b></p> <p>Indefensible</p> <p>Not sure</p>	<p>Comments:</p> <p>Full details were given of the study design, sample selection, data collection procedures and the analysis.</p>
<p><b>Data collection</b></p>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <p>Are the data collection methods clearly described?</p> <p>Were the appropriate data collected to address the research question?</p> <p>Was the data collection and record keeping systematic?</p>	<p><b><u>Appropriately</u></b></p> <p>Inappropriately</p> <p>Not sure/inadequately reported</p>	<p>Comments:</p> <p>Data collection was described in great detail. The topics addressed were given and the style of the focus groups was described.</p> <p>There was no mention of data storage.</p>
<p><b>Trustworthiness</b></p>		
<p><b>5. Is the role of the researcher clearly described?</b></p> <p>For example:</p> <p>Has the relationship between the researcher and the participants been adequately considered?</p> <p>Does the paper describe how the research was explained and presented to the participants?</p>	<p>Clearly described</p> <p>Unclear</p> <p><b><u>Not described - fully</u></b></p>	<p>Comments:</p> <p>It was clear how the participants were recruited and that they provided 'written informed consent' but no details as to how they were informed. No information of the researchers/participant relationship</p>

<p><b>6. Is the context clearly described?</b></p> <p>For example:</p> <p>Are the characteristics of the participants and settings clearly defined?</p> <p>Were observations made in a sufficient variety of circumstances</p> <p>Was context bias considered</p>	<p><u><b>Clear</b></u></p> <p>Unclear</p> <p>Not sure</p>	<p>Comments:</p> <p>Clear rationale given for the use of focus groups as opposed to individual interviews. The FGs were undertaken in a variety of settings to address the particular needs of the participants. Bilingual researchers were employed to conduct a group of Latino women.</p>
<p><b>7. Were the methods reliable?</b></p> <p>For example:</p> <p>Was data collected by more than 1 method?</p> <p>Is there justification for triangulation, or for not triangulating?</p> <p>Do the methods investigate what they claim to?</p>	<p><u><b>Reliable</b></u></p> <p>Unreliable</p> <p>Not sure</p>	<p>Comments:</p> <p>The method does address the question.</p>
<p><b>Analysis</b></p>		
<p><b>8. Is the data analysis sufficiently rigorous?</b></p> <p>For example:</p> <p>Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</p> <p>How systematic is the analysis, is the procedure reliable/dependable?</p> <p>Is it clear how the themes and concepts were derived from the data?</p>	<p><u><b>Rigorous</b></u></p> <p>Not rigorous</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Clear and detailed report given of data analysis including how and who was involved in theme development.</p>
<p><b>9. Is the data 'rich'?</b></p> <p>For example:</p> <p>How well are the contexts of the</p>	<p><u><b>Rich</b></u></p> <p>Poor</p> <p>Not sure/not</p>	<p>Comments:</p> <p>Very thorough and balanced reporting of the findings.</p>

<p>data described?</p> <p>Has the diversity of perspective and content been explored?</p> <p>How well has the detail and depth been demonstrated?</p> <p>Are responses compared and contrasted across groups/sites?</p>	<p>reported</p>	
<p><b>10. Is the analysis reliable?</b></p> <p>For example:</p> <p>Did more than 1 researcher theme and code transcripts/data?</p> <p>If so, how were differences resolved?</p> <p>Did participants feed back on the transcripts/data if possible and relevant?</p> <p>Were negative/discrepant results addressed or ignored?</p>	<p><u><b>Reliable</b></u></p> <p>Unreliable</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>The process of theme development, procedure for transcription and data analysis was given.</p> <p>There was no mention of participants feeding back on the transcription.</p>
<p><b>11. Are the findings convincing?</b></p> <p>For example:</p> <p>Are the findings clearly presented?</p> <p>Are the findings internally coherent?</p> <p>Are extracts from the original data included?</p> <p>Are the data appropriately referenced?</p> <p>Is the reporting clear and coherent?</p>	<p><u><b>Convincing</b></u></p> <p>Not convincing</p> <p>Not sure</p>	<p>Comments:</p> <p>Each of the items listed is addressed.</p> <p>The findings are clear to follow and are supported by the literature.</p>
<p><b>12. Are the findings relevant to the aims of the study?</b></p>	<p><u><b>Relevant</b></u></p> <p>Irrelevant</p> <p>Partially relevant</p>	<p>Comments:</p>
<p><b>13. Conclusions</b></p>	<p><u><b>Adequate</b></u></p>	<p>Comments:</p>

<p>For example:</p> <p>How clear are the links between data, interpretation and conclusions?</p> <p>Are the conclusions plausible and coherent?</p> <p>Have alternative explanations been explored and discounted?</p> <p>Does this enhance understanding of the research topic?</p> <p>Are the implications of the research clearly defined?</p> <p>Is there adequate discussion of any limitations encountered?</p>	<p>Inadequate</p> <p>Not sure</p>	<p>Good discussion which explores the findings.</p> <p>Study limitations fully acknowledged.</p>
<b>Ethics</b>		
<p><b>14. How clear and coherent is the reporting of ethics?</b></p> <p>For example:</p> <p>Have ethical issues been taken into consideration?</p> <p>Are they adequately discussed e.g. do they address consent and anonymity?</p> <p>Have the consequences of the research been considered i.e. raising expectations, changing behaviour?</p> <p>Was the study approved by an ethics committee?</p>	<p><u><b>Appropriate</b></u></p> <p>Inappropriate</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Favourable ethical approval reported.</p> <p>There is acknowledgment that the issue under discussion is potentially sensitive with women being asked to consider whether they are the subject of ageism.</p>
<b>Overall assessment</b>		
<p>As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)</p>	<p>++</p> <p>±</p> <p>–</p>	<p>Comments:</p>

## Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Husain, L. S., Collins, K., Reed, M., & Wyld, L. (2008). Choices in cancer treatment: a qualitative study of the older women's (> 70 years) perspective. <i>Psycho-Oncology</i> , 17(4), 410-416	
<b>Guidance topic:</b> Choices in cancer treatment	Key research question/aim: Factors that influenced older women's Rx choice	
<b>Checklist completed by:</b>	MB	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example:  Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?  Could a quantitative approach better have addressed the research question?	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  Study explores the factors that influence treatment decision making.
<b>2. Is the study clear in what it seeks to do?</b>  For example:  Is the purpose of the study discussed – aims/objectives/research question/s?  Is there adequate/appropriate reference to the literature?  Are underpinning values/assumptions/theory discussed?	<u><b>Clear</b></u>  Unclear  Mixed	Comments:  Aims of the study are clearly identified. Literature is used to make the case for the study and discuss the theories surrounding treatment decision making in older women.
<b>Study design</b>		
<b>3. How defensible/rigorous is the research design/methodology?</b>	<u><b>Defensible</b></u>	Comments:  Rationale clearly articulated for the use of

<p>For example:</p> <p>Is the design appropriate to the research question?</p> <p>Is a rationale given for using a qualitative approach?</p> <p>Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</p> <p>Is the selection of cases/sampling strategy theoretically justified?</p>	<p>Indefensible</p> <p>Not sure</p>	<p>qualitative approach, the sample used and the technique of data analysis.</p>
<b>Data collection</b>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <p>Are the data collection methods clearly described?</p> <p>Were the appropriate data collected to address the research question?</p> <p>Was the data collection and record keeping systematic?</p>	<p><u><b>Appropriately</b></u></p> <p>Inappropriately</p> <p>Not sure/inadequately reported</p>	<p>Comments:</p> <p>Detailed information was given about the conduct of the interviewing.</p> <p>An interview guide was used to ensure appropriate data were collected to answer the research questions.</p>
<b>Trustworthiness</b>		
<p><b>5. Is the role of the researcher clearly described?</b></p> <p>For example:</p> <p>Has the relationship between the researcher and the participants been adequately considered?</p> <p>Does the paper describe how the research was explained and presented to the participants?</p>	<p>Clearly described</p> <p><u><b>Unclear</b></u></p> <p>Not described</p>	<p>Comments:</p> <p>No reference is made regarding the researcher/participant relationship.</p> <p>Full details given of the invitation and recruitment of the participants..</p>
<p><b>6. Is the context clearly described?</b></p>	<p><u><b>Clear</b></u></p>	<p>Comments:</p> <p>The context was clearly set with details of the</p>

<p>For example:</p> <p>Are the characteristics of the participants and settings clearly defined?</p> <p>Were observations made in a sufficient variety of circumstances</p> <p>Was context bias considered</p>	<p>Unclear</p> <p>Not sure</p>	<p>participants and the setting being given. Although only interviews were undertaken bias was acknowledged.</p>
<p><b>7. Were the methods reliable?</b></p> <p>For example:</p> <p>Was data collected by more than 1 method?</p> <p>Is there justification for triangulation, or for not triangulating?</p> <p>Do the methods investigate what they claim to?</p>	<p><b><u>Reliable</u></b></p> <p>Unreliable</p> <p>Not sure</p>	<p>Comments:</p> <p>The findings from interviews are not expected to be transferable or generalisable. The findings could therefore be considered either as a as an initial phase which unearths issues for further investigation or used to inform the population from which they came. They do set fulfil the aims of the study.</p>
<b>Analysis</b>		
<p><b>8. Is the data analysis sufficiently rigorous?</b></p> <p>For example:</p> <p>Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</p> <p>How systematic is the analysis, is the procedure reliable/dependable?</p> <p>Is it clear how the themes and concepts were derived from the data?</p>	<p><b><u>Rigorous</u></b></p> <p>Not rigorous</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Within the bounds of the word count imposed by the journal full details the data analysis procedure is given.</p>
<p><b>9. Is the data 'rich'?</b></p> <p>For example:</p> <p>How well are the contexts of the data described?</p> <p>Has the diversity of perspective</p>	<p><b><u>Rich</u></b></p> <p>Poor</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Detailed reporting of the findings that included quotes form the participants.</p>



<p>and content been explored?</p> <p>How well has the detail and depth been demonstrated?</p> <p>Are responses compared and contrasted across groups/sites?</p>		
<p><b>10. Is the analysis reliable?</b></p> <p>For example:</p> <p>Did more than 1 researcher theme and code transcripts/data?</p> <p>If so, how were differences resolved?</p> <p>Did participants feed back on the transcripts/data if possible and relevant?</p> <p>Were negative/discrepant results addressed or ignored?</p>	<p><b><u>Reliable</u></b></p> <p>Unreliable</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Two other researchers independently verified the codes and the themes.</p> <p>No conflicts were reported.</p> <p>Member checking was not reported.</p>
<p><b>11. Are the findings convincing?</b></p> <p>For example:</p> <p>Are the findings clearly presented?</p> <p>Are the findings internally coherent?</p> <p>Are extracts from the original data included?</p> <p>Are the data appropriately referenced?</p> <p>Is the reporting clear and coherent?</p>	<p><b><u>Convincing</u></b></p> <p>Not convincing</p> <p>Not sure</p>	<p>Comments:</p> <p>Findings are clearly presented and evidenced with extract from the transcriptions given.</p> <p>Findings are discussed with reference to the literature.</p>
<p><b>12. Are the findings relevant to the aims of the study?</b></p>	<p><b><u>Relevant</u></b></p> <p>Irrelevant</p> <p>Partially relevant</p>	<p>Comments:</p>
<p><b>13. Conclusions</b></p> <p>For example:</p>	<p><b><u>Adequate</u></b></p> <p>Inadequate</p>	<p>Comments:</p> <p>Limited acknowledgement of the limitations.</p>

<p>How clear are the links between data, interpretation and conclusions?</p> <p>Are the conclusions plausible and coherent?</p> <p>Have alternative explanations been explored and discounted?</p> <p>Does this enhance understanding of the research topic?</p> <p>Are the implications of the research clearly defined?</p> <p>Is there adequate discussion of any limitations encountered?</p>	Not sure	Good discussion exploring the findings.
<b>Ethics</b>		
<p><b>14. How clear and coherent is the reporting of ethics?</b></p> <p>For example:</p> <p>Have ethical issues been taken into consideration?</p> <p>Are they adequately discussed e.g. do they address consent and anonymity?</p> <p>Have the consequences of the research been considered i.e. raising expectations, changing behaviour?</p> <p>Was the study approved by an ethics committee?</p>	<p><u><b>Appropriate</b></u></p> <p>Inappropriate</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Ethical approval was reported. To obtain a favourable ethical approval it is necessary to consider the possibility of raising sensitive issues and the need to obtain informed consent so although not explicitly stated it is 'known' that these will have been addressed.</p>
<b>Overall assessment</b>		
As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)	<p>++</p> <p>±</p> <p>-</p>	<p>Comments:</p> <p>No all addressed but very close. Limitation could be assigned to a lack of word count in the journal.</p>

Notes on the use of the qualitative studies checklist

## Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Wong, J. J. W., D'Alimonte, L., Angus, J., Paszat, L., Soren, B., & Szumacher, E. (2011). What do older patients with early breast cancer want to know while undergoing adjuvant radiotherapy?. <i>Journal of Cancer Education</i> , 26(2), 254-261.	
<b>Guidance topic:</b> Experience of older women with Br Ca.	<b>Key research question/aim:</b> to investigate the information needs of women 70 years and older with early stage breast cancer in relation to adjuvant treatment post-lumpectomy.	
<b>Checklist completed by:</b>	MB	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example:  Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?  Could a quantitative approach better have addressed the research question?	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  Clear rational given for the use of qualitative methodology.
<b>2. Is the study clear in what it seeks to do?</b>  For example:  Is the purpose of the study discussed – aims/objectives/research question/s?  Is there adequate/appropriate reference to the literature?  Are underpinning values/assumptions/theory discussed?	<u><b>Clear</b></u>  Unclear  Mixed	Comments:  The case is strongly made for the need of the study. Literature used address the underpinning values and make the case for the study.
<b>Study design</b>		
<b>3. How defensible/rigorous is the research design/methodology?</b>  For example:  Is the design appropriate to the	<u><b>Defensible</b></u>  Indefensible  Not sure	Comments:  Clear rational given for the use of qualitative methodology and the study design.

<p>research question?</p> <p>Is a rationale given for using a qualitative approach?</p> <p>Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</p> <p>Is the selection of cases/sampling strategy theoretically justified?</p>		<p>Full eligibility criteria were given.</p> <p>It was explained women were asked to complete a demographics questionnaire which seem to include more than demographic information e.g. whether they had received sufficient emotional and or physical support.</p>
<b>Data collection</b>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <p>Are the data collection methods clearly described?</p> <p>Were the appropriate data collected to address the research question?</p> <p>Was the data collection and record keeping systematic?</p>	<p><u><b>Appropriately</b></u></p> <p>Inappropriately</p> <p>Not sure/inadequately reported</p>	<p>Comments:</p> <p>Data collection methods are described but there is no information about storage.</p> <p>All data collected were appropriate to answer the research question.</p>
<b>Trustworthiness</b>		
<p><b>5. Is the role of the researcher clearly described?</b></p> <p>For example:</p> <p>Has the relationship between the researcher and the participants been adequately considered?</p> <p>Does the paper describe how the research was explained and presented to the participants?</p>	<p>Clearly described</p> <p>Unclear</p> <p><u><b>Not described - fully</b></u></p>	<p>Comments:</p> <p>Although all those involved in the data collection are identified there is no mention of the relationship between the researcher and the participant.</p> <p>No report is given of the how the participants were informed or whether informed consent was obtained.</p>
<p><b>6. Is the context clearly described?</b></p> <p>For example:</p> <p>Are the characteristics of the participants and settings clearly</p>	<p><u><b>Clear</b></u></p> <p>Unclear</p> <p>Not sure</p>	<p>Comments:</p> <p>The context is clearly defined with the setting and the groups being described. The procedure for summarising the discussion was given - it is possible that this was an attempt to allow feedback for</p>

<p>defined?</p> <p>Were observations made in a sufficient variety of circumstances</p> <p>Was context bias considered</p>		<p>the group.</p>
<p><b>7. Were the methods reliable?</b></p> <p>For example:</p> <p>Was data collected by more than 1 method?</p> <p>Is there justification for triangulation, or for not triangulating?</p> <p>Do the methods investigate what they claim to?</p>	<p>Reliable</p> <p>Unreliable</p> <p><b><u>Not sure</u></b></p>	<p>Comments:</p> <p>The methods (FGs &amp; demographics questionnaire) do address the question. There is no justification for not using another form of data collection by which triangulation could be undertaken.</p>
<b>Analysis</b>		
<p><b>8. Is the data analysis sufficiently rigorous?</b></p> <p>For example:</p> <p>Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</p> <p>How systematic is the analysis, is the procedure reliable/dependable?</p> <p>Is it clear how the themes and concepts were derived from the data?</p>	<p>Rigorous</p> <p>Not rigorous</p> <p><b><u>Not sure/not reported</u></b></p>	<p>Comments:</p> <p>The process of dealing with the data and development of themes was described.</p>
<p><b>9. Is the data 'rich'?</b></p> <p>For example:</p> <p>How well are the contexts of the data described?</p> <p>Has the diversity of perspective and content been explored?</p> <p>How well has the detail and depth been demonstrated?</p> <p>Are responses compared and contrasted across groups/sites?</p>	<p><b><u>Rich</u></b></p> <p>Poor</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Detailed reporting and discussion of the findings.</p>

<p><b>10. Is the analysis reliable?</b></p> <p>For example:</p> <p>Did more than 1 researcher theme and code transcripts/data?</p> <p>If so, how were differences resolved?</p> <p>Did participants feed back on the transcripts/data if possible and relevant?</p> <p>Were negative/discrepant results addressed or ignored?</p>	<p><b><u>Reliable</u></b></p> <p>Unreliable</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Themes were developed by one researcher but they were validated by two other researchers.</p> <p>More detail of the theme development could have been given.</p>
<p><b>11. Are the findings convincing?</b></p> <p>For example:</p> <p>Are the findings clearly presented?</p> <p>Are the findings internally coherent?</p> <p>Are extracts from the original data included?</p> <p>Are the data appropriately referenced?</p> <p>Is the reporting clear and coherent?</p>	<p><b><u>Convincing</u></b></p> <p>Not convincing</p> <p>Not sure</p>	<p>Comments:</p> <p>The findings are easy to read and clearly and logically presented.</p> <p>A number of pertinent quotes are given.</p>
<p><b>12. Are the findings relevant to the aims of the study?</b></p>	<p><b><u>Relevant</u></b></p> <p>Irrelevant</p> <p>Partially relevant</p>	<p>Comments:</p> <p>The study provides useful and relevant information</p>
<p><b>13. Conclusions</b></p> <p>For example:</p> <p>How clear are the links between data, interpretation and conclusions?</p> <p>Are the conclusions plausible and coherent?</p> <p>Have alternative explanations been explored and discounted?</p> <p>Does this enhance understanding of the research topic?</p> <p>Are the implications of the research</p>	<p><b><u>Adequate</u></b></p> <p>Inadequate</p> <p>Not sure</p>	<p>Comments:</p> <p>Good discussion exploring the findings with good use of the literature.</p>

clearly defined?		
Is there adequate discussion of any limitations encountered?		
<b>Ethics</b>		
<b>14. How clear and coherent is the reporting of ethics?</b>  For example:  Have ethical issues been taken into consideration?  Are they adequately discussed e.g. do they address consent and anonymity?  Have the consequences of the research been considered i.e. raising expectations, changing behaviour?  Was the study approved by an ethics committee?	<u><b>Appropriate</b></u>  Inappropriate  Not sure/not reported	Comments:  Favourable ethical was obtained. Informed consent was obtained but no description of how they were informed of the study.  Participants were given contact information at the end of the FG should they have concerns or require support.
<b>Overall assessment</b>		
As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)	++  ±  -	Comments:

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***Appendix 5: NICE Quality Appraisal Checklist -  
Article 2***

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## NICE Quality appraisal checklist – qualitative studies

<b>Study identification:</b> Include author, title, reference, year of publication	Burton, M., Collins, K. A., Lifford, K. J., Brain, K., Wyld, L., Caldon, L., Gath, J., Revell, D & Reed, M. W. (2015). The information and decision support needs of older women (> 75 yrs) facing treatment choices for breast cancer: a qualitative study. <i>Psycho-Oncology</i> , 24(8), 878-884.	
<b>Guidance topic:</b> Information and Decision-making preferences in older women with breast cancer.	<b>Key research question/aim:</b>  To investigate the information needs of older women (>75 years) regarding the use of surgery or primary endocrine therapy (PET) for the treatment of operable primary breast cancer;  2. to identify the preferred format and media for the presentation of this information;  3. to establish the preference of older women (>75 years) for involvement in treatment decision-making regarding the use of surgery or PET for the treatment of operable primary breast cancer	
<b>Checklist completed by:</b>	<b>MB</b>	
<b>Theoretical approach</b>		
<b>1. Is a qualitative approach appropriate?</b>  For example: <ul style="list-style-type: none"> <li>Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings?</li> <li>Could a quantitative approach better have addressed the research question?</li> </ul>	<u><b>Appropriate</b></u>  Inappropriate  Not sure	Comments:  Yes. Purpose of the study is to explore and establish views.
<b>2. Is the study clear in what it seeks to do?</b>	<u><b>Clear</b></u>  Unclear	Comments:  The aim of the study was clear.

<p>For example:</p> <ul style="list-style-type: none"> <li>Is the purpose of the study discussed – aims/objectives/research question/s?</li> <li>Is there adequate/appropriate reference to the literature?</li> <li>Are underpinning values/assumptions/theory discussed?</li> </ul>	<p>Mixed</p>	<p>Literature is used throughout.</p> <p>Underpinning assumptions are discussed.</p>
<b>Study design</b>		
<p><b>3. How defensible/rigorous is the research design/methodology?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>Is the design appropriate to the research question?</li> <li>Is a rationale given for using a qualitative approach?</li> <li>Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used?</li> <li>Is the selection of cases/sampling strategy theoretically justified?</li> </ul>	<p>Defensible</p> <p>Indefensible</p> <p><b><u>Not sure</u></b></p>	<p>Comments:</p> <p>The design is appropriate to address the research question but rationale given for a qualitative approach.</p> <p>Rationale for sampling, and data collection and analysis given.</p>
<b>Data collection</b>		
<p><b>4. How well was the data collection carried out?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>Are the data collection methods clearly described?</li> </ul>	<p><b><u>Appropriately</u></b></p> <p>Inappropriately</p> <p>Not sure/inadequately reported</p>	<p>Comments:</p> <p>Appropriate data was collected and the methods clearly reported. No information is given about data storage.</p>

<ul style="list-style-type: none"> <li>• Were the appropriate data collected to address the research question?</li> <li>• Was the data collection and record keeping systematic?</li> </ul>		
<b>Trustworthiness</b>		
<b>5. Is the role of the researcher clearly described?</b>  For example: <ul style="list-style-type: none"> <li>• Has the relationship between the researcher and the participants been adequately considered?</li> <li>• Does the paper describe how the research was explained and presented to the participants?</li> </ul>	Clearly described  Unclear  <u><b>Not described - fully</b></u>	Comments:  Although a description is given of how the women were approached and recruited the researcher / participant relationship is not addressed.
<b>6. Is the context clearly described?</b>  For example: <ul style="list-style-type: none"> <li>• Are the characteristics of the participants and settings clearly defined?</li> <li>• Were observations made in a sufficient variety of circumstances</li> <li>• Was context bias considered</li> </ul>	Clear  <u><b>Unclear</b></u>  Not sure	Comments:  The setting was partially described but more detail would have helped.  Only interviews were undertaken and it was not made clear to the reader that this was part of a MM study.
<b>7. Were the methods reliable?</b>  For example: <ul style="list-style-type: none"> <li>• Was data collected by more than 1 method?</li> <li>• Is there justification for triangulation, or for not triangulating?</li> </ul>	<u><b>Reliable</b></u>  Unreliable  Not sure	Comments:  No information on why no triangulation or only 1 method used. See comment above.  Methods do address the question and investigate the research aims.

<ul style="list-style-type: none"> <li>Do the methods investigate what they claim to?</li> </ul>		
<b>Analysis</b>		
<b>8. Is the data analysis sufficiently rigorous?</b> For example: <ul style="list-style-type: none"> <li>Is the procedure explicit – i.e. is it clear how the data was analysed to arrive at the results?</li> <li>How systematic is the analysis, is the procedure reliable/dependable?</li> <li>Is it clear how the themes and concepts were derived from the data?</li> </ul>	<u><b>Rigorous</b></u>  Not rigorous  Not sure/not reported	Comments:  Theme development and data analysis were reported to be undertaken in accordance with framework analysis. Framework is known for its rigorous structure and procedure.
<b>9. Is the data 'rich'?</b> For example: <ul style="list-style-type: none"> <li>How well are the contexts of the data described?</li> <li>Has the diversity of perspective and content been explored?</li> <li>How well has the detail and depth been demonstrated?</li> <li>Are responses compared and contrasted across groups/sites?</li> </ul>	<u><b>Rich</b></u>  Poor  Not sure/not reported	Comments:  Detailed reporting of the findings.
<b>10. Is the analysis reliable?</b> For example: <ul style="list-style-type: none"> <li>Did more than 1 researcher theme and code transcripts/data?</li> <li>If so, how were differences</li> </ul>	<u><b>Reliable</b></u>  Unreliable  Not sure/not reported	Comments:  Two researchers developed the themes and double coded 10% of the transcripts.  No report of participants reporting back on the transcripts

<p>resolved?</p> <ul style="list-style-type: none"> <li>Did participants feed back on the transcripts/data if possible and relevant?</li> <li>Were negative/discrepant results addressed or ignored?</li> </ul>		
<p><b>11. Are the findings convincing?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li><u>Are the findings clearly presented?</u></li> <li>Are the findings internally coherent?</li> <li><u>Are extracts from the original data included?</u></li> <li><u>Are the data appropriately referenced?</u></li> <li><u>Is the reporting clear and coherent?</u></li> </ul>	<p><b><u>Convincing</u></b></p> <p>Not convincing</p> <p>Not sure</p>	<p>Comments:</p> <p>Items underlined addressed.</p>
<p><b>12. Are the findings relevant to the aims of the study?</b></p>	<p><b><u>Relevant</u></b></p> <p>Irrelevant</p> <p>Partially relevant</p>	<p>Comments:</p> <p>The findings directly address the research aims.</p>
<p><b>13. Conclusions</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>How clear are the links between data, interpretation and conclusions?</li> <li>Are the conclusions plausible and coherent?</li> <li>Have alternative explanations been explored and discounted?</li> <li>Does this enhance understanding of the research</li> </ul>	<p><b><u>Adequate</u></b></p> <p>Inadequate</p> <p>Not sure</p>	<p>Comments:</p> <p>Full discussion in which the findings are explored with reference to the literature.</p> <p>Limitations are acknowledged and discussed.</p> <p>The findings contribute significantly to the current body of knowledge.</p> <p>Possible use of the findings is explored in the discussion.</p>

<p>topic?</p> <ul style="list-style-type: none"> <li>Are the implications of the research clearly defined?</li> </ul> <p><b>Is there adequate discussion of any limitations encountered?</b></p>		
<b>Ethics</b>		
<p><b>14. How clear and coherent is the reporting of ethics?</b></p> <p>For example:</p> <ul style="list-style-type: none"> <li>Have ethical issues been taken into consideration?</li> <li>Are they adequately discussed e.g. do they address consent and anonymity?</li> <li>Have the consequences of the research been considered i.e. raising expectations, changing behaviour?</li> <li>Was the study approved by an ethics committee?</li> </ul>	<p><u><b>Appropriate</b></u></p> <p>Inappropriate</p> <p>Not sure/not reported</p>	<p>Comments:</p> <p>Since a favourable ethical opinion was obtained it is safe to assume ethical issues were considered as the process is a detailed one.</p>
<b>Overall assessment</b>		
<p><b>As far as can be ascertained from the paper, how well was the study conducted? (see guidance notes)</b></p>	<p>++</p> <p><b>+</b></p> <p>–</p>	<p>Comments:</p>

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## *Appendix 6: Favourable Ethical Opinion*

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## Health Research Authority

### NRES Committee London - Surrey Borders

HRA  
Research Ethics Committee (REC) London Centre  
Ground Floor  
Skipton House  
80 London Road  
London SE1 6LH

Telephone: 020 7972 2554  
Facsimile: 020 7972 2592

24 October 2012

Ms Lynda Wyld  
Senior Lecturer in Surgical Oncology  
University of Sheffield  
K133, K Floor  
Royal Hallamshire Hospital  
Sheffield S10 2JF

Dear Ms Wyld

**Study title:** Bridging the Age Gap in Breast Cancer: Improving Outcomes  
for Older Women. Helping older women choose  
**REC reference:** 12/LO/1722

The Proportionate Review Sub-committee of the NRES Committee London - Surrey Borders reviewed the above application on 10 October 2012.

#### Ethical opinion

The sub-committee reviewed the above study. The subcommittee members were very happy with the lay summary in Q A6 and A13 of the IRAS application form.

The members of the subcommittee would be interested to know answers to the questions below:

1. **How quickly would support be available for participants in the study, if the interview would cause them distress?**
2. **If any concerns surfaced during the study, how would these be dealt with?**
3. **It was noted the name of the REC was wrong under the heading "Who has reviewed the study" – page 3 of the Participant Information Sheet**

The sub-committee confirmed that this study has no material ethical issues.

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

#### Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England





Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.**

#### **Approved documents**

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	from Ms Lynda Wyld	28 September 2012
Investigator CV	for Ms Lynda Wyld	18 September 2012
Letter of invitation to participant	Patient Interview invitation letter - Appendix 5; v1	07 September 2012
Other: Study Reply Form - Appendix 9	1	07 September 2012
Other: Patient questionnaire invitation letter for previous interview patients - Appendix 6	1	07 September 2012
Other: Letter for questionnaire only patients - Appendix 7	1	07 September 2012
Participant Consent Form: Interview Consent form - Appendix 8	1	07 September 2012
Participant Information Sheet: for Interviews - Appendix 10	1	07 September 2012
Protocol	1	17 September 2012
Questionnaire: Non-validated Questionnaire - Helping Older Choose - Appendix 13	1	07 September 2012
REC application		17 September 2012

#### **Membership of the Proportionate Review Sub-Committee**

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

#### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### **After ethical review**

This Research Ethics Committee is an advisory committee to London Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

### Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

<b>12/LO/1722:</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project

Yours sincerely  
PP



**Miss Stephanie Ellis**  
**Acting Chair**

Email: [NRESCommittee.London-SurreyBorders@nhs.net](mailto:NRESCommittee.London-SurreyBorders@nhs.net)

Enclosures: *List of names and professions of members who took part in the review*  
*"After ethical review – guidance for researchers" [SL-AR2]*

Copy to:

Dr Erica Wallis  
Clinical Research Office  
First Floor, 11 Broomfield Road  
Sheffield S10 2SE

Copy to:

Simon Heller  
R & D Department  
Sheffield Teaching Hospitals NHS Foundation Trust  
First Floor, 11 Broomfield Road  
Sheffield S10 2SE

This Research Ethics Committee is an advisory committee to London Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

**NRES Committee London - Surrey Borders**

**Attendance at PRS Sub-Committee of the REC meeting on 10 October 2012**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Stephanie Ellis – <b>Acting Chair</b>	Retired Civil Servant	Yes	
Mrs Anne Laurie	Lecturer in Clinical Communications	Yes	
Mrs Rebecca Quayle	Solicitor	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Alka Bhayani	Committee Coordinator

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## *Appendix 6A: Ethical Response Letter*

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**Academic Surgical Oncology Unit**

Ms Lynda Wyld, MBChB, BMed.Sci, PhD, FRCS  
(Eng)

Floor E  
Royal Hallamshire Hospital  
Sheffield S10 2JF

Senior Lecturer: 0114 271 2936  
Personal Assistant : 0114 271 2510  
Fax : 0114 271 3314  
*Email: [l.wyld@sheffield.ac.uk](mailto:l.wyld@sheffield.ac.uk)*

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25<sup>th</sup> October 2012

**Miss Stephanie Ellis**

Acting Chair  
NRES Committee London-Surrey Borders  
Research Ethics Committee (REC)  
London Centre, Ground Floor  
Skipton House  
80 London Road  
London  
SE1 6LH

Dear Miss Ellis

**Study Title: Bridging the Age Gap in Breast Cancer: Improving Outcomes for Older Women. Helping older women choose.**

**REC reference: 12/LO/1722**

Many thanks for reviewing our research study and for your letter informing us of the favourable ethical opinion.

Please find below details of the study that the subcommittee wished to know more about

**1. How quickly would support be available for participants in the study, if the interview would cause them distress?**

The researcher undertaking the interviews has substantial experience and expertise in undertaking qualitative interviews with this age group. However, in the unlikely event that a participant becomes distressed during the interview, the interview would cease and the researcher would offer appropriate support within the remit of her role as a researcher. She would also call the participant later on in the day to offer further support and advice as necessary. The participant also has the name and contact details of the lead PI for the study (within the Patient Information Sheet) that would become immediately available should the participant wish to discuss specific issues relating

to the study. If the participant required more clinical specialist input and support, the researcher will advise the participant to contact either their GP or a member of their hospital clinical team.

## **2. If any concerns surfaced during the study, how would these be dealt with?**

In the unlikely event that concerns surfaced during the study the lead PI (Lynda Wyld) would be alerted immediately. Depending on the concern surfacing, the PI would take the decision as to the most appropriate course of action. This might be to contact the NRES Committee London-Surrey Borders to ask for specific advice or to liaise with the Trust(s) with regard to any R & D concern.

## **3. It was noted the name of the REC was wrong under the heading “Who has reviewed the study” – page 3 of the Participant Information Sheet.**

Please find attached an amended version of the Patient Information Sheet (version 2)

In addition to the above I would like to submit our Interview Topic Guide document as a minor amendment. This was previously embedded in the protocol but to make it clear to all involved we have created this as a stand-alone document. The content of this document is a 'copy and paste' of the text in the protocol. Please find topic guide attached.

We hope these are satisfactory.

A handwritten signature in black ink, appearing to read 'L Wyld'.

Many thanks and best wishes

Lynda

Ms Lynda Wyld, (on behalf of the Study Team)

Senior Lecturer in Surgical Oncology and Honorary Consultant Surgeon  
Academic Unit of Surgical Oncology, University of Sheffield Medical School,  
E Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield

Tel: 0114 2268640

e-mail: l.wyld@sheffield.ac.uk

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## *Appendix 7: GCP Certificate*

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# CERTIFICATE of ACHIEVEMENT

This is to certify that

**Maria Burton**

has completed the course

Introduction to Good Clinical Practice eLearning (Secondary  
Care)

March 17, 2016

## Modules completed:

Introduction to Research in the NHS  
Good Clinical Practice and Standards in Research  
Study Set Up and Responsibilities  
The Process of Informed Consent  
Data Collection and Documentation  
Safety Reporting

*This course is worth 4 CPD credits*



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## *Appendix 8: Research Passport*

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## Research Passport Application Form – Version 3 01/09/2012

*Please refer to the guidance notes before completing the form.*


Section 1 - Details of Researcher <i>To be completed by Researcher</i>			
1.	Surname: BURTON		Prof <input type="checkbox"/> Dr <input type="checkbox"/> Mr <input type="checkbox"/>
	Forename(s): RITA MARIA (KNOWN AS MARIA)		Mrs X <input type="checkbox"/>
	Home Address: 6 HIGH GROVE, BESSACARR, DONCASTER, DN4 6LU		Miss <input type="checkbox"/> Ms <input type="checkbox"/> Other <input type="checkbox"/>
	Work Tel: 0114 225 5498		Mobile: 07919400781 Email:
2.	Date of birth: 29/04/1957	Gender: Male <input type="checkbox"/> Female X <input checked="" type="checkbox"/>	
	Ethnicity: WHITE BRITISH	National Insurance number:	
3.	Professional registration details, if applicable (Doctors undertaking any form of medical practice should confirm they have a licence to practise). N/A <input type="checkbox"/>		
4.	Employer: SHEFFIELD HALLAM UNIVERSITY		or place of study:
	Work Address/Place of Study: CENTRE FOR HEALTH AND SOCIAL CARE RESEARCH, 32 COLLEGIATE CRESCENT, SHEFFIELD, S10 2BP		
	Post or status held: SENIOR RESEARCH FELLOW		
Section 2 - Details of Research <i>To be completed by Researcher</i>			
5.	What type of Research Passport do you need? Project-specific <input type="checkbox"/> Multi-project X <input checked="" type="checkbox"/>		
	<i>If you will be conducting one project only please complete the details below. If you anticipate that you will be undertaking more than one project at any one time, please give details in the Appendix.</i>		
	Project Title: Bridging the Age Gap in Breast Cancer: Improving outcomes for older women.		
	Project Start Date: July 01/07/12		End Date: 31/08/2017
	Proposed start and end-date of 3-year Research Passport:		
	Start Date: January 2016		End Date: January 2019
	NHS organisation(s):	Dept(s):	Proposed research
			Manager in NHS

		activities:	organisation:
	See attached list		
<b>Section 3 – Declaration by Researcher</b> <i>To be completed by Researcher</i>			
6.	Have you ever been refused an honorary research contract?	Yes <input type="checkbox"/> No x <input type="checkbox"/>	
	Have you ever had an honorary research contract revoked?	Yes <input type="checkbox"/> No x <input type="checkbox"/>	
	If yes to either question, please give details:		
I consent to the information provided as part of this Research Passport and attached documents being used, recorded and stored by authorised staff of the NHS organisations where I will be conducting research.			
Signed:		Date:	
<i>When Sections 1-3 have been completed, the researcher should forward the form to the appropriate person to complete Section 4.</i>			

**Section 4 - Suitability of Researcher**

*To be completed by researcher's substantive employer, e.g. line manager, or academic supervisor*

7.a	Will this person's research activity mean that they may be undertaking regulated activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)? (please use the Research Passport algorithm to make this judgement)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
-----	---	---

7. b	I am satisfied that the above named individual is suitably trained and experienced to undertake the duties associated with the research activities outlined in this Research Passport form.	
	Signed: 	Date: 20 Jan 2016
	Name: Karen Collins	Job Title: Professor of Health Services Research
	Department and Organisation: Centre for Health and Social Care Research, Sheffield Hallam University	
	Address: 32 COLLEGIATE CRESCENT, SHEFFIELD, S10 2BP	
	Tel No: 0114 2255732	Email: k.collins@shu.ac.uk
	Managerial responsibility for the applicant: Day to day line management of work. Project lead for the current project.	

*When Section 4 has been completed, the researcher should forward the form to the appropriate person to complete Section 5.*

**Section 5 - Pre-engagement checks** *To be completed by the HR department of the researcher's substantive employer or registry at place of study*

8.	Does the above named individual's research involve Regulated Activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	If yes to the above, has the above named individual been checked against ISA barred lists for adults and/or children, as appropriate and have you received confirmation via the criminal record disclosure that the person is not barred from working with adults and/or children? <i>(NB individuals who are barred from working with adults or children must not undertake a regulated activity in the NHS with the vulnerable group from which they are barred, and you must not submit a Research</i>	Checked against: ISA Adults List? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> ISA Children's List?

Passport form in such cases).		Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Can you confirm that a clear criminal record disclosure has been obtained for the above-named individual, with no subsequent reports from the individual of changes to this record? <i>NB for Regulated Activity this must be an enhanced level criminal record check. For non-regulated activity, ensure the criminal record check is at the mandated level.</i>		Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
If yes, please provide details of the clear disclosure:		
Date of disclosure:	Type of disclosure:	
Disclosure No.:	Organisation that requested disclosure:	
9.	Have the pre-engagement checks described below been carried out with regard to the above-named individual and is confirmation of the necessary checks, including any required satisfactory documentary evidence, available in the employing organisation's/place of study's records?	
<ul style="list-style-type: none"> <li>▪ Employment/student screening: <ul style="list-style-type: none"> <li>○ ID with photograph</li> <li>○ two references</li> <li>○ verification of permission to work/study in the UK</li> <li>○ exploration of any gaps in employment</li> </ul> </li> <li>▪ Evidence of current professional registration</li> <li>▪ Evidence of qualifications</li> <li>▪ Occupational health screening / clearance</li> </ul>		
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the named individual on a fixed term contract or is the contract end imminent? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Please indicate current contract end-date      Date:		
Signed:		Date:
Name:		Job Title:
Organisation:		Department:
Address:		
Tel No:		Email:
Please return the form to the researcher.		

Section 6 - Instructions to applicants	
<i>To be completed by Researcher</i>	
<i>Please indicate which of the following documents are attached to this Research Passport:</i>	
Current curriculum vitae, including details of qualifications, training and professional registration (please use the template C.V. at <a href="http://www.rdforum.nhs.uk/docs/template_cv.doc">http://www.rdforum.nhs.uk/docs/template_cv.doc</a> )	Yes <input type="checkbox"/> No <input type="checkbox"/>
Researcher's copy of criminal record disclosure. NB where research involves regulated activity with children and/or adults as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), the disclosure must include confirmation of a check against the appropriate ISA barred list(s).	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Evidence of occupational health screening / clearance	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Appendix – List of projects and amendments	Appendix numbers:          N/A <input type="checkbox"/>

**You must inform all NHS organisations that have received this Research Passport of any changes to the information supplied above. Failure to do so may result in withdrawal of your honorary research contract or letter of access. As part of the quality control procedures for the Research Passport, random checks on the accuracy of the information held on this Research Passport may be made.**

## Section 7

**This section should be completed by HR in the Lead NHS organisation, only if additional checks are undertaken**

The following additional checks have been completed:

Having confirmed that the necessary additional pre-engagement checks have been completed, I am satisfied that the above named researcher is suitable to carry out the duties associated with their research activity outlined in this Research Passport.

Signed:

Date:

Name:

Job Title:

Organisation:

Department:

Email:

## Section 8 - For Office Use Only

*This section should be completed by the NHS R&D office that received the initial application. The NHS R&D office must countersign and date retained photocopies of the documents. The grey section must be completed before the form is returned to the applicant.*

CV reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Training?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Evidence of qualifications?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Appendix pages reviewed?	Numbers:
Professional registration details reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Occupational health clearance reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Criminal record disclosure reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Date of disclosure:	
		Disclosure No:	
For regulated activity as defined in the Safeguarding Vulnerable Groups Act 2006, as amended (in particular by the Protection of Freedoms Act 2012), did the criminal record disclosure confirm a satisfactory check against the appropriate ISA barred list(s)			Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Enter Electronic Staff Record Number (if issued):



Confirmation of valid Research Passport:	
Project specific <input type="checkbox"/> Three-year <input type="checkbox"/> Other End date <input type="checkbox"/> Date:	
Signed:	Date:
Name:	
NHS Organisation Name and contact details	
Date Honorary Research Contract/letter of access issued ( <i>delete as appropriate</i> )	

*If required, this section should be added to the Research Passport Form and completed by each NHS R&D office receiving the valid Research Passport. The original Research Passport form and documents should be returned to the applicant.*

Has the Research Passport been validated by a Lead NHS organisation and is this validation acceptable to this NHS organisation? Yes ☐ No ☐

CV reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Training?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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Evidence of qualifications?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Appendix pages reviewed?	Numbers:
-----------------------------	--	--------------------------	----------

Professional Registration details reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Occupational health clearance reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
---	--	---	--

Criminal record disclosure reviewed?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Date of disclosure:  Disclosure No:
--------------------------------------	--	---

For regulated activity <b>as defined in the Safeguarding Vulnerable Groups Act 2006, as amended by the Protection of Freedoms Act 2012</b> , did the <b>criminal record</b> disclosure confirm a satisfactory check against the appropriate ISA barred list(s)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
--	--

Checked Electronic Staff Record: Yes ☐ No ☐ N/A ☐

Signed:		Date:	
---------	--	-------	--

Name:

NHS organisation name and contact details:

Date honorary research contract/letter of access issued (*delete as appropriate*)

## Passport Appendix. List of projects and amendments

Appendix

1

Number:

*If you are applying for a three-year Research Passport, please use this section to enter details of projects and activities that will be covered by this Research Passport. Once you have a validated Research Passport, you may add details of subsequent projects during the three years that this Research Passport is valid.*

*If you are applying for a project-specific Research Passport, but need to add further sites to the project, please enter the details below.*

*Whenever you add further details, the full Research Passport and accompanying documents must be submitted to the relevant NHS organisations.*

<i>Title: Bridging the Age Gap in Breast Cancer, Improving Outcomes. Helping Older Women</i>		<i>Start Date:</i>	<i>End Date:</i>
<i>NHS organisation(s):</i>	<i>Dept(s):</i>	<i>Proposed research</i>	<i>Manager in NHS organisation</i>
<i>Sheffield Teaching Hospitals NHS FT</i>	<i>General Surgery</i>	<i>Interviews with</i>	<i>Matthew Winter</i>
<i>University Hospitals of Morecambe Bay NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with patients</i>	
<i>University Hospitals of Leicester</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Hull and East Yorkshire Hospitals NHS Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Nottingham University Hospitals NHS Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	<i>Miss Lisa Whisker</i>
<i>Mid Yorkshire Hospitals NHS Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	

<i>Title: Bridging the Age Gap in Breast Cancer, Improving Outcomes. Helping Older Women</i>		<i>Start Date:</i>	<i>End Date:</i>
<i>Chesterfield Royal Hospital NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Rotherham NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Tameside Hospital NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	<i>Stephanie Ridgeway</i>
<i>Milton Keynes Hospitals NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>University Hospitals Coventry &amp; Warwickshire NHS Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Royal Marsden NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Mid Essex Hospital Services NHS Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	
<i>Wrightington, Wigan and Leigh NHS Foundation Trust</i>	<i>Breast Surgery</i>	<i>Interviews with</i>	

### ***Amendments to the Research Passport***

*Please state what these are, e.g. they might be a change in name or employment details, or a change in research activities.*

*Please check with the NHS organisation where you are undertaking your research if you are unsure whether you will need to submit new evidence of pre-engagement checks on a new Research Passport form, which will need to be validated by the NHS organisation(s) hosting your research.*

<i>Date</i>	<i>Old Details</i>	<i>New Details</i>	<i>Office use only NHS R&amp;D contact details and signature</i>

***To add more projects please copy this page or download further blank pages. Each appendix page should be numbered.***

*For office use only:*

*A photocopy of the appendix should be retained whenever any amendments or additions to the appendix are made.*

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## *Appendix 9: Participant Invitation Letter (Interviews)*

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The  
University  
Of  
Sheffield.

**Sheffield  
Hallam  
University**

**Helping older women make informed choices about treatment for breast cancer.**

### **Participant Invitation Letter**

Dear [*insert name here*]

We would like to invite you to participate in a research study. The study is being carried out by researchers from The University of Sheffield and Sheffield Hallam University. We have invited you to take part because **we are interested in hearing the views and opinions of women over the age of 75 years who have had treatment for breast cancer.**



The aim of the study is to find out the views of older women about different types of treatment for breast cancer. We would also like to know what information and support they would like to help them decide what type of treatment they would prefer. The information we get from this study will be used to support older women in the future who are given a choice of treatment.

**We would like to interview you, at a time and place convenient to you, to ask your views on breast cancer treatment and how you would like to hear about the options for its treatment.**

**We have enclosed an information sheet for you to read and help you to think about whether you would like to take part. Taking part or not is entirely up to you.**

Whether you decide to take part or not, please complete the Study Reply Form and return it in the FREEPOST envelope provided. You do not need a stamp.

If you decide not to take part, please tick the box beside 'No, I do not wish to take part in this study' and return the form to us. You do not need to fill in any

other details on the form. The research team will not make any further contact with you about the study.

**If you wish to take part in the study, please tick 'Yes, I would like to take part in this study', fill in the contact details section on the Study Reply Form, and the consent form provided, and then return the form to us in the FREEPOST envelope provided.**

Once we receive the form, a member of our research team will contact you to arrange an interview at a time and place most convenient to you. If you do not want to be interviewed at present, but have no objections to being contacted in the future please tick '*I do not want to be interviewed but am interested in participating in other parts of the study at some time in the future*'.

If you would like to find out more about the study before deciding whether or not to take part please contact Mrs Maria Burton at the Sheffield Hallam University on 0114 225 5498 or *NAME OF RESEARCH SITE CONTACT & DETAILS TO BE INSERTED*.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Lynda Wyld'.

**Ms Lynda Wyld**

**Consultant Breast Surgeon**



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## *Appendix 10: Patient Information Sheet (Interviews)*

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## Patient Interview Information Sheet

To be printed on Hospital Headed notepaper



The  
University  
Of  
Sheffield.

**Sheffield  
Hallam  
University**

### **Helping older women make informed choices about treatment for breast cancer**

#### **Participant Information Sheet - Interview**

##### **Invitation to participate in the study**

We would like to invite you to take part in a research study. Before you decide you need to understand why it is being done and what it would involve for you. Please read the following information carefully and talk to others about the study to help you decide if you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

##### **What is the purpose of the study?**

For some women with breast cancer there are several different treatment options, all of which work well. Some chose to have an operation to remove it, while others chose to have tablets to prevent it growing and make it shrink. The decision about what treatment to have can be complex, with pros and cons for each option. The purpose of this study is to get a better understanding of what women think about the treatments offered, and what doctors and nurses can do to help women make their decisions.

##### **Why have you been invited to take part?**

You have been invited to take part in the study because you are a woman age 75 or older who has previously had treatment for

breast cancer, either with surgery or tablets (for example, Tamoxifen, Arimidex, Letrozole).

### **Do you have to take part?**

No. Taking part is entirely voluntary. If you do not want to take part you do not have to give a reason. If you decide to take part but later change your mind, you can do and you do not have to give a reason. **No one will be upset and your treatment or care would not be affected.**

### **What will happen to you if you take part?**

If you decide to take part, a member of the study team will contact you to arrange an interview at a time and place convenient to you. The interview could be at the hospital, in your own home or elsewhere if you prefer. If being interviewed meant you had to travel, we would refund your travel costs. If you would like a friend or relative to be at your interview, that is fine and we will refund reasonable travel costs. Interviews will take about an hour. The interview will be recorded with your consent. Recordings will be stored anonymously in a secure place.

In the interview, you will be asked to tell us your views on your breast cancer treatment and how you decided on which type to have. We will also ask you about the information and support you received that helped you make your decision about which treatment. In addition, we will ask you about the different ways this information can be presented – for example leaflets, videos, booklets etc. There are no right or wrong answers to the questions in this study. We want to know YOUR opinions.

### **What are the possible risks and disadvantages of taking part?**

There are no specific risks associated with taking part in this study. You do not have to talk about any issues you don't want to discuss. If you find the interview upsetting (which we do not expect) it can be stopped at any time. Specialist help and support is available if you feel any part of the study has upset or affected you in any way.

**What are the possible benefits of taking part?**

This research study will not directly benefit you, but it will give us a better understanding of the views and support needs of older women making decisions about their breast cancer treatment. This should help us to provide better guidance for women facing similar decisions in the future.

**Will your taking part in the study be kept confidential?**

Yes. All information that is collected about you during the course of the research will be kept strictly confidential.

**What will happen to the results of the research study?**

The results of the study will be presented at conferences and published in scientific journals. A copy of the research findings will be available to you at the end of the study if you would like it. It may be several years before this is available.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This has been done by the NRES Committee London - Surrey Borders. Some of the information from the study will be used as part fulfilment of an educational qualification (Doctor of Philosophy).

**What if you are harmed or unhappy about any aspect of the study?**

If you have any concerns or complaints about any aspect of the study please contact Ms Lynda Wyld (Senior Lecturer and Consultant Breast Surgeon), E Floor, Royal Hallamshire Hospital, Sheffield S10 2JF. Telephone 0114 2712510.

If you remain unhappy and wish to complain formally, you can go through the NHS Complaints Procedure by contacting Dr David Throssell, Medical Director, Sheffield Teaching Hospitals NHS

Foundation Trust, 8 Beech Hill Road, Sheffield, S10 2SB.  
Telephone: 0114 271 2178.

### **Who is organising the study?**

The study is being run by the University of Sheffield and Sheffield Hallam University. It has been funded by the UK Government's main research funding body, the National Institute for Health Research (NIHR)

### **Contact for further information**

If you would like any further information, or have any questions concerning this study, please contact Mrs Maria Burton 0114 22 55 498 or *NAME OF RESEARCH SITE CONTACT & DETAILS TO BE INSERTED*.

### **What do I need to do now?**

If you WISH TO take part please tick **"Yes, I would like to take part in this study"**, fill in the contact details on the Study Reply Form and return the form in the FREEPOST envelope provided.

If you do not want to be interviewed but you may be interested in participating in other parts of the study (for example a questionnaire and/or a discussion with other patients called a focus group) please tick **"I do not want to be interviewed but am interested in participating in other parts of the study at a later date"**. Please also fill in the contact details on the Study Reply Form and return the form in the FREEPOST envelope provided.

Feel free to call us with any queries you may have and/or talk the study over with anyone else.

**Please keep this information leaflet for future reference.**

**Thank you for reading this information sheet and for taking an interest in the research study.**

---

## *Appendix 11: Study Reply Form*

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The  
University  
Of  
Sheffield.

**Sheffield  
Hallam  
University**

**Helping older women make informed choices about treatment for breast cancer.**

**Participant Study Reply Form**

- ☐ Yes, I would like to take part in this study
- ☐ I do not want to be interviewed but I may be interested in participating in other parts of the study at a later date.

If you have ticked 'Yes, to either of the above statements please also give contact details (IN BLOCK CAPITALS):

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel. No. (inc. Code): \_\_\_\_\_

I would like to receive a copy of the research findings YES/NO

Please return this form in the FREEPOST envelope provided.

You do not need a stamp.

---

## *Appendix 12: Interview Consent Form*

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**Helping older women make informed choices about treatment  
for breast cancer.**

**Interview Consent Form**

**Please  
initial if  
you agree**

I confirm I have read and understood the information leaflet dated ..... Version ..... for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I give permission for the interview to be audio recorded.

I understand and agree that quotes from my interview may be used within written reports or publications, and that any quotes would be completely anonymous and could not be linked to me in any way.

I agree to take part in the above study.

Name of Person taking consent:

Signature:

Date:

Name of Participant:

Signature:

Date:

---

## *Appendix 13: Interview Topic Guide*

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## **Bridging the Age Gap in Breast Cancer: Improving outcomes for older women. Helping Older Women Choose**

The interviews will specifically explore the following areas:

- beliefs about the risks and benefits of treatment options in relation to cancer survival/recurrence rates and quality of life outcomes
- Timeline (beliefs about the duration of breast cancer and treatment options),
- Cure/control (beliefs about the efficacy of treatment options; perceived control over the treatment decision-making process and personal confidence in treatment decision-making)
- factors they have found positive or negative about their breast cancer treatment
- factors they have found positive or negative about the treatment decision-making process
- how specific treatments were decided upon
- which factors influenced their decision or the treatment undergone
- their decision-making preference
- sources of information they used, desired or would have preferred
- satisfaction with treatment and the treatment decision-making process
- whether they feel comfortable with computers/the internet
- barriers to use of different media (visual or auditory impairment, memory impairment)
- facilitators to the use of different media (family/BCN assistance, provision of equipment)
- preferred design and media of DSI to support decision-making
- discussion of the pros and cons and personal preferences for a range of demonstrated media tools
- views on the possible usefulness of DSI's
- Info needs - survival rates, chance of cure, Rx options, post-op state, side effects (drugs & surgery), surgery scarring pictures,

- Did you have enough, too much or too little info to make a decision.
- Check
  - Age,
  - time from diagnosis
  - PET / Surgery

---

## *Appendix 14: Study Questionnaire*

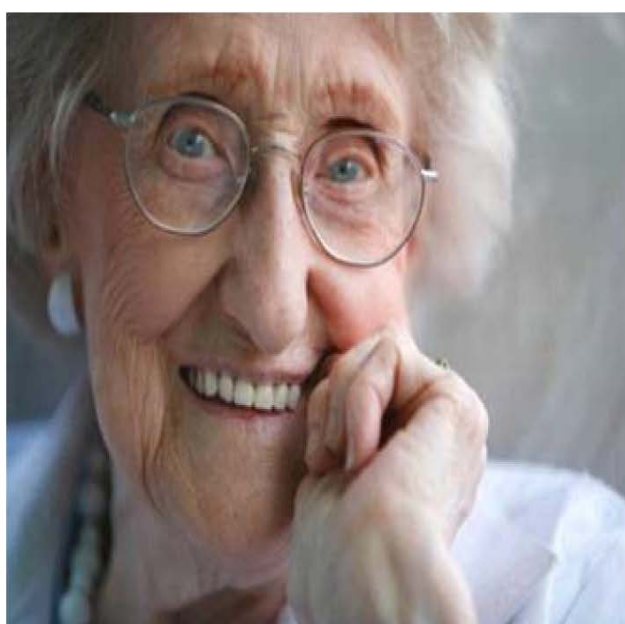
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## **Bridging the Age Gap in Breast Cancer: Improving Outcomes for Older Women**

Helping older women choose

### Questionnaire



## Introduction

Thank you for agreeing to help with our research study.

The following pages ask questions about your experiences.

We would like to know what you think about your breast cancer treatment, how you wanted decisions to be made, and what information and support you wanted to help you.

There are no right or wrong answers to these questions. We would like to hear about your personal experiences, views and opinions.

The questionnaire should take about 20 minutes to fill in.

When you have finished please return it to us in the PRE-PAID envelope provided. There is no need for a stamp.

Thank you for your time.

## Section 1 - First we would like to hear a bit about you

### How old are you?

Please write your age in years

### What type of treatment did you receive for your breast cancer?

An operation followed by tablets ☐

Tablets on their own without an operation ☐

### Level of education Please tick one box only

I left school at or before 16 years of age ☐

I left school at 18 years of age ☐

I went to University/college (or similar) ☐

Other, please specify: \_\_\_\_\_

### Which ethnic group do you belong to? Please tick one box only

White ☐

Mixed or multiple ethnic groups ☐

Asian or Asian British ☐

Black, African, Caribbean or Black British ☐

Other ethnic group ☐  
please specify: \_\_\_\_\_



## Section 2 - We would like to know what information was helpful to you before your treatment began

In addition to information from doctors and nurses at the hospital, did you find any of the following information helpful when deciding on your treatment?  
Please tick as many as apply.

	Yes
Discussions with my GP	<input type="checkbox"/>
The Internet	<input type="checkbox"/>
Leaflet/booklets provided by the hospital	<input type="checkbox"/>
Friends or family	<input type="checkbox"/>
Magazine articles	<input type="checkbox"/>
Other please specify	<input type="checkbox"/>

When your treatment was discussed with you, what information did you feel was helpful in deciding if surgery or tablets were best for you?

Please tick the relevant box/es

### I wanted to know:

	Yes	No	Unsure
how long I would be in hospital if I had an operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
how safe the operation would be for me to have at my age.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about what might happen after a general anaesthetic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I could be asleep (general anaesthetic) or awake (local anaesthetic injection) for the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about any possible complications or side effects of the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about the side effects of the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I needed to have my breast removed or could just have lump removal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I would look different after the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
what the scar from the operation would look like, e.g. see a photograph.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**When your treatment was discussed with you, what information did you feel was helpful in deciding if surgery or tablets were best for you?**

Please tick the relevant box/es

I wanted to know:	Yes	No	Unsure
if I would have pain after the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about the sort of pain relief I could have.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I would have the same level of independence when I went home after the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I would need/have extra help at home when I left the hospital after an operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
whether my family/friends would be able to look after me after the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about possible support for my loved ones while I was in hospital.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
if I would need any further treatment e.g. radiotherapy or chemotherapy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
how I would get the tablets.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
how long I would have to take the tablets for.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about the side effects of the tablets.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
how effective the treatments have been for others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
the likelihood of cure if I just had tablet treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
the likelihood of cure if I just had the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
the likelihood of cure if I had the operation and tablet treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
about the likelihood of the cancer coming back.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other, please specify:			

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### Section 3 - We would like to know how you made your decisions about your treatment

**When you were first told you had breast cancer did the specialist offer you a choice of treatments?** Please tick one box only

Yes, I was told I could have either an operation or just tablet treatment ☐

No, I was not offered a choice. The specialist offered me an operation only ☐

No, I was not offered a choice. The specialist offered me tablet treatment only ☐

I am not sure/don't know ☐

If you were not sure could you please tell us a bit more about this?

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**Please tick the box next to the statement that best describes the situation that you believe would be IDEAL.** Please tick one box only

I prefer to make the final selection about which treatment I will have. ☐

I prefer to make the final selection of my treatment after seriously considering my doctor/nurse's opinion ☐

I prefer that my doctor/nurse and I share responsibility for deciding which treatment is best for me. ☐

I prefer that my doctor/nurse makes the final decision about which treatment will be used, but seriously considers my opinion. ☐

I prefer to leave all decisions regarding my treatment to my doctor/nurse. ☐

**Please tick the box next to the statement that best describes the situation that ACTUALLY HAPPENED during your consultations. Please tick one box only**

- |  |                          |
|--|--------------------------|
| I made the final selection about which treatment I had   | <input type="checkbox"/> |
| I made the final selection of my treatment after I had seriously considered my doctor/nurse's opinion        | <input type="checkbox"/> |
| My doctor/nurse and I shared the responsibility for deciding which treatment was best for me.                | <input type="checkbox"/> |
| My doctor/nurse made the final decision about which treatment was used, but seriously considered my opinion. | <input type="checkbox"/> |
| My doctor/nurse made all the decisions regarding my treatment.   | <input type="checkbox"/> |

**What information helped you decide on treatment?**

- |  | Yes                      | No                       | Unsure                   |
|--|--------------------------|--------------------------|--------------------------|
| I was helped by talking to the doctors in breast clinic          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I was helped by talking to my breast care nurse in breast clinic | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I found the written leaflets given to me in clinic helpful.      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I found discussing my treatment with family and friends helpful  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Were there other things you found helpful? Please tell us what they were.

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#### Section 4 - Next, we would like to hear about how you would ideally wish to make decisions about treatment

Did you feel that you had enough information to decide what treatment to choose?

- Yes, I had all the information I needed ☐
- No, I would have liked more information ☐

Who would you prefer to talk to, about making a decision about your treatment?

- The doctor from the breast unit at the hospital ☐
- The nurse from the breast unit at the hospital ☐
- My GP or practice nurse ☐
- A doctor or nurse or similar on a telephone helpline ☐
- My family ☐
- My friends ☐
- No-one ☐
- Other, please specify: \_\_\_\_\_

We would now like to know whether you were happy with the treatment decision?

To what extent do you agree or disagree with the following statements about your treatment decisions?

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
It was the right decision	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I regret the choice that I made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would go for the same choice if I had to do it over again	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The choice did me a lot of harm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The choice was a wise one	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Section 5 - Next we would like to hear how you would prefer to be given information about breast cancer treatment**

**How would you like to receive information to help you decide about breast cancer treatment?**

- |  |                          |
|--|--------------------------|
| Booklet or leaflet                     | <input type="checkbox"/> |
| DVD or video                           | <input type="checkbox"/> |
| Friends with experience of cancer      | <input type="checkbox"/> |
| Audio tape or audio CD                 | <input type="checkbox"/> |
| Internet based information             | <input type="checkbox"/> |
| Face to face chat with a doctor        | <input type="checkbox"/> |
| Face to face chat with a nurse         | <input type="checkbox"/> |
| I do not require/want this information | <input type="checkbox"/> |
| Other - please specify                 | <input type="checkbox"/> |
- 
- 
- 

**Do you have access to the internet?**

- |  |                          |
|--|--------------------------|
| I have my own computer and use the internet at home                          | <input type="checkbox"/> |
| I can access the internet e.g. at some else's house or at the library        | <input type="checkbox"/> |
| I cannot use a computer myself but friends and relatives can use them for me | <input type="checkbox"/> |
| I have no access to a computer or the internet                               | <input type="checkbox"/> |
| I do not want to use a computer or the internet                              | <input type="checkbox"/> |

**If information was available on the internet which could give you the pros and cons of your breast cancer treatment options, how likely would you be to use this?**

- |                          |                          |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Very likely              | Somewhat likely          | I'm not sure             | Somewhat unlikely        | Very unlikely            |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



Please tick the box next to your **PREFERRED** way of being given this information

A statement in words, for example:

Breast cancer is a common cancer in women in the UK

☐

A number, for example:

1 in 8 women in the UK will get breast cancer

☐

A percentage, for example:

12% of women in the UK will get breast cancer

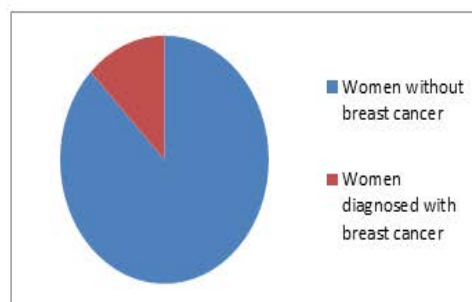
☐

A fraction, for example:

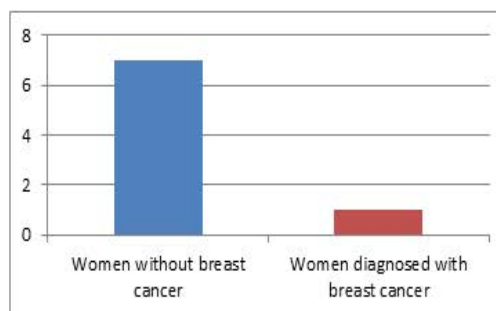
1/8th of women in the UK will get breast cancer

☐

A chart to show what fraction of women in the UK will get breast cancer, for example:

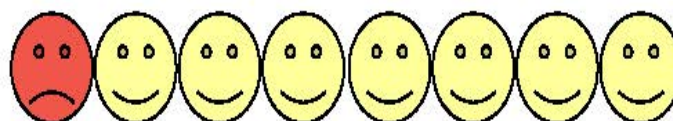
☐

A graph to show what fraction of women in the UK will get breast cancer, for example:

☐

Represented as a picture, for example:

1 in 8 women in the UK will get breast cancer

☐

The information above can also be put another way around. For example '7 out of 8 women in the UK do NOT get breast cancer.' Would it be helpful to see/hear both the positive and negative versions of this information?

Very unhelpful    Somewhat unhelpful    Undecided    Somewhat helpful    Very helpful

☐
☐
☐
☐
☐

We want to make any information we give to you relevant and interesting. The following are some suggestions of things that we can do. Please tick the relevant box.

	Yes	No	Unsure
I would like to see/hear the stories of other women who have had breast cancer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I like to see pictures of relevance to make the information more real and useful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I find lots of factual information useful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I find lots of diagrams off-putting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would like clear, straight forward information to help me make a proper decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would like detailed information to help me make a proper decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I would like to see a video of what happens when you come into hospital for an operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Section 6 - Finally, we would like to hear anything else you think we could do to help women with breast cancer that are choosing their treatment.**

**Please write anything else you would like to tell us**

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**Thank you for completing this questionnaire.**

**Please return it to us in the PRE-PAID envelope provided.**

If you cannot find the PRE-PAID envelope, please return the questionnaire to:

Maria Burton,  
Centre for Health and Social Care Research,  
Sheffield Hallam University,  
Faculty of Health and Wellbeing,  
Montgomery House,  
32 Collegiate Crescent,  
Sheffield,  
S10 2BP

Telephone +44 (0) 114 225 5498      Fax +44 (0) 114 225 4377  
Email: [m.burton@shu.ac.uk](mailto:m.burton@shu.ac.uk)      [www.shu.ac.uk/chscr](http://www.shu.ac.uk/chscr)

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## *Appendix 15: Study Amendment*

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**NRES Committee London - Surrey Borders**

HRA  
Research Ethics Committee (REC) London Centre  
Ground Floor  
Skipton House  
80 London Road  
London  
SE1 6LH  
Tel: 02079722580

28 November 2013

Maria Burton  
Principal Lecturer  
Postgraduate Research Tutor  
Centre for Health and Social Care Research  
Sheffield Hallam University  
32 Collegiate Crescent  
Sheffield S10 2BP

Dear Maria

**Study title:** Bridging the Age Gap in Breast Cancer: Improving Outcomes for Older Women. Helping older women choose  
**REC reference:** 12/LO/1722  
**Amendment number:** Amendment 5: 8/10/2013 (our ref: AM07)  
**Amendment date:** 22 October 2013  
**IRAS project ID:** 117023

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Investigator CV	Dr Karen Collins	
Appendix 7 Letter for Questionnaire Patients	3	08 October 2013
Updated REC Form	117023/5206 44/1/597	30 October 2013

Investigator CV	Maria Burton	
Covering Letter	Letter to Chairman from Lynda Wylid	22 October 2013
Appendix 6 Patient Questionnaire Invitation for Interview Patients	2	08 October 2013
Notice of Substantial Amendment (non-CTIMPs)	Amendment 5: 8/10/2013 (our ref: AM07)	22 October 2013

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

#### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>12/LO/1722:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Canon Christopher Vallins**  
Chair

E-mail: [NRESCommittee.London-SurreyBorders@nhs.net](mailto:NRESCommittee.London-SurreyBorders@nhs.net)

*Enclosures:* *List of names and professions of members who took part in the review*

*Copy to:* *Dr Erica Wallis, Sheffield Teaching Hospital NHS Foundation Trust*

**NRES Committee London - Surrey Borders**

**Attendance at Sub-Committee of the REC meeting on 28 November 2013**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Graham Tate	Tissue Bank Manager	Expert
Canon Christopher Vallins	Regional Chaplaincy Adviser	Lay Plus

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Amy Spruce	REC Assistant

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## ***Appendix 16: Participant Invitation (Questionnaire)***

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The  
University  
Of  
Sheffield.

**Sheffield  
Hallam  
University**

## **Helping older women make informed choices about treatment for breast cancer.**

### **Participant Invitation Letter**

Dear *[insert name here]*

You were recently invited to take part in a research study called 'Helping older women make informed choices about treatment for breast cancer' which is trying to find out the views of older women about different types of treatment for breast cancer and the information and support they would like to help them decide what type of treatment they would prefer. The information from this questionnaire will also be used as part fulfilment of an educational qualification (Doctor of Philosophy - a PhD).



At the time, you said you would be interested in taking part in another part of the study. We would now like to invite you to fill in a questionnaire. The information sheet you were given before contains more detail. Taking part or not is entirely up to you.

**If you wish to take part in this part of the study, please fill in the questionnaire provided, and return it in the FREEPOST envelope provided.**

If you would like to find out more before deciding whether or not to take part please contact Mrs Maria Burton at the Sheffield Hallam University on 0114 225 5498 or *NAME OF RESEARCH SITE CONTACT & DETAILS TO BE INSERTED.*

Yours sincerely

**Ms Lynda Wyld, Consultant Breast Surgeon**

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## *Appendix 17: Development of the QQ-10*

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## Development of the QQ-10

### QQ-10

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.....  
.....

QQ-10 Please circle the answers below each of the following 10 statements that best fit your feelings about the questionnaire that you recently completed. Please use the boxes at the bottom of the next page to make additional comments.

#### **The questionnaire helped me to communicate about my condition**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire was relevant to my condition**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire was easy to complete**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire included all the aspects of my condition that I am concerned about**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **I enjoyed filling in the questionnaire**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **I would be happy to complete the questionnaire again in the future as part of my routine care**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire was too long**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire was too embarrassing**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

#### **The questionnaire was too complicated**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

**The questionnaire upset me**

Strongly agree Mostly agree Neither agree or disagree Mostly disagree  
Strongly disagree

**Do you have any comments or suggestions on how the questionnaire you used could be improved (e.g. its structure, appearance or design)?**

**Were any of your important symptoms, problems or concerns missed out by the questionnaire you used?**

**Do you feel that any areas or problems in the questionnaire you used were over-represented?**