Factors influencing GP Referrals to Symptomatic Breast Units in Ireland

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Factors influencing GP Referrals to Symptomatic Breast Units in Ireland

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A thesis submitted to the Royal College of Surgeons in Ireland, in fulfilment of the degree of Doctor of Philosophy in the division of Population Health Sciences, Faculty of Medicine and Health Sciences

Supervisors: Professor Anne Hickey, Professor Ronán Conroy and Professor John Browne

September 2015
I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree of Doctor of Philosophy is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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Student Number:  08506639

Date _______________________________________________________

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List of Abbreviations

AJCC  American Joint Committee on Cancer
ANP  Advanced Nurse Practitioner
ARIMA Autoregressive Integrated Moving Average
BCT  Behaviour Change Taxonomy
BCW  Behaviour Change Wheel
CEO  Chief Executive Officer
CHO  Community Healthcare Organisations
CME  Continuous Medical Education
CNS  Clinical Nurse Specialist
CPR  Clinical Prediction Rule
CSM  Common Sense Model
CSO  Central Statistics Office
DML  Dublin mid Leinster
DNA  Did not Attend
DNE  Dublin North East
DoH  Department of Health
DoHC  Department of Health and Children
EBM  Evidence-Based Medicine
ED  Electoral District
ESRI  Economic and Social Research Institute
GP  General Practitioner
GRAMS  Good Reporting of a Mixed-methods Study
HBM  Health Belief Model
HIPE  Hospital In-Patient Enquiry Scheme
HIQA  Health Information and Quality Authority
HSR  Health Services Research
HR  Hazard Ratio
HRB  Health Research Board
HSE  Health Service Executive
IACR  International Association of Cancer Registries
IARC  International Agency for Research on Cancer
ICD  International Classification of Diseases
ICGP  Irish College of General Practitioners
IOM  Institute of Medicine
KPI  Key Performance Indicator
KTE  Knowledge Transfer and Exchange
MDT  Multidisciplinary Team
MRI  Magnetic Resonance Imaging
NAC  Neo-adjuvant Chemotherapy
NCCP  National Cancer Control Programme
NCRI  National Cancer Registry of Ireland
NHS  National Health Service
NICE  National Institute for Health and Care Excellence
NICR  Northern Ireland Cancer Registry
OECD  Organisation for Economic Cooperation and Development
OR  Odds Ratio
<table>
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<tr>
<td>PICO</td>
<td>Population, Intervention, Control, Outcome</td>
</tr>
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<td>PPI</td>
<td>Public and Personal Involvement</td>
</tr>
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<td>PPV</td>
<td>Positive Predictive Value</td>
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<tr>
<td>QSR</td>
<td>Qualitative Software for Research</td>
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<td>RCSI</td>
<td>Royal College of Surgeons in Ireland</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>SAHRU</td>
<td>Small Area Health Research Unit</td>
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<td>SBD</td>
<td>Symptomatic Breast Disease</td>
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<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>SPHeRE</td>
<td>Structured Population and Health Services Research Education</td>
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<tr>
<td>STARD</td>
<td>Standards for Reporting of Diagnostic accuracy studies</td>
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<tr>
<td>TAC</td>
<td>Triple Assessment Clinic</td>
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<tr>
<td>TDF</td>
<td>Theoretical Domains Framework</td>
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<tr>
<td>TNM</td>
<td>Tumour Node Metastases</td>
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<tr>
<td>TPB</td>
<td>Theory of Planned Behaviour</td>
</tr>
<tr>
<td>UCL</td>
<td>University College London</td>
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<tr>
<td>VIF</td>
<td>Variance Inflation Factor</td>
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**Hospital acronyms**

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<td>BH</td>
<td>Beaumont Hospital</td>
</tr>
<tr>
<td>MMUH</td>
<td>Mater Misericordiae University Hospital</td>
</tr>
<tr>
<td>SVUH</td>
<td>St Vincent’s University Hospital</td>
</tr>
<tr>
<td>SJH</td>
<td>St James's Hospital</td>
</tr>
<tr>
<td>WUH</td>
<td>Waterford University Hospital</td>
</tr>
<tr>
<td>CUH</td>
<td>Cork University Hospital</td>
</tr>
<tr>
<td>ULH</td>
<td>University of Limerick Hospital</td>
</tr>
<tr>
<td>GUH</td>
<td>Galway University Hospital</td>
</tr>
<tr>
<td>LRH</td>
<td>Letterkenny Regional Hospital</td>
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Summary

Background
A policy of centralisation of symptomatic breast services was implemented in Ireland in 2009. This included centralising surgical services in eight Symptomatic Breast Disease (SBD) units and introduction of evidence-based GP referral guidelines for suspected cancer.

Aim
To investigate the factors influencing GP referrals to SBD units in Ireland.

Methods
Four individual studies were conducted in a mixed-methods design. Study 1 analysed breast cancer referral and detection rates. Studies 2 and 3 comprised in-depth interviews with 9 cancer centres (hospitals) and 28 randomly-selected GPs to explore factors influencing GP referral. The impact of centralisation on referral patterns was analysed in Study 4, using the national cancer database.

Results
Referrals to breast units in Ireland increased by almost 60% in five years, without a corresponding increase in breast cancers detected. Reasons for referral included mastalgia (15%) and family history (9%). Clinical and non-clinical factors were identified as influencing referrals, such as;

- GP factors, including fear of missing a cancer and risk aversion
- Resources, including ease of access to breast clinics and high quality of the service
- Social influences, such as patient anxiety, media and patient expectations.
A significant increase was identified in analysis of national data of the proportion of patients having their diagnosis and surgery at designated cancer centres rather than non-cancer centres, indicating a high level of policy implementation. Cox proportional-hazards regression showed prompt access for GP referrals.

**Conclusions**

This is the first study to examine the effects of centralisation of breast cancer services in Ireland. The results provide useful evidence on the impact and effectiveness of this policy initiative and show early indicators of success. GP referrals are influenced by GP, health service, social and clinical factors, which can be both social and contextual in nature. GP beliefs about consequences coupled with social influences are challenging barriers to address and will require multifaceted interventions to overcome.
Acknowledgements

First and foremost, I would like to acknowledge my supervisory team; Professor Anne Hickey, Professor Ronán Conroy and Professor John Browne who helped me to bridge the gap between health service practitioner and health service researcher and provided the support and expertise to keep me on track.

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Thank you to the participants of this research; the GPs and consultants who gave up their time to participate in the interviews and to the National Cancer Registry for their assistance, particularly Fiona Dwane and Dr Sandra Deady.

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Chapter 1: Introduction

1.1 Introduction

This health services research thesis examines factors influencing GP breast cancer referrals from primary to secondary care in the Republic of Ireland. The phenomenon of unexplained increases in referrals from General Practitioners (GPs) has been identified as a key issue by practitioners and policy makers in the Irish healthcare system and internationally (1-5). The increase in GP referrals to SBD Units in Ireland between 2006 and 2010 was identified as an issue requiring investigation by breast care consultants and in the Health Information and Quality Authority (HIQA) report on Symptomatic Breast Services in 2010 (6). This thesis investigates whether organisational structures, medical factors, non-medical factors, or a combination of factors influence GP referral patterns to symptomatic breast clinics in Ireland.

The impact of organisational factors is investigated through examination of the impact of reconfiguration (centralisation) of breast cancer services in Ireland on breast cancer outcomes and referral patterns, respectively.

The impact of reconfiguration on breast cancer referrals is investigated through examination of breast cancer referral patterns and outcomes before and after a major reconfiguration of cancer services in Ireland in 2009. Evidence-based GP referral guidelines for suspected cancers were introduced as part of the centralisation process. The impact of these GP referral guidelines is investigated by examining GP referrals from primary to secondary care and exploring the opinions of clinicians on the health service factors, GP factors and social factors influencing referrals to breast cancer units in Ireland.

The thesis aims to identify factors influencing GP referral patterns and to make recommendations to ensure that urgent cases are seen quickly and non-urgent cases are seen in the most appropriate setting.
1.2 Background and context of the study

Centralisation of breast cancer surgery in high-volume specialist centres has been shown to improve patient outcomes (7-10). Based on the recommendations of the Irish National Cancer Strategy (2006) (11), the National Cancer Control Programme (NCCP) was established in 2007 to manage, organise and deliver cancer services on a whole-population basis.

In accordance with the cancer strategy, the NCCP has centralised cancer surgery for the main invasive cancers. Breast cancer surgery is now carried out at 8 designated public Symptomatic Breast Disease (SBD) units and one satellite unit, compared to 35 public hospitals providing SBD services in 2007 in the Republic of Ireland (12). This centralisation of services is shown in Figure 1.1 below.

![Figure 1.1: Hospitals providing symptomatic breast services. Source: Health Atlas Ireland](image)
As a result of this centralisation process, patients attending the SBD units in Ireland are now treated by cancer specialists in multidisciplinary teams.

Primary care is usually the first point of access for the patient into the healthcare system and the role of the General Practitioner as gatekeeper is widely acknowledged (13, 14). The GP role in the care of the patient with suspected cancer is key to early detection and referral at an early stage of disease to improve prognosis. Wide variation in all aspects of care has been found consistently in general practice research (15). Explanatory factors have been divided by Wilkin (15) into 3 broad categories: healthcare system variables, patient variables and provider variables. Wilkin discusses the consequences of variation and questions whether some patients are being treated unnecessarily, with possible adverse consequences in terms of iatrogenic disease. He asks “Are we wasting scarce hospital resources in treating patients whose problems could be dealt with at least as well in general practice?” (p.87)(15).

Based on the evaluation of the 1996 cancer strategy by Deloitte in 2003 (16) which recommended enhanced coordination of cancer services and optimisation of primary care, the second Irish National Cancer Strategy (2006) (11) recommended that GPs should have comprehensive information available to enable them to assess a patient with suspicious symptoms and findings, and to make an informed referral for specialist assessment (17). The recent centralisation of cancer services in Ireland has streamlined the GP referral pathway for patients with cancer. GP referral guidelines for suspected breast cancer were developed by the NCCP in 2009, with comprehensive education for GPs, as part of the centralisation process (3). These referral guidelines (included in Appendix A) were disseminated to GPs nationally in 2009 with the following objectives (18):

- Provide accurate and clear information for GPs referring patients to the designated Symptomatic Breast Disease Units
- Streamline the symptomatic breast referral process
• Improve the quality of referral information and thereby improve accuracy of triage by the hospital clinical teams

The total number of new referrals for breast disease nationally has increased substantially (23,575 referrals to 37,631) in the last five years (3), without a corresponding increase in breast cancers detected. This increase is in addition to the effect of reconfiguration, where cancer centres are now taking patients who would previously have gone elsewhere.

Breast cancer services in Ireland are provided through two routes: a screening service and a symptomatic service, as shown in Figure 1.2 below. The screening service is a national population breast screening service for all women aged 50-65 years (to be extended to 69 years end 2015). Women are invited through a call-recall system every two years. These are asymptomatic women and the service aims to detect breast cancers before they become palpable. This is a free service and is operated by the national breast screening service (BreastCheck). Where something suspicious is detected in BreastCheck, these women are treated in BreastCheck i.e. the route for these women is different to referral to the SBD units.

The Symptomatic Breast Service, as the name suggests, is for those patients of any age who present to their GP with breast symptoms.

These two breast services (screening and symptomatic) are totally separate services in the Irish health care system, as shown in Figure 1.2 below. The BreastCheck screening service was established by an independent agency ‘BreastCheck’, which has subsequently been subsumed into the HSE. This research examines the phenomenon of increased GP referrals to the symptomatic breast disease service and therefore focuses on factors influencing GP referrals to the Symptomatic Breast Disease (SBD) units.
This thesis aims to examine both the medical and non-medical influences on GP referrals to Symptomatic Breast Disease Units in the Republic of Ireland. The overall impact of centralisation of breast cancer services will be examined using National Cancer Registry data, thus providing evidence on the effects of the Cancer Control Programme shortly after its implementation.

Figure 1.2: Structure of breast services in Ireland
1.3 Research overview
This thesis comprises 4 individual studies as part of a mixed methods design.

Chapter 1: An introduction to the context and rationale for the research is presented to set the scene for this study.

Chapter 2: A summary of the key literature in this area is presented, commencing with the international profile of breast cancer and then focuses on patterns in Ireland. The evidence from the literature is presented on clinical, patient, provider and health service factors influencing breast cancer referral patterns.

Chapter 3: An overview of national research, policy and strategic frameworks is given as a backdrop for the rationale for this study.

Chapter 4: The aims and objectives of the overall thesis and individual studies are presented and the anticipated impact of the research is described. An overview of international research and strategy is outlined.

Chapter 5: The key models and conceptual frameworks considered to underpin this thesis are discussed.

Chapter 6: The methodology used for this study and the rationale for using this approach is described. Details of the mixed-methods iterative sequential design are provided and the integration of each of the individual studies within the mixed-methods study is described.

Chapters 7-10: These chapters present the methods and results for each individual study. A comparison of results between the hospital and GP interviews is also discussed.
Chapter 11-12: These chapters discuss the results, and provide a critique of the strengths and limitations of the research. They also highlight practical implications for patients and health services and suggest areas for future research.

1.4 Summary
This study investigates the factors influencing GP referrals to symptomatic breast disease units in Ireland, including the impact of centralisation and GP referral guidelines. This research question originated from questions arising within cancer services delivery in the health service. Findings are intended to contribute to international HSR literature and the development and implementation of evidence-based cancer policy.
Chapter 2: Literature Review of the Factors Influencing Referrals to Breast Cancer Units

A comprehensive literature search was conducted. Studies which examined factors associated with cancer referral patterns were identified through electronic searches of relevant databases. Bibliographic databases used for this study included the Cochrane Collaboration, Pubmed, Medline, Embase, CINAHL and Web of Knowledge. Reference lists from retrieved articles, policy documents, grey literature, unpublished work, personal contacts with experts and recently published abstracts at scientific meetings were also used to identify relevant literature.

The research question in PICO format (population-intervention-control-outcome) was used for the literature search strategy. Boolean operators were used to link the terms in the overall research question: “Or” was used to expand the search to include any descriptor or synonym of the population or interventions being considered. “And” was used to narrow the search to papers that addressed both the population and intervention components of the question. A detailed description of the literature search strategy including search terms is contained in Appendix B.

The original database searches were carried out in June 2010. This search yielded 1,989 articles. Following duplicate removal, title and abstract screening, and retrieval of papers, 267 studies were included in the initial literature review of the research question. E-mail alerts were set up to update these searches. A complete update of the literature search was carried out in September 2014.
Additional focussed literature searches were conducted for some of the key influencing factors which emerged from the initial research, including:

- diagnostic yields for breast cancer
- mastalgia/breast pain
- family history of breast cancer
- seasonal variation in breast cancer

The literature review will present the available literature on breast cancer, centralisation in health services and factors influencing referral patterns.

2.1 Cancer

2.1.1 Cancer epidemiology

While cancer comes second to diseases of the circulatory system as the leading cause of mortality in OECD (Organisation for Economic Co-operation and Development) countries, it is considered a larger burden than heart attacks and stroke in terms of potential years of life lost (19). The OECD also estimates that a third of cancer cases could potentially be cured if they are detected on time and treated properly (19). Modifiable risk factors for cancer include smoking, alcohol, overweight, lack of physical activity, unhealthy diet and sexually-transmitted HPV infection (20).

The OECD recommends that, for cancer care, we “follow evidence-based guidelines covering the whole patient pathway: early detection, diagnosis, treatment, monitoring and palliative care” (p.11) (19). Three priorities for action are identified in their 2013 policy report Cancer Care: Assuring Quality to Improve Survival:

- Resources (workforce, equipment, drugs)
- Practices (affordable and timely access to evidence-based health care)
- Governance (national plans, targets, guidelines and monitoring)
The policy report highlights in particular that:

“Perhaps the most critical element in improving an individual’s chances of surviving cancer is diagnosing it at an early stage and starting treatment quickly...once cancer is diagnosed, patients need to access high quality care quickly, with minimal waiting times to see specialists. As a policy priority, countries should develop a clear understanding of the pattern of excessive or inequitable waiting times for cancer care in their population and respond with policies suited to the local context” (p.12) (19).

The three cancers that currently cause the most economic impact across the world have been identified as lung cancer (US$188/€168 billion), colorectal cancer (US$99/€88 billion) and breast cancer (US$88/€79 billion) (19). The OECD recommends the development of national clinical guidelines for the management of the most common cancers in order to reduce variation in processes or standards of care. Combining these developments with equitable access to multidisciplinary care and specialist cancer centres, the efficiency and quality of cancer care can be improved.

2.1.2 Cancer incidence

Over 5 million new cancer cases are diagnosed each year in OECD countries, averaging approximately 261 cases per 100,000 population (19). The OECD report in 2013 on assuring quality to improve survival reports that cancer incidence is higher among men than women across OECD countries, with the gender gap ranging from 10% (in Denmark, Israel and Mexico) to 50% (in Poland, Turkey, Spain and Japan). Another recent OECD report states that colorectal and lung cancer are currently the most common cancers in OECD countries, with prostate cancer being the most common cancer in men and breast cancer the most common in women (21).
2.1.3 Cancer mortality
The OECD estimates that cancer is responsible for more than 25% of all deaths (19). After diseases of the circulatory system, cancer is the second leading cause of death. With the decline in cardiovascular diseases, cancer has become the number one cause of death in some OECD countries, such as Canada, Denmark, France, Japan and the Netherlands (21). Both female and male mortality rates for cancer in Ireland are close to those found in the UK (22).

2.1.4 Cancer in Ireland
2.1.4.1 Cancer incidence in Ireland
An average of 18,500 invasive cancers (excluding non-melanoma skin cancer) were diagnosed in Ireland per year between 2008 and 2010 – an incidence rate of 423 cases per 100,000 population per year, which is higher than the OECD average. This may reflect variation in screening activities between countries, particularly for breast and prostate. Incidence rates were 26% higher in men than in women and the cumulative risk of cancer diagnosis over a lifetime was 1 in 3 for men and 1 in 4 for women. The most common invasive cancers diagnosed in Ireland during this period were non-melanoma skin cancer, breast, prostate, colorectal and lung cancer (22). Figure 2.1 shows the relative frequency of the main invasive cancers diagnosed in Ireland from 2008 – 2010.

For females, the most commonly diagnosed invasive cancers (excluding non-melanoma skin cancer) were breast, colorectal, lung and melanoma. The median age of patients when diagnosed with invasive cancer was 66 years in Ireland for the years 2008-2010. This varied considerably between cancer types e.g., the mean age of those diagnosed with in-situ cervical cancer (31 years), Hodgkin’s lymphoma (32 years) and invasive testicular cancer (33 years), compared with over two thirds of patients with cancer of the lung, prostate, oesophagus, stomach and colo-rectum diagnosed when aged 65 or over. The median age of patients diagnosed with invasive breast cancer was 59 years (22).

Prevalence of cancers in Ireland can be calculated from 1994, when national cancer registration commenced in Ireland. From 1994 to 2010, 242,058 patients were diagnosed with cancer in Ireland (116,081 females and 125,977 males). Total prevalence for this 17-year timeframe shows that 104,367 patients in this cohort were still alive at the end of 2010 (40% of male patients and 47% of female patients) (22).

2.1.4.2 Cancer mortality in Ireland

The frequency of the main cancer deaths in Ireland in 2010 is shown in Figure 2.2. Lung, breast and colorectal cancer were the highest causes of cancer mortality for females while lung, colorectal and prostate cancer were the highest for males. Cancer mortality was 35% higher in males than in females.

![Figure 2.2: Relative frequency of the main cancer deaths in Ireland, 2010. Source: NCRI 2013. Cancer in Ireland 2013. Annual Report of the National Cancer Registry (22)
In 2010, the median age at death from cancer in Ireland was 73 years. Almost half of cancer patients were over 75 years at death. Cancer accounted for 30% of all deaths in Ireland in 2010 and was the second most common cause of death, after circulatory diseases (34%) (22).

2.1.4.3 Cancer projections in Ireland
Cancer incidence data from the National Cancer Registry Ireland (NCRI) from 1994 to 2010 and population projections from the Central Statistics Office (CSO) have been combined to estimate the number of new cancer cases expected in Ireland, in five-year intervals, from 2015 to 2040 (23). The number of cases of invasive cancer is projected to increase from 28,480 in 2010 to almost 60,000 in 2040, based on demographic change alone, in the absence of any change in incidence rates (23).

The total number of new invasive cancer cases (including non-melanoma skin cancer) is projected to increase by 84% for females and 107% for males between 2010 and 2040, based only on changes in population size and age distribution (demography). If trends in incidence since 1994 are also taken into account, the number of cases is expected to increase by 86%-125% for females (depending on the method of projection used) and by 126%-133% for males (23).

The NCRI cancer projections in 2014 estimated that demographic change will be the main factor driving the increase in numbers of cancers in Ireland. However, trends in risk factor prevalence such as tobacco, diet, obesity, alcohol and low physical activity will also have an impact (23). The median age of cancer patients at diagnosis is expected to increase, based on ageing population and improving life expectancy in Ireland (23). One of the NCRI population projections, based on CSO data, projects a 14% increase in the female population and a 15% increase in the male population between 2015 and 2040 in Ireland, with a decrease in the population aged 35-49 years and an increase in the population over 85 years.
2.1.4.4 Cancer in Ireland compared to other European countries

Cancer incidence in Ireland is amongst the highest in Europe, with females ranked 5\textsuperscript{th} and males 8\textsuperscript{th} of 27 countries. Incidence rates were 15\% higher for females and 10\% higher for males than the overall EU average. However, variability between countries was low and Irish incidence rates were generally close to those found in several other north-western European countries (22). The incidence rate of prostate cancer in Ireland was 4\textsuperscript{th} in the EU and the incidence rate for breast cancer was 6\textsuperscript{th} in the EU in 2012, possibly reflecting the impact of increased screening for these two cancers (22).

Figure 2.3 shows the estimated cancer incidence and mortality in Europe in 2012 for all invasive cancers, excluding non-melanoma skin cancer.

![Figure 2.3: Estimated cancer incidence and mortality in Europe 2012. Source: Cancer in Ireland 2013, (NCRI, 2013)(22).](image-url)
Irish females ranked 6th in EU mortality rates (13% higher than the EU average), with Irish males ranked 21st (9% lower than EU average), similar to UK rates (22).

The OECD reports that cancer incidence rates tend to be higher in high-income countries, as people in these countries are more likely to consume more alcohol, be overweight and inactive (19). In addition, lower detection rates in lower income countries may contribute to the lower reported incidence (24). Within Europe, an east-west gap still exists despite recent improvements in cancer control and screening programmes in eastern European countries (19, 25).

2.1.5 Summary

In summary, the data on cancer incidence and mortality is readily available from well developed cancer registries. However, the quality of data differs within and between countries, particularly in relation to staging data. This may result from incomplete staging information or the level of specialist imaging performed, which can result in stage migration (26). Cancer incidence data is also influenced by screening. Countries with population screening programmes (such as BreastCheck in Ireland) will impact on detection rates and may not be directly comparable to other countries without established national population screening programmes, such as the US.
2.2 Breast Cancer

2.2.1 Epidemiology of breast cancer
The main risk factors for breast cancer are early age at menarche (27), late age at first birth (28), low parity (27, 28) and late menopause (27). Risk factors for breast cancer also include family history of breast cancer, alcohol consumption, oestrogen replacement therapy and obesity (19, 23, 29, 30).

2.2.2 Incidence of breast cancer
While incidence rates have been decreasing in recent years in some cancers, such as cervical, lung and colorectal cancers, the incidence of breast cancer has increased in almost all OECD countries, mostly due to improvements in detection through screening and improved diagnostic investigations (19). Breast cancer was the most common cancer among women in the OECD in 2008, with 639,000 cases (27% of all new female cancers) (24).

2.2.3 Mortality from breast cancer
Breast cancer is the most prevalent type of cancer in women worldwide and accounted for almost 508,000 deaths in 2011, according to the WHO Global Health Estimates (31). According to the OECD, one in every nine women in the western world will develop breast cancer during her lifetime and one in thirty will die from the disease. In the USA, patients without health insurance were more likely to have a higher mortality rate from breast cancer (32) and to have late-stage cancer (33).

2.2.4 Survival and breast cancer
Breast cancer survival has improved with the introduction of screening programmes and improved treatment (19). The survival estimates for breast cancer in most OECD countries is over 80% at 5 years. Staging data, including stage at diagnosis, is considered important when examining survival rates for cancer (34-36). Improvements in diagnostics may lead to stage migration (37), lead-time bias (38), or the detection of early-stage cancers which may never have developed symptoms (39).
Multidisciplinary care incorporating surgery, chemotherapy and radiation has also improved treatment, with many women now receiving breast conservation therapy (breast conserving surgery plus local radiation) and an increase in the use of neo-adjuvant chemotherapy and systemic therapies (40).

2.2.5 Breast cancer in Ireland

2.2.5.1 Breast cancer incidence in Ireland

The annual average incidence of invasive breast cancer between 2009 and 2011 in Ireland was 2,805 cases per annum, which represents 31% of female invasive cancers, excluding non-melanoma skin cancer. The incidence rate per 100,000 females was 123.7. The 2012 estimated incidence rates of female breast cancer (122.4) in Ireland was 5% lower than in the UK (129.2) but 13% higher than the European average (108.8). The majority of cases of breast cancer occur in women aged over 50 years. On average, 23 men are diagnosed with breast cancer in Ireland annually (41).

2.2.5.2 Breast cancer mortality and survival in Ireland

The number of deaths from breast cancer in 2010 in Ireland was 649 women and 10 men, a death rate of 26.5/100,000 for females and 0.5 per 100,000 for males. Ireland improved 5-year relative survival rates for breast cancer from 72.3% in 1997-2002 to 80.3% in 2004-2009 (19). Breast cancer is a very treatable disease when detected at an early stage, which is reflected in the increase in survival rates. The five-year age-standardised estimates of cumulative net survival for Irish female breast cancer patients has increased from 72% in the period 1994-1999 to 81% in the period 2006-2011 (42).

2.2.5.3 Projections for breast cancer in Ireland

Cancer incidence data from the NCRI from 1994 to 2010 and population projections from the CSO have been combined to estimate the number of new cancer cases expected in the years 2015 - 2040. The NCRI describes how:
“Trends in cancer incidence are determined principally by two elements: population change and changes in risk factor prevalence. Case numbers may also be affected by a number of other factors: screening programmes, changes in medical practice leading to the discovery of more incidental cancers, changes in diagnostic or histological classification and changes in the completeness of registration” (p.64) (23).

There was a significant upward trend in female breast cancer between 1994 and 2010 of 4% annually. Projections for breast cancer were made more difficult, due to recent short-term variation in incidence trends influenced by the introduction of a national breast cancer screening programme. Breast cancer is expected to increase in Ireland by about 130% between 2010 and 2040 (23). Table 2.1 shows the projected numbers of incident cases 2015-2040, based on demography only, with percentage increase compared to 2010.

Table 2.1: Projected numbers of breast cancer cases 2015-2040

<table>
<thead>
<tr>
<th>Year</th>
<th>Projected incidence (n)</th>
<th>Percentage increase (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>3,209</td>
<td>11</td>
</tr>
<tr>
<td>2020</td>
<td>3,577</td>
<td>24</td>
</tr>
<tr>
<td>2025</td>
<td>3,937</td>
<td>36</td>
</tr>
<tr>
<td>2030</td>
<td>4,252</td>
<td>47</td>
</tr>
<tr>
<td>2035</td>
<td>4,514</td>
<td>56</td>
</tr>
<tr>
<td>2040</td>
<td>4,701</td>
<td>63</td>
</tr>
</tbody>
</table>


2.2.5.4 Breast cancer in Ireland compared to other European countries
The European Cancer Observatory has produced estimates of national cancer incidence and mortality for all European countries for 2012. Female breast cancer incidence in Ireland was 12.5% higher than the EU average and ranked 6th highest of 27 countries overall. Irish mortality rates were 3rd highest, after Belgium and Denmark and were 22% higher than the EU overall, as shown in Figure 2.4 (22).
2.2.6 Diagnostic yields for breast cancer

The diagnostic yield is the proportion of referrals with a cancer diagnosis relative to the overall number of referrals. The diagnostic yield in breast clinics is typically low, i.e., the majority of patients referred to breast cancer clinics will not be diagnosed with cancer.

Studies in the UK have reported diagnostic yields ranging from 6% to 10% (5, 43-46). In a study with symptomatic patients in Wales, the rate was 6.3% (44). Cochrane and colleagues found a rate of 6%, which was unchanged following the introduction of GP referral guidelines in Wales in 1995 (43). In contrast, Imkampe (47) compared diagnostic yields before and after the introduction of the 2-week rule in the UK (an initiative to see all urgent cancer referrals within 2 weeks of referral) and found that the rate dropped from 10% in 1999 to 7% in 2003-2004, after the introduction of the rule. A similar UK study (5) found a drop in the percentage of patients diagnosed with cancer, from 12.8% in 1999 to 7.7% in 2005, in the group referred under the 2-week rule.
The proportion of referrals to breast clinics in Ireland which had a cancer detected was 9.1% in 2006 before centralisation, 5.8% in 2009 during the centralisation process and 5.3% in 2010 after centralisation of breast cancer surgery was complete (12, 48). A single centre study in a breast unit in Ireland in 2011-2012 yielded 4.9% primary breast cancers (49). In this thesis, the factors influencing this increase in benign referrals to breast clinics will be explored.

2.2.7 Summary
In summary, the incidence and prevalence of breast cancer is rising internationally, with improvements in breast cancer survival, a trend which is replicated in Ireland. The risk factors for breast cancer are well defined and treatment at an early stage of disease offers a good prognosis. The number of GP referrals for benign breast disease is high in studies conducted in the UK and Ireland. However, literature is scant on characteristics of GP referrals in other countries, which tend to focus on the diagnosed breast cancers and not the overall cohort of benign and malignant referrals.
2.3 Centralisation

2.3.1 Introduction

The centralisation of breast cancer services and of cancer services in general continues to be debated in the international literature. This review of the current literature will examine the policy and practice of centralisation in healthcare in general, followed by a more focussed examination of centralisation in the area of cancer and then breast cancer specifically. Each section will commence with the international literature, followed by the UK and then Ireland. The terminology in the literature varies between centralisation, specialisation and the volume-outcome debate. A comprehensive literature search of published papers, policy documents and grey literature was conducted. The literature search strategy with details of search terms is contained in Appendix B.

2.3.2 Health policy and centralisation of services

Health policy in the area of centralisation of health services continues to evolve internationally, but the level of implementation varies. There continues to be ongoing tension between access and quality in the provision of healthcare. Some areas of centralisation derive from professional sub-specialisation, requiring a high volume of procedures to maintain skill, and others from advances in technology such as telemedicine (50, 51). A brief overview of general health policy analysis theory is included here, focussing on policy implementation, before specifically focusing on discussion of implementation of cancer centralisation policy.

Walt and Gilson (52) developed the health policy analysis framework, outlining the traditional approaches of rationalism, incrementalism and public choice theory, while highlighting the importance of the role of ‘actors’ in policy analysis, in addition to the content, context and process of the policy (policy triangle framework). They explain how health policy can fail to deliver the desired outcomes if we focus too much on the content of the policy without understanding the implementation process and the factors influencing this process. Walt and colleagues (53) describe several
approaches to health policy analysis, including the stages heuristic (54) (55),
the policy triangle framework (52), multiple streams theory (56) and
punctuated equilibrium theory (57). Several approaches to stakeholder
analysis are presented within these theories, which include 3 distinct
activities; identifying the policy actors, assessing their political resources and
understanding their position and interests (53, 58, 59). Each of these
theories is described in more detail below.

The stages heuristic (54) (55) is a framework which divides the public policy
process into four stages: agenda setting, formulation, implementation and
evaluation. This framework assists in the understanding of the public policy
process, however, it assumes a linear process with defined steps in the
public policy process which rarely happens in reality (53). While the
development of national cancer strategies in Ireland has traditionally followed
defined 10-year time intervals (1996, 2006, 2016), which included evaluation
processes, this has not been planned according to a particular framework.

The policy triangle framework developed by Walt and Gilson (52) considers
how actors, context and processes interact to shape policy formulation (53).
This framework has been used in the areas of health service reform,
reproductive health and mental health (60) but not cancer services
specifically.

Punctuated equilibrium theory (57) proposes that “the policy making process
is characterized by periods of stability with minimal or incremental policy
change, disrupted by bursts of rapid transformation” (p.311)(53). This theory
has been used to examine policy making in the areas of control of malaria,
polio and tuberculosis (61) and US tobacco policy (57). Some similarities can
be seen in the reorganisation of cancer services in Ireland, when rapid
transformation followed a series of high profile cancer misdiagnosis (62, 63).
The Kingdon model of agenda setting (56) is described by Buse et al. (64). They describe how policy windows can provide optimal opportunities for issues to be addressed on the Government agenda. This necessitates the convergence of three streams at the same time; the problem stream, the policy stream and the political stream. This multiple streams theory (56) describes the policy stream, the problem stream and the political stream as independent streams in agenda setting. Windows of opportunity arise in the public policy process when these three streams merge and governments make a decision to act (53). This theory has been used to explain how certain health issues progressed in the public policy process, for example, child health (65) and tuberculosis (66) (53). Just such a policy window materialised for cancer control policy in Ireland in 2006, with the concurrent national focus on the burden of disease from cancer, the publication of the National Cancer Strategy by the Department of Health and political will from the Minister for Health, Mary Harney TD. Multiple streams theory can therefore be used effectively to describe the accelerated progress of cancer control in Ireland.

Gilson (67) reviews implementation gaps through health policy analysis and highlights the significance of how stakeholders use their power in taking forward, resisting, blocking or challenging policy implementation. Lipsky (68) found that the practices of street level bureaucrats can effectively become public policy rather than the intentions or objectives developed at a central level. Buse et al. (64) describe the process of policy making as a contextual one, whereby the content of a policy is shaped by pressures from the various stakeholders as well as the evidence base. The policy triangle (52) is influenced by actors such as individuals, organisations and groups. This paper also describes Public Choice Theory; how power is distributed in policy making and lists lobby groups and the state/government as individual interest groups in this process (64). The strength of local lobby groups was demonstrated during the centralisation of cancer services in Ireland, such as the local support to retain a breast unit in Sligo.
While aspects of a number of theories are reflected in the development of cancer services in Ireland as described above, the Government approach to hospital reconfiguration and to centralisation of particular services in Ireland appears to have followed a mixed scanning approach traditionally: the use of evidence-based healthcare combined with decisions that are made on the basis of geography or politics.

Local politics has been heavily involved in the centralisation debate of Irish healthcare. However, the incrementalist approach to decision making of local politics, or ‘muddling through’, has been fostered by pluralistic approaches of local lobby groups to maintain the status quo within their local/regional area of interest (69). Policies developed to promote equity can challenge the existing structures and eligibility criteria, questioning the status quo (70).

The policy of centralisation can also be viewed as challenging existing equitable structures, such as the former provision of cancer services in all acute hospitals in Ireland. There was significant press coverage following the centralisation of cancer services in Ireland. For example “Medical experts fury at blunder over cancer test” in the Irish Daily Mail, in August 2007 (62), relating to a case in Galway and “60 women to return to Portlaoise Hospital for review following misdiagnosis”, relating to a case in Portlaoise, reported in the Irish Independent, in November 2007 (63).

Whilst the cancer services in Ireland have not followed one designated model or framework throughout its development, the Kingdon model of agenda setting best describes the process and success of the centralisation of cancer services in Ireland.

2.3.3 Rationale for centralisation of health services

Centralisation of health services has been promoted on the basis of improved quality of care leading to improved patient outcomes. The Institute of Medicine (IOM) in the USA has described quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired outcome and are consistent with current professional knowledge”
Quality of care can be evaluated on the basis of structure, process and outcome (72-74). Brook advises assessing quality largely based on process criteria, in order to ensure patients receive quality care (74) while Donabedian focuses on the link between outcome and organisational characteristics within the process of care (72). Centralisation encompasses structural and process aspects of this quality framework and uses patient outcomes to measure its effectiveness.

In the USA, the Institute of Medicine’s (IOM) aims for the 21st-century health care system (75) recommends that health care should be safe, effective, patient centred, timely, efficient and equitable. The IOM proposes that improvement in these six dimensions would better meet the needs of patients and that patients would receive care that was “safer, more reliable, more responsive, more integrated and more available” (p.6) (75). Quality has become a powerful health policy driver (76). This IOM model has previously been used to assess quality of cancer care (77) and care of the dying (78).

Components of this model can be seen in the centralisation of cancer services in Ireland, with key performance indicators established for access to services. Quality assurance criteria have been established for the symptomatic breast service (79). These criteria are structured around the eight themes of quality and safety developed by HIQA in ‘Safer Better Healthcare’ (80) to provide high quality safe and reliable care, centred on the service user. This framework has not yet been evaluated by HIQA.

2.3.4 Centralisation in health services
2.3.4.1 Centralisation – international
In a European Observatory report on health systems and policies, Ettelt et al., (81) propose that the extent to which healthcare is retained centrally or devolved to regions is a function of the size of the country. There is strong evidence supporting the volume-outcome debate, that units with high-volume activity have better clinical outcomes, in particular for the specialised areas of cancer (82, 83) and cardiac surgery (84).
The majority of routine services can continue to be provided locally and a WHO report concludes that with imaginative approaches to service redesign, smaller hospitals can be sustainable (85). Large-scale health care reforms cause years of disruption (86). Roland estimated that health care in England would go through 3 – 4 years of disorganisation before benefits would be seen following a change programme such as the NHS ‘Equity and Excellence: liberating the NHS’ in 2010. Also in the UK, Farrington (87) makes the case that “more lives can be saved if services are centralised in more specialist hospitals” (p.9). Improvements in mortality and length of stay were also observed following centralisation of acute stroke services in London and Manchester (88). Posnett (89) argues that, with centralisation, “the trade-off is that greater concentration leads, inevitably, to reduced patient access” (p.100) and advises service planners to ensure that hospital services are locally provided and easily accessible (90).
2.3.4.2 Centralisation – Ireland

A number of policies and strategies have shaped the structure of acute hospital services in Ireland, which are summarised below. A broad spectrum of acute services has traditionally been provided in all acute hospitals in Ireland, with few tertiary specialist centres.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1968</td>
<td>The Fitzgerald report in 1968 (91) initiated the debate about hospital location in Ireland through its recommendations on rationalising hospitals into a national network, with 4 regional specialist centres, 12 general hospitals and the remaining centres as community health centres. However, these recommendations were not included in the 1970 Health Act and were not activated in terms of implementation for several decades.</td>
</tr>
<tr>
<td>1993</td>
<td>The Medical Manpower (Tierney) report in 1993 (92) analysed medical staffing in acute hospitals in Ireland, highlighting the low number of consultant posts in place to provide specialist care for all specialities.</td>
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<tr>
<td>1994</td>
<td>In 1994, the Department of Health and Children developed the first National Health Strategy ‘Shaping a Healthier Future’ (93). This strategy recommended that acute hospitals in the Republic of Ireland should be organised into a network of larger specialist units and smaller local units.</td>
</tr>
</tbody>
</table>
| 2001 | The second National Health Strategy ‘Quality and Fairness – A Health System for You’ (2001) (94) built on the previous strategy’s recommendations of hospital networks and was based on four key principles:  
  • Better health for everyone  
  • Fair access  
  • Appropriate care in the appropriate setting  
  • High performance |
### 2001

A parallel government strategy document for primary care was also released in 2001 ‘Primary Care: a new direction’ (13). This strategy outlined plans to strengthen the primary care system through establishment of primary care teams in the community, with the “potential to deliver much of the care currently provided by specialist services” (p.27). Enhanced integration between primary and acute care was proposed through:

- referral guidelines and protocols for consultant care and diagnostics
- integrated care pathways

### 2001

A third report examining the economic implications of these proposed reforms of the health system, entitled “Audit of the Irish Health System and Value for Money” (95) was published the same year. This report also endorsed the model of hospital networks and criticised the existing hospital structures for their lack of integration and economic effectiveness. Wren (96) commented on the findings of the Value for Money audit and agreed that local politicians had shown no political will to make “hard political decisions about hospital rationalisation” (p.197).

### 2003

The Report of the National Task Force on Medical Staffing (Hanly report) was commissioned to provide updated information on medical staffing. This report in 2003 (97) described the historical evolution of acute hospitals in Ireland. It described how acute hospitals “were developed in response to local needs, or owe their origins to history, rather than to clear national or regional priorities” (p.60). The Hanly report outlined the benefits of centralisation or ‘regional hubs’ in terms of benefits for patients and cost effectiveness: “Better clinical outcomes are achieved in units with appropriate number of specialist staff with relevant skills and experience, high volumes of activity and access to appropriate diagnostic and treatment facilities” (p.72). However, there was no implementation plan, no timeframe and no budget to support this plan (98). Local campaigners and health services action groups labelled the policy ‘anti-rural’ and ‘socially destructive’ (98), an example of public choice theory in action.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event/Report</th>
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<tbody>
<tr>
<td>2003</td>
<td>In 2003, Michael Martin TD, the then Minister for Health, announced the Health Service Reform Programme (99), calling for significant reform in the structure, funding and management of the health service through the development of the Health Service Executive (HSE). At the same time, the Prospectus report which audited the structures and functions of the health system (100) recommended the consolidation of fragmented structures in the health service to ensure high quality services and value for money. The same year, the Brennan report carried out an examination and review of the financial management and control systems in the health service in Ireland (101) and recommended substantial changes in relation to the structure and management of the health service.</td>
</tr>
<tr>
<td>2006</td>
<td>The HSE Transformation Programme (2007-2010) (102) recommended that hospital services needed to be configured to deliver optimal and cost-effective results. In relation to hospital reconfiguration, the report recommended an integrated care model that is “evidence-based, efficiently run and quality assured” (p.14), focussing on maternity, paediatric and emergency services.</td>
</tr>
<tr>
<td>2006</td>
<td>A subsequent (2006) report <em>Improving Health and Achieving Better Standards</em>, referred to as the “Teamwork report” (103), found that the number of acute hospitals in the Northeast region of Ireland could not be justified.</td>
</tr>
<tr>
<td>2008</td>
<td>The review of acute hospital services in Cork and Kerry in 2008 (104) recommended a regional specialised centre with a network of local general hospitals while the HSE action plan for the Mid West region (105), also in 2008, supported the policy of centralisation and specialisation of services in large regional hospitals, whilst strengthening local primary, community and continuing care services (98).</td>
</tr>
<tr>
<td>2008</td>
<td>An OECD report in 2008 on integrated public services in Ireland (106) promoted centralisation of health services, stating “It is better to rationalise the delivery of highly specialised surgical and acute medical procedures so that surgeons are given the chance to perform procedures often enough to maintain their skills” (p.39) but criticised the lack of concurrent development of primary, community and continuing care services to support and enable the downgrading of local hospitals.</td>
</tr>
<tr>
<td>Year</td>
<td>Description</td>
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<tr>
<td>2009</td>
<td>An Irish report from the Economic and Social Research Institute (ESRI) in 2009 (107) advised that in order to moderate future demand for hospital services, the development of integrated care in the community is essential.</td>
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<tr>
<td>2012</td>
<td>Future Health: A Strategic Framework for Reform of the Health Services 2012-2015 (108). This framework outlines the programme for government to introduce universal health insurance. Service reform will include moving away from the current hospital-based model of care towards a new model of integrated care.</td>
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<tr>
<td>2013</td>
<td>The establishment of Hospital Groups as a transition to independent Hospital Trusts (109) is outlined in the Higgins report (2013) which reiterates the policy of centralisation of specialist and complex care and outlines the formation of hospital groups to facilitate integration and patient flow across the continuum of care.</td>
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The debate about provision of acute hospital services in Ireland has been documented in policy and strategy documents since 1968. These strategies outline the government direction towards specialised centralised services based on international evidence and best practice. However, implementation of these recommendations has been poor historically, due to opposition from local politicians and residents, lack of implementation plans, lack of sufficient medical manpower, and fragmented primary care services. The formation of independent Hospital Trusts in Ireland aims to provide “optimum configuration for hospital services to deliver high quality, safe patient care in a cost effective manner” (p.8) (109). The efficacy of this approach will need be monitored to assess patient outcomes.
2.3.5 Centralisation – cancer
2.3.5.1 Centralisation – cancer – international

The OECD have reported that centralisation of cancer care delivery seems to have contributed to “higher quality cancer care and improved evidence based care delivery” (p.58)(19), although strategies differ across countries. The association between hospital or physician volume and patient outcomes for cancer has been debated in the literature since the 1970s, when Luft demonstrated a relationship between surgical volume and mortality (110). Hannan (111) builds on Luft’s (112) previous theory in relation to volume outcome and poses the question:

“Do higher-volume hospitals have better outcomes because their experience enables them to improve their performance (practice makes perfect) or do hospitals with better outcomes have higher volumes because their competence is well known and rewarded (selective-referral hypothesis)” (111) (p.1678).

He cautions that volume “should not be considered the final determinant of quality” (p.1678) and recommends that more accurate data should be collected on the relationship between process and outcome.

Begg et al. (113) studied the impact of hospital volume on 30-day mortality for major cancer surgery. They found that mortality rates for complex cancer surgery were lower in specialist centres, in particular for oesophagectomy and pancreatectomy. However, breast cancer surgery was not included in the Begg et al. study and is not considered a particularly complex surgery. In order to ascertain if specialist centres were operating on a more favourable group of patients, the distribution of co-morbidity, age and cancer stage were examined and found to be independent of hospital volume.

Smith et al. (114) found the volume–outcome evidence so pervasive and persuasive, that they recommended that public and private funders should set requirements of a minimum case volume as a condition for reimbursement. The authors added that clinical outcomes can also be improved with clinical practice guidelines and with standardised care.
Lipscomb (115) questioned whether the benefit of surgeon volume on patient outcome in cancer care is due to specialty training and exposure or to “technical skills enhancement through repetitive performance of the procedure itself” (p.151) and recommends that additional factors should be considered, including patient choice, physician speciality and processes of care.

Weitz (116) carried out a review of the impact of volume and specialisation for cancer surgery. He concurred with previous studies on the volume–outcome relationship, but observed that the magnitude of this relationship varied between malignancies. He also questioned the threshold that should be used to define a high-volume provider, a question also raised by Hannan (111) and by Epstein (117). While volume most likely affects quality of care, better hospitals and clinicians could potentially attract more patients (111, 118). Hannan also cautioned against using volume as the final determinant of quality.

Two studies commissioned by the Institute of Medicine (IOM) in the USA outlined the benefits of centralisation of cancer care (118, 119). Hillner et al. (118) reviewed the literature from 1988-1999 on the relationship of volume and outcome in cancer care and summarised the benefits of higher caseloads for complex surgery such as oesophageal, gastric, pancreatic and non-small-cell lung cancer. However, Hillner acknowledged the possibility of publication bias of the included studies and noted that less research had been carried out for less complex surgery, such as breast cancer. This was consistent with Halm’s (119) subsequent systematic review, which also included breast cancer surgery, showing that higher surgical case volume was associated with better peri-operative and 30-day mortality, but the magnitude of this association varied greatly. Halm’s systematic review included 135 published studies across a range of 27 surgical procedures and conditions which examined both individual surgeon caseload and hospital caseload. The majority of studies found a direct relationship between case volume and patient outcomes, which was strongest for complex surgery and cancer treatment. However,
methodological weaknesses of individual studies made it difficult to make robust recommendations for policy making. For example, most studies examined the effect of hospital volume or physician volume only, the quality of risk adjustment techniques varied between studies, only two studies measured the appropriateness of patient selection and only 10 studies examined different processes of care between high volume and low volume providers.

Learn and Bach (120) discussed the possible reasons behind the lack of centralisation policy in the USA. These include concerns about the “validity and reliability of the volume–outcome relationship as a policy tool” (p.1041) (121-123), as well as concerns about diminution in patient access (124) (125, 126) and an increase in volume of patients and associated activity at specialised centres, which could affect quality (127, 128). The authors discussed how the question of improving outcomes for high-risk oncological surgery “remains highly charged by substantial competing interests, valid logistical concerns and a dearth of solid prospective data” (p.1048). In their study of high-risk cancer surgeries which included pancreatectomy, oesophagectomy, gastrectomy and major lung resection, they concluded that the generalised decreases in in-patient mortality were due to improvements within volume categories.

Collective evidence on this debate appears to favour the volume–outcome argument, although the thresholds and parameters for volume varied. For example, some studies measured practitioner volume while others measured hospital volume. In a study on colorectal cancer surgery, Harmon (129) found that surgeons with medium annual case volume (5 – 10) achieved results equivalent to surgeons with high-case volume (>10), when they operated at high (>70) to medium-volume (40 – 70) hospitals. A systematic review to assess the impact of specialisation on processes and outcomes of care for cancer patients was conducted by Grilli et al. (130) which included 46 eligible studies. Specialised centres/clinicians were found to have lower mortality rates. However, methodological flaws were noted in the included studies, such as lack of comparability of patients seen at specialised and
non-specialised centres, findings derived from secondary analysis and possible publication bias. A systematic review and meta-analysis from Gruen et al. (131) on the effect of provider case volume on cancer mortality included 101 publications involving greater than one million cancer patients (oesophageal, gastric, hepatic, pancreatic, rectal and colon cancer). A significant volume–outcome effect was found for the majority of gastrointestinal cancers. However, heterogeneity of results from individual studies was noted.

Billimoria et al. (132) examined whether differences in hospital surgical volume for complex cancers had a greater effect on peri-operative mortality (60 days) or on long-term survival (5 years). The cancers included were colon, oesophageal, gastric, liver, lung, pancreatic and rectal cancers. While the results showed that quality improvement initiatives were required to address peri-operative mortality, the authors concluded that more deaths could be avoided if quality initiatives were focused on factors related to long-term survival. The authors emphasised the importance of hospital characteristics and processes of care for improving patient outcomes, both in low-volume and high-volume hospitals.

A German study (133) examining variation in breast cancer care identified potential for improvement in the areas of early detection and adherence to treatment standards for breast cancer. The development and implementation of national guidelines for cancer was identified as a priority, in line with the Council of Europe (134) and WHO directives (135).

In summary, the debate on volume-outcome continues in the extant literature. It is apparent that both physician caseload and hospital volume need to be considered as individual factors influencing patient outcomes. However, other factors such as clinical practice guidelines, standardised care and care processes will also influence patient outcomes. The balance between patient access and centralised specialist care is a policy decision to be made by individual cancer control programmes. The OECD recommends
coordination of care across providers, including primary care, as not all cancer care is delivered in specialist centres (19).

2.3.5.2 Centralisation – cancer – UK

The UK Calman-Hine report on cancer services was developed by the Chief Medical Officers in England and Wales in 1995 (136). This report recommended that all patients should have access to a uniformly high quality of cancer care wherever they may live. This report aimed to improve cancer outcomes and reduce inequalities through the establishment of specialist cancer centres with multidisciplinary teams. Prior to the Calman-Hine report, cancer care in the UK had been described as the ‘cancer lottery’, referring to patient’s access to cancer specialists (137).

In an editorial on the launch of the Calman-Hine report, Haward (138) commented that “cosmetic changes in hospital designation will not achieve the consistent quality of cancer service that is the cornerstone of the Calman policy” (p.531). In 2006, he reported on the implementation of the Calman-Hine report and concluded that the implementation was not sufficiently addressed, resulting in variation both across and within sites (137). He reported that shortages in staffing and facilities were exposed and the lack of cohesion between the commissioners of the process and the managers of the service impeded its effective implementation (137). Morris (139) found a major shift in the specialisation of colorectal and breast cancer surgery in Yorkshire. She found that the level of specialisation varied across Hospital Trusts and that the centralisation process had commenced before the publication of the Calman-Hine report.

The recommendations of the Calman-Hine report were accepted by the Campbell report in Northern Ireland in 1996 (140, 141). This report recommended similar changes in cancer care, including centralisation, increased specialisation, multi-disciplinary care, enhanced communication between GPs and secondary care, and enhanced palliative care.
The UK Department of Health produced the National Cancer Plan in 2000 (142). This plan made cancer networks responsible for improving care, with financial resources provided for staffing and equipment. Following publication of this plan, 34 cancer networks and 1,600 multidisciplinary cancer teams were established, with a commitment of significant investment. Key areas for development included prevention, screening, community services, reduction in waiting times, clinical guidelines, palliative care, workforce planning, cancer research and investment in equipment. The NHS Cancer Reform Strategy (2007)(143) and the UK 2011 Cancer Strategy ‘Improving Outcomes: a Strategy for Cancer’ (144) built on the progress of the National Cancer Plan. The achievements of the Cancer Plan were acknowledged in the areas of survival, screening services, smoking cessation, multidisciplinary teams, expanded workforce and faster access to treatment. A programme for further action was outlined in the areas of prevention, diagnosing cancer earlier, ensuring better treatment, living with and beyond cancer, reducing cancer inequalities, and delivering care in the appropriate setting.

Proposals to consolidate cancer services in England through the commissioning process have been challenged in some areas, such as Manchester, on the basis of anti-competitiveness (145).

2.3.5.3 Centralisation – cancer – Ireland
The first National Cancer Strategy in Ireland (146) entitled *Cancer Services in Ireland*, was published in 1996 and included the following recommendations:

- Services must be of uniformly high quality throughout the country
- The services should be based on an integrated multi-disciplinary approach, determined by patient needs rather than by accidents of domicile, location of services or traditional patterns of referral
• There must be agreement about the types of cancer which would be inappropriate to particular hospitals because of size, expertise or other factors

• There must be agreement regarding the minimum and maximum caseloads for clinicians

The structure of cancer services was proposed as follows:

• Regional services provided by designated groups of hospitals with a remit to treat specific cancers according to agreed protocols and best practice

• Supra-regional services responsible for treating the full range of cancers and for providing the more highly specialised therapies not available in regional services

The outcome of this strategy was that, whilst there were some developments in the areas of regional coordination and cancer care nursing coordinators, the structure of cancer services remained largely unchanged.

The second National Cancer Strategy; *A Strategy for Cancer Control in Ireland* was published ten years later, in 2006 (11). This second strategy focussed on the restructuring of cancer services into managed cancer control networks and quality in cancer control. Based on the recommendations of this second National Cancer Strategy (11), the National Cancer Control Programme (NCCP) was established in 2007 to manage, organise and deliver cancer services on a whole-population basis. As a result, cancer surgery has been centralised in Ireland by the NCCP for a number of cancers including breast, lung, prostate, pancreatic, rectal, oesophageal and brain tumours.

The National Cancer Strategy (11) also recommended that GPs should have comprehensive information available to enable them assess a patient with suspicious symptoms and findings, and to enable them to make an informed
referral for specialist assessment (17). The NCCP GP referral guidelines for suspected cancers (commencing with breast, prostate and lung cancers) were developed and disseminated in 2009 to provide the following benefits (18):

- Provide accurate and clear information for GPs referring patients
- Streamline the symptomatic breast referral process
- Improve the quality of referral information and thereby improve accuracy of triage by the hospital clinical teams

These GP guidelines have been in use since 2009. This thesis will examine the effects of the implementation of these referral guidelines on a number of outcomes, to be described in detail in Chapter 9.

2.3.6 Centralisation – breast cancer

2.3.6.1 Centralisation – breast cancer – international

Studies of breast cancer have shown that variability in treatment can be reduced by implementing treatment protocols (147, 148). Centralisation of breast cancer surgery in high-volume specialist centres has been shown to improve patient outcomes (7-9, 149, 150) and quality of care (150). Many volume–outcome studies focus on in-patient or 60-day mortality as their primary outcome variables. However, as deaths following breast cancer surgery are rare, long-term survival is a more useful parameter to examine for this cohort.

Skinner et al. (8) found a 33% reduction in the 5-year risk of death for breast cancer patients being treated by specialist surgical oncologists compared to non-specialists in a study conducted in Los Angeles with 29,666 eligible patients. This study also demonstrated a 23% reduction in the risk of death at 5 years in hospitals treating >125 breast cancer patients per year. The authors attribute the differences to several factors including volume, surgical skill, multidisciplinary care and more appropriate use of adjuvant therapies. The authors conclude that “long-term survival in breast cancer can be improved by concentrating the care of these patients in high volume centres
where the patient will be treated by a surgeon who performs such surgeries regularly” (p.614)(8). Whilst data from population based tumour registries provide large numbers, with reduced risk of institutional or selection bias, they are limited by the quality and validity of those data.

These results from Skinner and colleagues in 2003 are consistent with an earlier study in New York State by Roohan (151), which found that at 5 years, patients from very low-volume hospitals (≤ 10 cases per year) had a 60% greater risk of all-cause mortality than patients from high-volume hospitals (performing >150 breast cancer surgeries per year). Factors other than surgery may also contribute to survival and Roohan recommends examining the process of care, including adjuvant treatment post-surgery. Both Roohan (151) and Morrow et al. (152) documented improved long-term survival after mastectomy for breast cancer at high-volume centres.

In a systematic review to assess the impact of specialisation on processes and outcomes of care for cancer patients conducted by Grilli and colleagues (130), specialised centres/clinicians were found to have lower mortality rates, as indicated earlier in this chapter. For breast cancer, a pooled estimate of the effect of specialisation showed that specialised cancer care was associated with an 18% reduction in mortality. The level of specialisation (hospital level, clinician level) varied between individual studies. The authors commented on the lack of studies with conflicting results in this area, raising the possibility of publication bias.

Nattinger (153) also raises the possibility of selection bias in volume–outcome studies which could over-state the benefit of specialisation. The direction of the causal relationship has also been debated – whether volume affects quality or whether better units and clinicians attract more patients (111, 118, 154). In an observational cohort study in the USA using tumour registry and Medicare claims data for 12,216 women with breast cancer, Nattinger found that the relationship between surgeon volume and patient outcome was due to all-cause mortality as opposed to breast cancer mortality. She found that “treatment by a high-volume surgeon was
associated with younger patient age, white race, less co-morbidity and residence in a more affluent zip code” (p.1958)(153).

Despite some concerns raised about possible publication bias and patient selection processes, there is considerable evidence that higher volume of breast cancer surgery is associated with better patient outcomes and it is this evidence that largely has informed the development of policy in this area.

2.3.6.2 Centralisation – breast cancer – UK
Griffith and Turner presented a national approach for the redesign of cancer services in the UK in 2004 (155). They identified major issues for breast cancer including: access to services and rapid access clinics, multi-disciplinary team working and pathways of care.

A number of UK studies have reported a significant relationship between surgeon caseload and patient outcomes. For example, one study (156) involving 12,861 women found improved outcomes where surgeon caseload was greater than 30 cases per year. Survival benefit was also found to be attributed to greater use of chemotherapy. However, this study was conducted over a nine year period and the authors acknowledge that treatment types, chemotherapy regimens and multidisciplinary care have changed in cancer care during that timeframe. In a study on surgeon workload and survival from breast cancer, Mikeljevic (157) found that patients treated by low case volume surgeons (<10/year) had poorer survival. The 5-year survival rate for this group was 60%, compared to 68% in the high volume (≥50/yr) group. The authors concluded that greater specialisation in addition to improved diagnostics and multidisciplinary organisation of breast cancer services, have contributed to improved survival for breast cancer patients in the UK.

In relation to surgeon specialisation in the west of Scotland, Gillis (158) found that the 5-year survival rate was 9% higher and the 10-year survival rate 8% higher for patients cared for by specialist breast surgeons, for all patient, clinical and social categories. This study found a reduction of 16% in
5-year risk of death from breast cancer in patients treated by a breast surgeon in a dedicated multidisciplinary breast clinic, compared with non-specialists. This retrospective study with 3,786 patients was adjusted for age, tumour size, socioeconomic status and nodal involvement, but not for speciality training or individual surgeon case volume. A subsequent Scottish study by Kingsmore et al. (9) found improved surgical management, lower local and regional recurrences and better survival in specialised breast units. They concluded that adequate surgical management and “adequacy and appropriateness of all treatment is the key to explaining improvements in survival outcomes” (p.1924).

Morris (159) examined the impact of the UK Calman-Hine report for breast cancer patients in Yorkshire. She found that, while the level of implementation of the Calman-Hine recommendations varied, there were improvements in processes and outcomes of care for breast cancer patients. Rouse (160) examined the case volume of breast cancer surgeons before and after the Calman-Hine report in the UK. Whilst a move towards specialisation was found, this trend had commenced prior to the publication of Calman-Hine.

Singhal et al. (161) reviewed the fast-track breast cancer referral system in Birmingham following the introduction of the 2-week rule. Of those referred, 71.7% met the referral criteria. The authors concluded that the system of categorising into urgent and non-urgent referrals should continue despite calls to move to a 2-week wait for all referrals. Since the introduction of the 2-week rule, longer waiting times for patients referred routinely have been reported in the breast clinics (162). A study in Northern Ireland examining the 2-week rule concluded that “the safest and fairest policy would be to abandon the concept of urgent referral criteria and see all patients in a timely fashion” (p.71)(162).

The Northern Ireland Health and Social Services Board has established triple-assessment clinics and multidisciplinary teams for breast cancer, in accordance with the Campbell report (163). Collaborative links have been
established between the Northern Ireland Cancer Registry (NICR) and the National Cancer Registry of Ireland (NCRI) and all-Ireland cancer reports have been jointly published, thus facilitating an all-island perspective on cancer strategy and management, as well as enabling important comparisons of cancer management and outcomes between the different health systems in the two jurisdictions.

A study on the reorganisation of the breast cancer service was carried out in Northern Ireland following the centralisation process (164). It found that breast cancer surgery was being carried out in fewer hospitals by fewer surgeons, in line with the specialisation policy, but that further research was required on patient outcomes.

A study in Northern Ireland compared breast cancer services in 2006 to 2001, following centralisation of services into Trusts, which was completed in 2001. Survival had improved (observed survival 94.3% after one year and 90.6% after two years, compared to 92.7% and 87.7% in 2001). The proportion of patients referred to oncology centres had increased from 87% in 2001 to 93% in 2006. Patients diagnosed in 2006 were diagnosed at a later stage of disease, which was attributed to stage shift, due to changes in diagnostic imaging technology. However, there was a reduction in the proportion of patients being seen within 14 days of referral and proportion of patients having surgery within 14 days of diagnosis (165).

2.3.6.3 Centralisation – breast cancer – Ireland
The National Cancer Forum published the ‘Development of Services for Symptomatic Breast Disease’ in 2000 (166), the first report of its kind in Ireland. This report outlined the recommended structure for specialist breast units, diagnostic principles, treatment principles and quality-assurance standards. The National Cancer Strategy (2006) (11) built on this report and recommended that the newly-established Health Service Executive should conduct a review of the number of centres required for the management of symptomatic breast disease. The National Quality Assurance Standards for Symptomatic Breast Disease Services were published by The Health
Information and Quality Authority (HIQA) in 2007 (167). HIQA conducted a national review of the Symptomatic Breast Disease (SBD) Services in 2009. Their report set out 18 recommendations on clinical governance, standards, audit and system assurance. These recommendations are detailed in Table 2.2 below (6).

Table 2.2: Recommendations from the HIQA review of SBD services (2010)  
Source: HIQA, 2010 (6)

<table>
<thead>
<tr>
<th>HIQA Recommendation</th>
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<tr>
<td>1 The HSE should formally establish a national network of the SBD lead clinicians with a view to identifying and addressing mutual development and support needs.</td>
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<td>2 The HSE together with the designated centres should formally evaluate the implementation of Standard Operating Procedures on a phased and prioritised basis, to ensure that they are fully embedded and being applied consistently within and between designated centres.</td>
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<td>3 The HSE should ensure that designated centres have robust governance arrangements in place, including a Service Level Agreement, to effectively manage relationships with third-party providers. Such arrangements for the outsourcing of radiation oncology should be established promptly. These should cover the requirements of the Standards and in particular quality, safety and the formalised exchange of information.</td>
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<td>4 The HSE should put in place formal national clinical governance arrangements, to ensure that the eight centres build on robust local clinical governance arrangements, in order to operate as a cohesive national clinical network for the purposes of clinical audit, sharing of good practice and problem solving.</td>
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<td>5 The HSE should put specific actions in place to ensure that its new directorate structure incorporates a clear mandate for describing and implementing the National Cancer Control Plan. In particular this should include clarity in the governance, accountability, responsibility, authority and resource allocation for the eight designated centres.</td>
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<td>6 The HSE should work with designated centres, to assess the organisational development needs of the newly-established designated centres and introduce focussed support as required.</td>
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<td>7 The HSE together with the designated centres should carry out a risk assessment to identify areas in the designated centres where service continuity and sustainability, or the ongoing meeting of Standards, could be threatened by the absence of key staff and ensure that contingency plans are in place as needed.</td>
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<td>8 The HSE should work with the designated centres, and the relevant training bodies, to develop a standardised framework for assuring the skills, education and training of staff in the centres are maintained at the necessary levels.</td>
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<td>HIQA Recommendation</td>
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The NCCP was established in 2007 to implement the recommendations of the 2006 National Cancer Strategy. While some of the smaller hospitals had already ceased breast cancer surgery, the main centralisation process into designated cancer centres took place throughout 2009. This centralisation of breast cancer surgery was completed in December 2009, facilitated by strong political support. There are now 8 designated public Symptomatic Breast Disease (SBD) Units and one satellite unit, compared to 35 public hospitals providing SBD services in Ireland in 2007 (12). Patients attending the SBD Units in Ireland are treated by cancer specialists in multidisciplinary teams. In tandem with centralisation of breast cancer surgery, GP referral guidelines with standardised referral forms for suspected cancers were developed and introduced nationally by the NCCP in 2009, with comprehensive education on their use provided for GPs (3).

2.3.7 Disadvantages of centralisation

2.3.7.1 Disadvantages of centralisation in healthcare

While the weight of evidence appears to support the benefits of healthcare centralisation, there is also evidence to the contrary. One report from Wales (168) claims that “the link between volume and outcome for many surgical procedures is often overestimated, the financial benefits do not always materialise and access is reduced with a greater burden on older and poorer people” (p.6). A Canadian study (169) on equity in health and healthcare in a decentralised context concluded that within-area variation is the most important source of income-related inequalities, while income-related inequities in health care use are mostly driven by differences between provinces. This has implications for service centralisation in Ireland as the HSE regional networks vary greatly in terms of rurality and demographics. However, the centralisation process in Ireland has been structured such that each cancer network provides services for approximately 500,000 people.

2.3.7.2 Disadvantages of cancer centralisation

Centralisation of cancer services has also been documented as having some disadvantages.
Surgical training
Greenberg and colleagues (170) outlined their concerns for the impact of centralisation of cancer surgery on surgical training, in particular for general surgery as the majority of cancer surgery is carried out by general surgeons.

Access
Posnett (90) advised that the indirect costs of centralisation “in terms of patient access should not be ignored” (p.1065) and cautions that decreased access is generally associated with a shift in costs from the NHS to patients, rather than with a reduction in use, with the exception of diagnostic or screening services.

Rurality
A number of studies highlight the potential introduction of inequity in healthcare access through centralisation of services. A study by Baird, a GP in rural Scotland (171) on the experiences of cancer patients in his area, found that a significant proportion of their time was spent travelling for care. He recommended improved transport options and mobile imaging/investigations. Patients from more remote rural areas have been found to have more advanced disease at diagnosis and poorer survival (172-174). A study from Liff et al. (174) which included patients with breast cancer, found that patients from rural areas had more advanced disease than patients from urban areas. Stevenson (175) conducted a study with health professionals in Scotland who were treating cancer patients in rural areas. Participants agreed on priorities for cancer care for people in remote and rural areas, which included fast access to diagnostic services, a link person at the local general hospital, effective multidisciplinary team-working and good transport to specialist centres. Carr-Hill et al. found that reducing access did not deter patients from seeking health care (176). However, Mungal (51) describes ‘distance decay’ as the inverse relationship between the distance of the patient from the hospital and the utilisation of services, and describes how this affects certain populations more than others, e.g.,
lower socioeconomic groups, those with poorer access to transport and older people.

Access to colorectal cancer care in cancer centres vs. non-cancer centres was assessed in Scotland. Pitchforth et al. (177) found that patients admitted to a non-cancer hospital were less likely to receive chemotherapy as part of their treatment. The authors highlight that it is “crucial that any increase in physical distance from specialised services does not exacerbate inequalities in uptake of specialist care” (p.1221).

Geographical variation

Geographic variation in breast conserving treatment is described by Nattinger (178). Following adjustment for hospital and patient characteristics, this study found significant variation in the use of breast conservation therapy, which was more commonly used in urban areas, teaching hospitals and hospitals with radiation oncology services.

Structure of services

A study in the breast clinic in a Dublin hospital in 2004 (179) concluded that rapid-access clinics are “an efficient method of dealing with symptoms suspicious of cancer” (p.2966) but that low-risk patients should be dealt with in a different forum.
2.4 Factors influencing GP referrals

Wide variation in all aspects of care has been found consistently in general practice research (15). Explanatory factors have been divided by Wilkin (15) into 3 broad categories:

- Patient variables
- Provider variables
- Healthcare system variables

He discusses the consequences of variation and questions whether some patients are being treated unnecessarily, with possible adverse consequences in terms of iatrogenic disease. He asks “are we wasting scarce hospital resources in treating patients whose problems could be dealt with at least as well in general practice?” (p.87).

The Health Belief Model (180) (181) has also been used in the area of breast cancer screening to predict attendance at screening visits (182).

Non-clinical influences on decisions in clinical practice have been studied internationally. Hajjaj (183) concluded that these non-clinical influences may be the “biggest obstacle to the reality of practicing evidence-based medicine” (p.178). Examples of these non-clinical influences included:

- Socio-economic status
- Patient expectations
- Patient wishes
- Clinician characteristics
- Private vs. public practice

Hillner et al. (118) reviewed the evidence on the effect of hospital or physician volume on the outcome of cancer care. The authors presented a framework of factors affecting treatment processes and outcome which included:

- Physician / Provider factors: specialist training/focus, case volume
- Health-system factors: multidisciplinary care, type of centre, case volume
• Patient and geographical factors: education, income, co-morbidity, location, distance from treatment

This review of relationship between volume and outcome concluded that despite weaknesses such as dated data, different methods in controlling for case mix and possible publication bias, most of the evidence supported a positive volume-outcome relationship in cancer treatment. However, the direction of the causal relationship was questioned; i.e. whether the case volume affects quality of cancer care or alternatively, that specialist units and physicians attract more patients (118).

Each of these factors will now be examined individually in relation to breast cancer referral.

2.4.1 Patient factors influencing GP referrals

2.4.1.1 Clinical / patient factors
A clinical prediction rule for breast cancer, developed and validated in Ireland in 2014, found that independent clinical predictors for breast cancer were: increasing age, breast lump, nipple changes and nipple discharge (49). This is consistent with a clinical prediction rule previously developed in the UK (184). However, it is well established that patients are referred to specialist centres for further investigation for a range of reasons and symptom presentations (46, 118, 183). Most notable among these is referral because of family history of breast cancer and referral for mastalgia (179, 185-187).

2.4.1.1.1 Family history of breast cancer
GPs have been found more likely to refer women who have a family history of breast cancer in a UK study (185). Women with a family history of breast cancer have been found to overestimate their risk of breast cancer (188) (189).

Strict adherence to referral guidelines has been recommended for referral of patients with a family history of breast cancer (190). However, an Irish study
reported that while rapid-access breast clinics experienced “cluttering by low risk women” (p.2961), 10% of those with a benign diagnosis had a significant family risk and required assessment of future risk. This cohort study of 1,429 women attending a rapid assessment breast clinic in Dublin found that 143 patients with a benign diagnosis had significant family risk, which was separate to the reason for their initial referral. Future risk was based on NICE guidelines for familial breast cancer (www.nice.org.uk).

Another Irish study on the development and validation of a clinical prediction rule for breast cancer using regression analysis found that family history was not predictive of breast cancer despite the fact that family history was present in one third of the cohort (49). This study derived a clinical prediction rule for breast cancer in women attending one of the Symptomatic Breast Units in Ireland. A total of 6,590 patients were included in the derivation cohort of this prospective study, of which 4.9% were diagnosed with cancer. However, this was a single centre study, with the validation cohort from the same centre, which can result in over-estimation of model fit.

2.4.1.1.2 Mastalgia
Mastalgia (breast pain) can affect 10-30% of women (191). Joyce et al. (186) conducted a prospective study with 14,325 patients referred to two SBD units in Ireland to identify a cohort of women who could be suitable for management by their GPs. 3,331 of these patients were referred with mastalgia as their only symptom and the incidence of breast cancer in this group was 1.2% (40 patients), all of whom were over 35 years of age. The authors recommended that women under 35 with mastalgia could be suitable for management in the primary care setting and outlined the resources in terms of time and costs of assessing these women in the hospital setting (192).

Several studies in the UK and Ireland found that the presence of breast pain was not associated with the presence of breast cancer (187) (49, 184).
Campbell et al. (187) in a prospective study with 2,064 patients referred to a breast clinic in the UK found that the presence of breast pain was not associated with the presence of cancer. In a study to develop a clinical prediction rule for breast cancer in Ireland, Galvin et al. (49) found that although almost a third of their cohort presented with mastalgia, this was not independently predictive of breast cancer. In an additional study developing a clinical prediction rule in the UK, McCowan (184) found similar results.

2.4.1.1.3 Follow-up after breast cancer
Long-term follow-up of women with early breast cancer in specialist breast units has been found not to confer a survival advantage (193, 194). The National Institute for Health and Care Excellence (NICE) in the UK recommends that routine follow-up visits for breast cancer should be limited to 2 – 3 years, as the practice has not been shown to be effective beyond this timeframe (195). This policy formed part of the strategy to increase clinic capacity for new referrals in the UK (196).

Smyth, McCaughan et al. (197) discussed the need for follow-up care and support programmes for breast cancer survivors and recommended that future research should focus on the needs of specific age-groups. A systematic review of patient and healthcare professionals’ views about cancer follow-up concluded that “GPs are thought to be unwilling and to have insufficient time and expertise to conduct follow-up” (p.248) (198).

The follow-up policy in Ireland was developed in 2010 and is more liberal than the UK, recommending discharge to primary care after five years (199). A review of follow-up processes in Ireland (200) found that 15.4% of clinic appointments were used for routine follow-up, with a third of these patients at least five years post-surgery. The study found that intensive follow-up investigations did not confer any additional survival benefit or improved quality of life.

Patients attending follow-up clinics have reported an ‘attachment’ to the specialist service and sought clarity on responsibility for care between the
specialist hospital service and the GP. Some women felt that follow-up in primary care would not provide the same level of reassurance and had expectations of long-term follow-up in the acute setting (200). McCaughan and McSorley (201) also found that attending review clinics were ‘an integral part’ of the patients’ treatment and “were necessary to help them cope with the continuous uncertainty they now experienced” (p.421). This study in Northern Ireland found that many psychosocial needs were not addressed at follow-up clinics and recommended a nurse-led follow-up service as an alternative model of service delivery. However, another Irish study found that 64% of patients were satisfied with cancer follow-up provided by their GPs (202).

Approximately half of GPs supported the NCCP policy of transfer of follow-up to general practice after five years, in a recent study with Irish GPs in 2014 (203). However, concerns were expressed about possible increased workload and medico-legal risks.

There is a concern that routine follow-up provides false reassurance and may delay patients’ presentation until their next scheduled visit (196). Lewis et al. (198) found that patients were anxious about recurrent disease and were reassured by regular follow-up. However, the authors concluded that although the service was intended to allay the patient’s anxiety, it exacerbated their need for reassurance.

2.4.1.2 Patient demographics
Non-medical factors such as gender, age, quality of life, socioeconomic status, patient wishes and expectations influence medical decision-making in general (151, 183, 204). Patient characteristics can explain much of the variation in GP referral rates (205-207).

Healthcare rationing by a patient’s insurer is described by Hillner (118) as hindering prompt access to cancer care. An editorial by Woodman (208) comments on the report by the Campaign for Effective and Rational
Treatment in the UK which outlines concerns about unequal access to treatments in the NHS. However, a study by McKinlay (209) found that patient attributes (age, race, gender, socio-economic group) had no influence on clinical decision making.

The majority of urgent referrals to breast units have been found to be younger women, despite the fact that only 1% of breast cancers were in women under 30 years (210). Zafar describes a “numerical age bias against treating older patients” (p.119)(211).

Deprivation was found to be associated with a higher referral rate in a GP study in the UK (212). While this could be due to GP referral decisions, it may also be due to co-morbidities in this population. In the USA, primary care physicians were found to be influenced by socio-economic status and changed the patient management plan accordingly, based on what they perceived was affordable and feasible for the patient, e.g., cheaper medications for those with income or insurance restrictions and “excessive care for more affluent patients” (p.56) (213-215).

The relationship between hospital admission rates and travel time has been explored in Scotland (171). The authors found that patients travelling more than one hour to the specialist cancer centre had lower admission rates and concluded that the inverse care law appeared to apply to these more remote patients. A Welsh study describes ‘the edge effect’, where rurality affects patient’s decisions to attend appointments, based on distance, accessibility and travel time (216).

McCaughan and McKenna (217) discuss how gender may influence the assessment of needs of cancer patients. Men tend to visit their GPs less frequently than women, which could delay the referral process. The authors recommend ‘gender friendly’ cancer care services, including enhanced communications with male patients.
2.4.1.3 Patient expectations

The relationship between the patient and the referring doctors can influence GP referral decisions (218). Referral rates can be influenced by the extent that GPs perceived patient pressure (219, 220). Younger GPs and GPs with higher referral rates have reported perceiving greater pressure from patients to be referred to specialist services, in particular from patients referred privately or referred for reassurance (219, 220).

The wishes and preferences of patients can influence referral and treatment decisions, even in cases where this treatment is not evidence-based or necessary (183). Patient’s wishes were found to be the most important non-medical factor related to GP referral decisions in a study with GPs and consultants in Canada (221). Doctors working in practices which are client-dependant have been found to “respond more readily to the wishes of patients” (p.184) (183).

Patient expectations, patient’s ability to assert their views and the doctor-patient relationship have been described as important non-medical factors influencing referrals (218). In a study with GPs examining attitudes to clinical guidelines, Carlsen et al. (222) found that GPs’ desire to respond to patients’ needs and requests frequently conflicted with adherence to GP guidelines, and was related to GPs’ fear of jeopardising the GP-patient relationship (223). The influence of patient expectations on referral has been documented in the area of breast disease (220, 224).

The Common Sense Model (CSM) of illness representation (225) addresses how cognitive factors can influence illness coping behaviours and outcomes. Hagger and Orbell (226) reviewed the model and concluded that “moderate-to-strong relationships exist between illness cognitions, coping behaviours and illness outcomes” (p.181).

GPs in the UK have reported a loss of autonomy since the introduction of the 2-week rule for cancer referrals and have “acknowledged an element of over-
referral under this rule due to the effects of clinical uncertainty and patient pressure” (p.82) (227).

2.4.1.4 Patient pressure
Little et al. (228) examined doctor’s perception of patient pressure and found that doctors’ perception of patient pressure was strongly associated with prescribing, examination, referrals and investigation. The doctor’s perception of patient pressure in this study was found to be a stronger predictor than the patient’s preference. The authors recommend that doctors should ask patients directly about their expectations, to avoid iatrogenesis and unnecessary use of resources.

Salmon et al. (229) conducted a study examining why primary care practitioners propose medical care to patients with medically unexplained symptoms. This study found that the medical care provided was unrelated to patient demands and that patients’ overt pressure for treatment was rare (230). There was a higher likelihood of referral for specialist review or investigations after patients elaborated on their symptoms. Salmon attributed this to the physician’s reactions to extended accounts of symptoms (229). However, an alternative interpretation is provided by Persaud (230) who proposes that when patients and doctors “depart from the reassuring moorings of physical disease” (p.993)(230) into non-physical or psychological mechanisms, the pathways are less clear and the patient may not be ready to relinquish the ‘sick role’.

The assumptions that doctors make about patient preferences may not always be accurate, with research suggesting that “pressure from patients may be stronger in the doctor’s mind than in the patient’s mind” (p.416)(231).
2.4.1.5  Patient anxiety

Patel and colleagues found that an increase in demand for access to specialist cancer services appeared to be mainly a reflection of increased media attention: “asymptomatic patients simply suffering from media-induced anxiety about breast cancer could also be appropriately reassured by their GP” (p.454) (46).

The influence of patient anxiety as well as patient expectation of referral in breast disease should be considered in the development of guidelines (224). The psychological morbidity experienced by routine, non-urgent patients, as they wait several weeks for an appointment has been documented (196). However, Campbell (187) recommends that “anxiety alone should not be an indication for referral” (p.248) and cautions that an urgent referral can actually increase anxiety and distress.

GP’s empathy for anxious patients can overrule clinical guidelines in their decision-making process (232). A considerable number of women who present to the breast clinics over-estimate their risk of breast cancer and are seeking reassurance (179, 233). An Irish study (49) recommended alternative pathways than referral, such as watchful waiting and reassurance in primary care. A systematic review and meta-analysis (234) of patients with a low pre-test probability of serious illness on the effect of diagnostic tests on anxiety and worry about illness found that diagnostic tests did little to reassure patients or decrease their anxiety. However, another Irish study by Toomey et al. (179) advised that many of these patients require assessment of future risk in addition to reassurance.

2.4.2  Provider factors influencing referrals

Wide variation in GP referral rates for suspected cancer has been documented. Baughan (235) suggested that “there are significant differences in the thresholds for individual GPs to refer symptomatic patients for further investigation” (p.703). The authors recommended further evaluation of variation in GP referral rates and the development of guidelines, referral pathways and education for GPs.
The personal characteristics of physicians can influence their decision-making process – physicians characterised as interventionists have been found to be more disease-oriented and more likely to take immediate action whilst physicians who focused more on health maintenance were more patient-oriented, willing to observe the situation (236).

McCowan et al. (184) identified several factors driving a lower referral threshold for GPs in the UK, including; patient preferences, risk aversion and ease of access to breast clinics, characteristics which are similar to the structure and trends observed in recent years in Ireland.

The Health Information and Quality Authority (HIQA) in Ireland conducted a national review of the Symptomatic Breast Disease (SBD) Services in 2009, and made several key recommendations regarding cancer referral practices, including:

“The HSE, together with the designated centres should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians” (p.75) (6).

This thesis will examine these referral processes in Ireland.

2.4.2.1 GP characteristics
Characteristics of physicians (age, race, medical specialty) can influence medical decision-making (209) (237, 238). McKinlay (209) in his results on an experiment, questioned whether economics, organisation interests and social prejudices also influence clinical decisions. In France, female physicians were found to be more likely to refer patients for breast screening than male physicians, but physicians’ age did not have an impact (239). Female doctors have also been found to have higher referral rates (237) and are more likely to be influenced by patient expectations and patient psychosocial factors (240). Chan (241) found that female primary-care
physicians made 8% more referrals than male physicians and that older physicians referred more patients to specialists, because they saw more older patients.

A review by Hajjaj et al. in 2010 (183) discussed the influences of physician gender, age and ethnicity on referral decisions, e.g., female clinicians were more likely to spend more time with their patients and be influenced by patient expectations, younger clinicians were more likely to order more tests and cultural differences influenced the intensity of treatment for end of life care. The authors found lack of uniformity in clinical decisions between physicians and between hospitals, leading to lack of equality of treatment for patients.

The gatekeeping role of the GPs is considered an efficient system to prioritise referrals to the symptomatic breast clinics (184, 206). GPs’ attitudes to their role were investigated in a UK study (242). The authors noted that GPs in the UK were taking an “increasingly restricted view of their core responsibilities” (p.143) and that this could impact on the volume of referrals to specialists. GPs have been found to support the protection of professional autonomy, in particular when guidelines appear to be economically motivated (232).

2.4.2.1.1 Beliefs about capabilities
Beliefs about capabilities has been defined as ‘acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use’ (243). Beliefs about capabilities is one of the domains in the ‘Theoretical Domains Framework’ (244), a theoretical framework developed for use in implementation research of evidence-based practice. Fourteen domains relevant to changing the behaviour of healthcare professionals were included in this framework, which can be used to assess barriers and facilitators to implementation of evidence-based practice, such as clinical guidelines (245). Examples of beliefs about capabilities include self-confidence, perceived competence, self-efficacy, beliefs, self-esteem,
empowerment and professional confidence (245). This framework is described in detail in Chapter 5 in this thesis.

GP confidence has been identified as an important factor in GP referral decisions (246). Younger doctors have been found to order more tests than older doctors, using hypothetical scenarios (209). Langley describes how referral decisions can be influenced by the GP’s uncertainty about their ability to deal with the clinical problem, previously termed ‘the uncertainty hypothesis’ by Wennberg (247).

GP’s skills and beliefs about their own capabilities can influence their use of clinical guidelines and their negotiation with patients to provide reassurance when specialist review and imaging is unnecessary (248, 249). Using psychological theory to understand factors influencing clinical behaviour can assist in designing and implementing effective interventions for behaviour change (244, 248-251).

2.4.2.1.2 Beliefs about consequences
Beliefs about consequences is also a domain in the Theoretical Domains Framework (244) and is defined as ‘Acceptance of a truth, reality or validity about outcomes of a behaviour in a given situation’ (243). Examples of beliefs about consequences include outcome expectancies and anticipated regret (245).

Doctor’s anxiety about legal implications, their tendency to take risks, and tolerance of uncertainty are important non-medical factors influencing referrals (205, 206, 218). Newton (218) found that some doctors in their study referred ‘just in case’ while others adopted watchful waiting. Bailey (252) questions whether GPs are “less willing to take risks in the face of uncertainty or because they simply experience greater uncertainty” (p.14).

Dowie modelled the referral process on the Janis and Mann conflict model, where the GP referral decision is based on the coping mechanism adopted
to deal with the uncertainties and risks involved (253-255). The GP’s “emotional burden of missing a diagnosis and fear of litigation” (p.974) (232) has been described as a reason for risk aversion, defensive practice and the subsequent increase in total referrals (256).

Beliefs about consequences can influence referral behaviour through reflective motivation (251). The GP’s beliefs about positive and negative consequences of their behaviour, e.g., the possibility of missing a cancer, can influence their referral decisions (248). Using the Theoretical Domains Framework to understand barriers and facilitators to implementation of evidence-based practice can assist in the design and implementation of effective interventions and policies to reduce the gap between evidence and practice (244, 248, 249, 251).

2.4.2.2 Knowledge and skills
The capability of the referring physician can influence referral decisions (257). The knowledge, skills and attitudes of individual practitioners can affect the quality of diagnosis in primary care (238).

The influence of knowledge and skills on GP cancer referral patterns has been widely debated in the literature. Clinicians’ knowledge, experience and confidence has been found to influence their referral decisions (218, 257). High referral rates may reflect GPs’ excessive use of expensive hospital resources or, alternatively, low referral rates may indicate that the GP is not sufficiently sensitive to the specialist care requirements of their patients (258). Wilkin (259) found a greater proportion of more experienced doctors in those with high referral rates. Similarly, in an Irish study with GPs (260), experienced GPs felt they had a higher index of suspicion for cancer. Tracy (240) found that clinicians who identified strongly with evidence-based medicine were less likely to consider contextual factors in their clinical decisions. Referral accuracy of GPs has been shown to improve following education sessions but the benefits have been found to be short-lived (261).
In study of cancer referral patterns in England, Lyratzopoulos et al. (262) found that the probability of 3 or more consultations before referral was greater in younger patients, those from ethnic minorities and women. The authors proposed that increased professional awareness of cancer symptoms may be an influencing factor for some of the more common cancers. A postal survey of GPs in the UK highlighted the knowledge and education gap within primary care in relation to urgent referrals (263). The authors concluded that these factors in part explain the variability in referral practice and recommended GP education to improve implementation of referral guidelines. A systematic review (264) of primary care innovations and patterns of referral found that interventions such as guidelines or education had an impact on clinical behaviour, but less of an impact on referral rates.

A study with GPs in Ireland (260) found that GPs would welcome further education and clinical practice guidelines on identification of early-stage cancer “with appropriate investigative pathways and referral criteria” (p.73). The Irish National Cancer Strategy (2006) (11) recommended that GPs should have comprehensive information available to enable them to assess a patient with suspicious symptoms, and to make an informed referral for specialist assessment. The National Cancer Control Programme (NCCP) developed national GP referral guidelines and standardised referral forms for Symptomatic Breast Services in 2009 which were disseminated to all GPs in April 2009 and also made available on the NCCP website. GP guidelines were developed, agreed, designed, printed and distributed by the NCCP. These breast cancer referral guidelines and referral forms were distributed to all GP in the country, to provide the following benefits (18):

- Provide accurate and clear information for GPs referring patients to the NCCP Symptomatic Breast Clinics
- Streamline the GP symptomatic breast referral process
- Improve the quality of referral information and thereby improve accuracy of triage by the hospital clinical teams
GP education was carried out by the NCCP through Continuous Medical Education (CME) groups, hospital GP study days, newsletters, conferences and other educational events. These included input from consultants and their teams from the Cancer Centres (3).

2.4.2.3 Referral practices
With the transfer of power on deciding the urgency of referrals from the specialist to the GP, Khawaja and colleagues (265) concluded that there has been a decline in the diagnostic accuracy of GPs in the UK. This was a single centre study with small sample size. An audit of referrals to a rapid-access breast clinic in the UK found that 20% of GP referrals were inappropriate (266).

Newton (218) describes referral as a social act which is a complex interaction between non-clinical and clinical factors. McKinlay (209) discussed the ‘social control’ of the clinician in the doctor-patient relationship, while remaining non-judgemental. In a study on breast cancer, Ludke (267) found that the attitude of the clinicians’ colleagues towards referring was an important factor relating to referral decisions.

The responsibility for decision-making in relation to referral priority has been discussed in the context of the UK 2-week rule (47, 162, 268, 269). Consultants have complained that the transfer of responsibility to the non-specialist compromises the consultant’s professional autonomy, while GPs are referring patients urgently due to fear of missing a cancer (269, 270).

Referral rates were higher in wealthier areas and in urban areas in a Canadian study, after adjusting for case mix. Wilkin (259) also found higher rates of referral of patients in higher social classes. Studies in England and Canada have shown higher referral rates in urban GPs closer to hospitals compared to rural GPs (271) (257). Higher referral rates have also been found in single-handed practices (212) and in smaller practices (272).
Galvin et al. (49) discuss the “trade-off between clinical utility and patient referral” (p.7), and the need to explore the optimal referral threshold while considering the risks of missing some cancers, and the corollary of unnecessary investigations. Watchful waiting and reassurance in the primary care setting is recommended as an option for consideration. However, GPs’ referral threshold to specialist breast cancer clinics is reportedly falling. McCowan et al. (184) attribute this lowering of the referral threshold to a number of factors, including:

- “Patient preferences (women being averse to reassurance without specialist assessment)
- Health professional related factors (lack of awareness concerning indicators for referral or risk aversion, missing a case of breast cancer).
- Health-system related factors (ease of availability of breast care clinic)” (p.212) (184).

Appropriate referral makes the best use of resources, skill and time (210). According to Coulter (273), each referral should be necessary, timely and effective.

The Kings Fund (238) described how a high quality referral involves several key elements:

- Necessity: patients referred when necessary
- Destination: patients referred to the most appropriate place
- Process: referral letters contain all necessary information, patients are involved in the decision making process and appropriate investigations are performed.

Studies of appropriateness of GP referral need to acknowledge the different needs and perspectives of the referring GP, the specialist and the patient (274). GPs may have unique referral thresholds based on characteristics
2.4.2.4 Clinical decision making

In investigating decision-making for hospital referrals, Jones (276) divided clinical decision-making into two areas – decision analysis and the psychological approach. Decision analysis often uses decision trees or algorithms to chart “a rational course through a diagnostic and therapeutic maze, from which outcomes are judged on the basis of their clinical efficacy and cost effectiveness” (p.93). The psychological approach “seeks to analyse the thought processes occurring in the mind of the decision-maker in an attempt to provide a description of the cognitive events leading to a clinical decision” (p.93).

Bayes’ theorem of diagnostic reasoning, published by Thomas Bayes (an English clergyman and mathematician) in 1763 is a mathematical formula used for calculating conditional probabilities. Decision-making is made in the light of external evidence and prior plausibility of hypothesis (277-281). The rule is defined as “a mathematical relationship between conditional probabilities that relates the posterior probability of parameter values, on the one hand, to the probability of the data given the parameter values, and the prior probability of the parameter values, on the other hand” (p.293) (279). Applying Bayes’ theorem, Summerton (280) examined the likelihood of disease in identical patients presenting in primary and in secondary care. He found that the probability of disease in secondary care is higher, as the interpretation of the clinical presentation should depend on the prior probability of disease (281).

McKinlay (282) investigated the non-medical influences on medical decision-making and found that variability in decision-making was “not entirely accounted for by strictly rational Bayesian inference” (p.769). The authors found that non-medical factors such as patient’s age, gender and health insurance also had significant influences on medical decisions. However, the use of Bayesian reasoning has raised the possibility that “acting as a
good Bayesian makes for a bad diagnostician” (p.104)(209), if physicians are not considering patient attributes in their medical decision-making. Clinicians’ clinical diagnostic decision-making may differ depending on whether it is based on Bayes’ theorem or clinical intuition (278). The authors suggest that clinical reasoning in experienced physicians is linked to pattern recognition. A Bayesian approach is more likely to be used by clinicians trained in evidence-based medicine (283). Alternatively, medical decision-making can be viewed as a social construct, with factors other than biomedical factors influencing decision-making, which cannot be explained purely by Bayesian inference (282).

Clinical decisions involve making choices to maximise effectiveness and minimise harm (284). The role of the GP involves decision making to marginalise danger, and maximise clinical outcomes and patient safety (75, 238), using mental shortcuts to make reasonable decisions (285).

Evidence based medicine (EBM) was developed in the 1990s to promote evidence based decision making in health care (286) (287) and is defined as “the conscious, explicit and judicious use of current best evidence in making decisions about the case of individual patients” (p.71)(288). However, guidelines and rule-based reasoning may not accommodate the complexity of clinical decision making, patient values and patient preferences (289) (290) (291). An alternative approach using epistemological responsibility has been proposed, where the doctor is accountable for their clinical decisions (289). Van Baalen (289) proposed in 2015 that doctors should take responsibility for their clinical decisions, using a more subjective approach, instead of deferring responsibility to clinical guidelines.

The nature of presentation in primary care can make clinical decision making a challenge in the absence of diagnostic tests and medically unexplained symptoms (238). “The diagnostic process in general practice is more often a combination of shortcuts, loops and dead ends than a straight line from presentation to diagnosis” (p.12) (238). A summary of the diagnostic strategies used in consultations was presented by Heneghan et al. (285) as shown in Table 2.3 below.
Table 2.3: Diagnostic strategies in primary care

<table>
<thead>
<tr>
<th>Diagnostic strategies in primary care</th>
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<tbody>
<tr>
<td><strong>Stage 1: Initiation of diagnostic hypotheses</strong></td>
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<tr>
<td>• ‘Spot’ diagnoses (unconscious, almost instantaneous, pattern recognition)</td>
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<tr>
<td>• Self-labelling (patient tells you what they perceive to be the diagnosis)</td>
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<tr>
<td>• Presenting complaint (most often used)</td>
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<tr>
<td>• Pattern-recognition trigger (elements in the history or examination or both).</td>
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<tr>
<td><strong>Stage 2: Refinement of the diagnostic hypotheses</strong></td>
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<tr>
<td>• Restricted rule-out (depends on learning the most common cause of the presenting problem and a shortlist of more serious diagnoses to rule out)</td>
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<tr>
<td>• Step-wise refinement (based on either the anatomical location of the problem or the putative underlying pathological process)</td>
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<tr>
<td>• Probability-based reasoning (specific but probably imperfect use of symptoms, signs, and tests to rule in or rule out a diagnosis)</td>
</tr>
<tr>
<td>• Pattern recognition fit (most often used – symptoms and signs are compared with previous patterns or cases and a disease recognised)</td>
</tr>
<tr>
<td>• Clinical prediction rule (formal version of pattern recognition fit, based on a widely validated series of similar cases).</td>
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<tr>
<td><strong>Stage 3: Defining the final diagnosis</strong></td>
</tr>
<tr>
<td>• Known diagnosis (&lt;50 per cent cases, sufficient level of certainty to start treatment or rule out serious disease)</td>
</tr>
<tr>
<td>• Ordering further tests (to rule in or rule out a disease, or if no obvious pattern of disease)</td>
</tr>
<tr>
<td>• Test of treatment (response to treatment used to refute or confirm diagnosis)</td>
</tr>
<tr>
<td>• Test of time</td>
</tr>
<tr>
<td>• No diagnostic label applied (strategies could include re-calling patient for further review, using an exploratory investigation, sharing uncertainty with patient, and referral for second opinion).</td>
</tr>
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Clinical decision analysis was developed to apply the concept of decision analysis to healthcare, using methodologies for decision making such as
Bayes theorem, decision tree design, receiver-operating-characteristics curves, sensitivity analysis and utilities assessment (286). However, clinical decision analysis has been shown to be time consuming in a busy clinical setting and factors such as patient preference and cost implications may not be accurately reflected (292) (286).

There is so much information available to a decision maker, it is frequently not possible to process; a situation known as ‘bounded rationality’ and clinicians rely on truncated information or evidence to make a good decision, a term known as ‘satisficing’ (293). Bate et al. (293) described two key processes used in dual process theory of decision making; system 1 which uses quick intuitive decisions and system 2 which uses an analytical approach.

System 1 is used unconsciously, based on experience, repetition and patterns (293). It is considered independent of language and general intelligence and based on the ability to recognise patterns (294). However, there is a concern that clinicians may rely on this pattern of knowledge without activating the system 2 analytic approach to check for new innovations or evidence (291), termed “dysrationalia over-ride” (p.617)(293). Hazard alerts on medication prescribing systems have been used to alert clinicians to this risk (293). System 2 involves a rational analysis of the available evidence, involving the mental and cognitive faculties associated with logical thinking and is often rule-based (293) (294) (291). However, this approach can be time consuming and not always feasible in a clinical environment such as a GP practice.

Marcum (294) developed a model of clinical reasoning which integrates both the dual process theory of cognition (system 1 and system 2) with metacognition theory which feeds back to reinforce or alter the cognitive process. The benefits of this process are to enhance accuracy of future decisions termed “the paradoxical relationship between experience and expertise” by Marcum (p.954) (294).

Ingemansson (291) conducted focus groups with GPs in Sweden in 2014 to explore how GPs use practice guidelines in their decision making process.
This study found that GP decision making involves both intuition and analytic thinking (dual process theory). Key influencing factors included GPs own experiences, access to short trustworthy guidelines and feedback through peer learning and collaboration. However, GPs who participated in this study felt controlled by strict practice guidelines and disrespected as specialists. This has implications for the uptake and adherence to GP referral guidelines here in Ireland.

**Hypothetico-deductive model**

The hypothetico-deductive model is a form of clinical reasoning described by Elstein (295). Elstein found that clinicians formulate a number of hypotheses to resolve medical problems and make a diagnosis. These hypotheses are then used to obtain additional evidence to ultimately make a diagnosis and plan treatment (294).

The information processing model is common in medical decision making and uses the hypothetico-deductive approach (296). This approach can incorporate decision trees to assist decision making. However, the use of decision trees may be flawed if there are inaccurate probabilities in its structure (296). The hypothetico-deductive model is also limited by its inability to incorporate implicit cues (294) and has been criticised for its lack of consideration of context, intuition, experiential learning, affect and emotion (297).

**Intuitive-humanist model**

The intuitive-humanist model is based on intuition, gained from knowledge and experience. Recognition of cues or pattern recognition are characteristics of clinical decision making using intuition. The pattern recognition model has been proposed as a more holistic model than the hypothetico-deductive model, but critics claim that this “trivializes the complex cognitive activities” (p.956) (294) involved in clinical reasoning and lacks scientific reasoning (296). Seidel (298) discusses the tension between
intuition and evidence based medicine and recommends additional research on the relationship between literature reviews and intuition.

Clinical prediction rules

Clinical prediction rules are “mathematical tools that are intended to guide clinicians in their everyday decision making” (p.8312) (299) and provide a mechanism of implementing evidence based medicine (49) (184). Clinical prediction rules have several advantages over human decision making, including multi-factorial statistical models, consistency of results and accuracy (299). Clinical prediction rules have been criticised for their lack of universal high quality (238), not being user-friendly and the fact that there are a multitude of models available (299). However, initiatives such as the Standards for Reporting of Diagnostic accuracy studies (STARD) (300) aim to improve this. In a review of clinical prediction rules, Toll et al. (301) found that despite the growing number of publications on clinical prediction rules, very few described validation or clinical impact. A clinical prediction rule for breast cancer was developed and validated in Ireland in 2014 (49) in response to the exponential rise in breast referrals to SBD units. However the uptake and use of this CPR by GPs in Ireland has not yet been assessed.

Mindlines

Mindlines are defined as “collectively reinforced, internalised tacit guidelines, which were informed by brief reading, but mainly by their interactions with each other and with opinion leaders, patients and pharmaceutical representatives and by other sources of largely tacit knowledge that built on their early training and their own and their colleagues experience” (p.1013) (302). Gabbay (302) reported that clinicians make medical decisions based on mindlines rather than formal written guidelines. A systematic review of mindlines (290) in 2015 found that mindlines accommodate context, which may be absent in conventional evidence based medicine.
Shared decision making

Shared decision making, involving the patient in decisions about their care (293) enables informed choices by patients (238). Shared decision making provides an opportunity for patients to become engaged in their own health (303), where patients and clinicians share the responsibility of clinical decision making (304). This compares to the paternalistic model (305) where the patient has little input and the informed model where the patient is the sole decision maker (304).

In the US, shared decision making is also helping to control the care cost (303). Legare et al. (303) described three essential elements of shared decision making:

- Recognising and that a decision is required
- Understanding the best available evidence
- Incorporating patient preferences and values

However, it was recognised that in order to adopt a shared decision making approach, clinicians required additional training, patients required access to the available evidence in suitable and accessible format and GPs required more time with their patients (303) (306) (307). Elwyn et al. (306) highlight that there is currently a lack of guidance on how to accomplish shared decision making in routine clinical practice.

Shared decision making is most appropriately used in areas of uncertainty (308), when there are several clinical options to choose from, or when the evidence is scant or conflicting (303). Time constraints have been identified by clinicians as a barrier to shared decision making (303) (307). Clinical guidelines have been criticised for overlooking the importance of shared decision making, and for not outlining all the available clinical options (303). The role which patients wish to play in decision making about their own health has not been extensively researched. Thompson (309) conducted a study with patients in England and found that the level to which individual patients wished to be involved in clinical decision making varied depending
on the type of illness, seriousness of the disease, and their relationship with health professionals.

Can we afford shared decision making? A study in the UK (307) questioned whether GPs could manage the dual responsibility of individual patient care and equitable use of NHS resources. This may pose a conflict to practitioners who are employed by the state and have a responsibility of a gatekeeping role. However GPs in Ireland are independent practitioners running their own business and are not responsible for managing the scarce resources in secondary care.

The models which relate most closely to GPs referral include evidence based medicine, shared decision making and the intuitive-humanist model. GPs must assess the clinical signs and symptoms, appraise the relevant evidence, discuss options with the patient and make a decision based on the clinical factors, research evidence, their own experience and contextual factors which are unique for each patient.

Biases in clinical decision making

Bate et al. (293) describes cognitive and affective biases in decision making, including personal problems, stress and fatigue. Cognitive bias is “a pattern of deviation in judgement” (p.618)(293). Bate et al. outlined some of the cognitive biases in clinical practice, which are outlined in Table 2.4 below.
Table 2.4: Cognitive biases in clinical practice

<table>
<thead>
<tr>
<th>Cognitive bias</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Anchoring bias</td>
<td>Undue emphasis is given to an early salient feature in a consultation</td>
</tr>
<tr>
<td>Ascertainment bias</td>
<td>Thinking shaped by prior expectation</td>
</tr>
<tr>
<td>Availability bias</td>
<td>Recent experience dominates evidence</td>
</tr>
<tr>
<td>Bandwagon effect</td>
<td>‘We do it this way here’, whatever anyone else says or whatever the data say</td>
</tr>
<tr>
<td>Omission bias</td>
<td>Tendency to inaction, as events that occur due to natural disease progression, are preferred to those due to action of physicians</td>
</tr>
<tr>
<td>Sutton’s slip</td>
<td>Going for the obvious diagnosis</td>
</tr>
<tr>
<td>Gambler’s fallacy</td>
<td>The tendency to think that a run of diagnosis means the sequence cannot continue, rather than taking each case on its merits</td>
</tr>
<tr>
<td>Search satisficing</td>
<td>Having found one diagnosis, other co-existing conditions are not detected</td>
</tr>
<tr>
<td>Vertical line failure</td>
<td>Routine repetitive tasks lead to thinking in silos</td>
</tr>
<tr>
<td>Blind spot bias</td>
<td>‘Other people are susceptible to these biases but I am not’</td>
</tr>
</tbody>
</table>

Source: Bate et al. (2012). How clinical decisions are made (293)

In summary, the literature on clinical decision making can be divided into 2 approaches.

One system evaluates probabilities through information processing and rule based systems such as referral guidelines and decision support tools while the other involves negotiation between the GP, patient and secondary care providers as part of a social process of diagnosis and referral through communications and shared decision making (238). Current quality and evaluation measures tend to focus on the first approach, measuring compliance with evidence.
2.4.2.5 GP referral guidelines

GP referral guidelines have been introduced in many areas to manage referrals from primary to secondary care. Guidelines can improve the standardisation and consistency of care, ensuring that the patient receives the same treatment regardless of location or clinician (310). The Institute of Medicine has defined clinical practice guidelines as “systematically developed recommendations about some or all aspects of decision-making for a particular condition or clinical situation” (311) (p.164). Clinical guidelines, particularly evidence-based guidelines, can improve the quality of clinical decisions and highlight ineffective practice (310). In the context of cancer, clinical practice guidelines were found to improve the management and outcomes of patients with cancer by bridging the gap between research results and clinical practice (312). In a systematic review of referral guidelines from primary to secondary care (313), Clarke and colleagues found that, while guidelines can improve appropriateness of care, they did not find strong evidence of improved practitioner knowledge.

A BMJ paper on potential benefits, limitations and harm of clinical guidelines concluded that “clinical guidelines can promote distributive justice, advocating better delivery of services to those in need” (310) (p.527).

In the UK, the ‘2-week wait rule’ for cancer referrals from primary to secondary care became effective in December 2000 for all cancers treated by the National Health Service, whereby urgent cancer referrals were guaranteed to be seen within 2 weeks. The aim of this initiative was to improve access to specialist services, thus facilitating early diagnosis and treatment (5). Reduced waiting times for urgent referrals have been reported in the UK since this rule was introduced (227). However, other UK studies report unchanged waiting times for urgent referrals, with increased waiting times for non-urgent referrals (162, 265, 314).
Potter and colleagues (5) questioned the scientific foundation of the 2-week rule: “the poor predictive value of fast-track referral guidelines, together with poor adherence in primary care has flooded one-stop clinics with large numbers of inappropriate referrals” (p.288). This had been predicted several years earlier by Fentiman (315) who warned that “if GPs do not act as a screen but as an open gateway, there is a risk that specialist one-stop clinics will become over-run by the worried well” (p.1251). He recommended the establishment of nurse-led clinics for those with a family history of cancer, for example, instead of referral to Symptomatic Breast Units.

A study of urgent GP referrals by Allgar et al. (256) suggested that the increase in total referrals was caused by “GPs gaming the system by referring patients in order to get them seen within 2 weeks and GPs being anxious at missing a diagnosis” (p.361). They concluded that “the predictive power of the referral guidelines as a marker for cancer diagnosis is low, resulting in significant numbers of patients who are urgently referred but do not have cancer” (p.361). This is consistent with a study from Jones and colleagues, who found the predictive values of symptoms suggestive of cancer in primary care to be poorly defined (316).

The breast clinics in the UK have become victims of their own success (46). Patel and colleagues found that an increase in demand for access to specialist cancer services appeared to be a reflection mainly of increased media attention: “asymptomatic patients simply suffering from media-induced anxiety about breast cancer could also be appropriately reassured by their GP” (p.454)(46).

A review of the ‘2-week rule’ by Hanna and colleagues concluded that common concerns included the low yield of malignancy, quality of referral guidelines and adherence to guidelines (317). The development and validation of a clinical prediction rule for breast cancer in Scotland (184) found that the 2-week rule for cancer referrals in the UK had not improved the diagnostic process. They suggest that “the poor performance of breast cancer referral guidance is attributed to the limited diagnostic value of the
clinical criteria on which the guidelines are based” (p.205). Their clinical prediction held that “increasing age, presence of a discrete lump, presence of a lump ≥2cm in size, thickening of the breast, lymphadenopathy and the presence of a lump tethered to the skin or chest wall, all independently increase the probability of a woman having breast cancer” (p.209).

Clinical guidelines may increase GP referrals to secondary care by reducing “their willingness to tolerate uncertainty and manage problems in primary care” (p.462)(206). O’Donnell recommends focusing on increasing the number of appropriate referrals through joint working between hospitals and GPs. A study of GPs’ attitudes to the use of guidelines (223) concluded that the process for development of GP referral guidelines should be transparent and should be explicit in relation to the evidence base and any economic considerations, as GPs’ adherence to guidelines can be influenced by whether they consider the guidelines trustworthy. In a qualitative study by Cornford et al. (269), clinicians reported that the 2-week rule in the UK compromised their professional autonomy. This was a small study with 20 participants including nine GPs and eleven secondary care providers.

The report of the UK National Audit Office ‘Progress in improving cancer services and outcomes in England’ (2015) reviewed the progress of the UK Cancer Strategy ‘Improving outcomes – Strategy for cancer’ (2011) (144). Progress was reported in improving cancer services but it found that significant variations in outcomes and access to services persisted across England. An increase of 51% in urgent GP referrals for suspected cancer was reported between 2009-10 and 2013-14. The report outlined the commitment to the current commissioning process established in 2012 for certain cancer services and the roles of clinical commissioning groups, strategic clinical networks and the care quality commission. However, concerns were expressed about the lack of national oversight of cancer commissioning across a range of complex treatment pathways. This report also described the plans announced by NHS England in January 2015 to set up a taskforce to develop a 5-year action plan for cancer services by summer 2015, with the aim of improving survival rates (318).
2.4.2.5.1 Evaluation of referral guidelines

In a systematic review of referral guidelines from primary to secondary care in 2010, Clarke and colleagues found that guidelines can improve appropriateness of care by improving diagnostics and treatment prior to referral, but did not find strong evidence of additional benefits such as practitioner knowledge or health outcomes (313). The authors advised that referral guidelines on their own are unlikely to improve referrals and concluded that high-quality evaluations of referral guidelines were still needed. None of the 24 eligible studies in this review included guidelines for cancer. The authors acknowledged possible publication bias in the included studies, they noted that all included studies were from high income countries and there were disparities in treatment interventions, definitions and outcome measures between studies, which hindered the formulation of overall quantitative conclusions.

Gagliardi et al. (319) conducted a systematic review of guideline implementation and found that education and print material were most commonly used for dissemination. Interventions designed to address specific barriers to implementation are more likely to improve professional practice (320).

A Cochrane systematic review in 2008 (321) of interventions to improve outpatient referrals from primary care to secondary care, found that strategies that were effective included dissemination of guidelines with structured referral sheets and involvement of consultants in educational activities. This is consistent with an earlier systematic review on interventions to improve professional practice (322) which found that dissemination alone was not effective and that outreach visits or local opinion leaders were useful.
An evaluation of GP referrals to breast clinics in Wales (323) found that the UK national guidelines could be useful in the targeting of resources towards high-risk urgent referrals. Cabana (324) cited lack of agreement with existing guidelines, differences in interpretation of the evidence, loss of clinician autonomy and belief that the risks to the patient outweighed the benefits as reasons for non-adherence to clinical practice guidelines.

A 3-month single-centre prospective study was conducted in the Symptomatic Breast Unit in Galway University Hospital in 2010 to evaluate the efficacy of the breast cancer referral guidelines at identifying patients with breast cancer. The study found that the NCCP referral criteria were 91% sensitive for triaging breast cancer patients into the correct (urgent) category, with a specificity of 69%. Neary and colleagues concluded in this study that “the NCCP guidelines are accurate and should be considered the gold-standard for referral to the symptomatic breast service” (p.39) (325), as these guidelines were 91% sensitive for triaging patients with breast cancer into the correct (urgent) category. The authors recommended the NCCP referral guideline as a tool for GPs to prioritise patients for referral to SBD units.

Hospital consultants, hospital managers and referring GPs may have different opinions on what constitutes an appropriate referral. An audit of compliance with cancer guidelines and referrals in 516 GP practices in Scotland (235) found that compliance with referral guidelines was 91%. They found wide variation in GP referral rates for suspected cancer and suggest that “there are significant differences in the thresholds for individual GPs to refer symptomatic patients for further investigation” (p.703).

2.4.3 Health service factors
2.4.3.1 Environmental context and resources
A distinction has been made between medical appropriateness and societal decisions about what our health services can afford (274). In a needs assessment for early diagnosis of cancer with GPs in Ireland, Daly and Collins (260) found that poor communications between GPs and hospital
services, and lack of equity in access to hospital services, were barriers to the early detection of cancer in primary care. A Scottish study with GPs (326) found similar results and recommended improved communication between primary and secondary care and the development of referral guidelines.

In a GP study by the King’s Fund (327) in the UK, access, geography and transport were key considerations in the referral process.

In a study on breast cancer, Ludke (267) found that the most important factor relating to referral decisions was quality of patient management in the hospital, i.e., the type and quality of medical care the patient would receive, as determined by the referring clinician.

2.4.4 Other factors influencing referrals

2.4.4.1 Media
Mass media interventions have been shown in a Cochrane review to be effective in promoting health service utilisation (328) but the duration of effect was uncertain. The methodological quality of the 20 included studies was reported to be variable, with nine studies using inappropriate statistical tests (328). Mass media has been recommended to “encourage the use of effective services and discourage those of unproved effectiveness” (p.7) (328).

Patel and colleagues found that an increase in demand for access to specialist cancer services in the UK appeared to be mainly a reflection of increased media attention, resulting in the breast clinics becoming victims of their own success (46).

GPs have reported over-referring due to media pressure (5, 227). Elstein and Schwartz (278) described how diseases that get considerable media coverage are often thought of as occurring more often than they actually do. The authors also suggest that the probability of more serious diseases can be overestimated because the treating clinician would hate to miss one. They conclude that even with the introduction of clinical decision support, expert
clinical judgement is still required. RoshanLall describes how media coverage, education and screening have increased the GP workload by increasing the awareness of breast disease in the population (210).

In the UK, the effect of the singer Kylie Minogue’s breast cancer diagnosis on breast clinic referrals has been studied. There was a significant increase (61%) in referrals in the month after Kylie’s diagnosis, but no increase in breast cancers detected (329). Twine et al. concluded that “the media played on the susceptibility of young women to breast cancer” (p.669). Concerns were expressed about the increased exposure to radiation from diagnostic imaging and also an increase in anxiety and cancer phobia. Celebrity illness in relation to breast cancer was also seen in the 1980s with the US Presidential wives Betty Ford and Nancy Reagan in the USA (330). More recently, ‘the Angelina Jolie effect’ was seen following media coverage of the decision of the actress Angelina Jolie to undergo genetic testing for the BRCA1 gene and subsequently undergo risk-reducing mastectomy. Referrals to family history and genetic services increased by more than 2.5-fold in the UK (331) and a 3-fold increase was reported in Australia during this period (332).

Cultural changes, such as increased awareness of breast cancer and patient assertiveness are seen as important contextual factors in referrals for suspected breast cancers (269). Patient information leaflets and media messages have been criticised for encouraging younger women to seek specialist referral, while the incidence of breast cancer in younger women is low (210).

The role of education in Irish public service broadcasting has been reviewed by Grummell (333). She discusses the balancing act between the public service and commercial elements and the shift in broadcasting from the cultural and social needs of the population to the needs of the population as consumers. She describes how the “institutional demands of the political and economic systems” (p.5) have shaped the contribution of education in Irish broadcasting and the lack of attention to the civic role of broadcasting.
2.4.4.2 Seasonal variation

A Swedish study examining seasonal variation in cancer diagnosis (334) found that the number of new breast cancer cases diagnosed were lower during the summer months and in December, with the highest mean number of cases reported in November. The decrease in June and July was attributed to reduced activity in mammography screening programmes in the summer months and may also be due to patient delay during vacation time. Similarly, it was suggested in a study in Singapore (335) that self-referrals fell during the New Year festivities (December – February). The Cardiff Breast Group (43) noted some seasonal variation in their breast cancer referrals, with peaks observed in the spring and autumn.

Hormonal variation across the seasons has been examined in breast cancer (336, 337). A study in New Zealand examined the season in which breast cancers were detected as a predictor of survival. The study found that women who detected their breast cancer in spring/summer (which is September – February in New Zealand) had significantly longer survival and suggested that this may reflect seasonal changes in hormone-dependent growth of the tumour (338).

2.4.4.3 Social influences

Social influences include societal decisions and prejudices. There is a distinction between medical appropriateness and societal decisions about what our health services can afford (274). Variation in medical decision-making may also “reflect economic and organizational interests and social prejudices” (p.94) (209).

Where medical decisions are made based on social attributes, these attributes “should reflect the social patterning of disease” (p.93) (209). It is the responsibility of breast cancer charities to ensure that breast cancer awareness is focussed on the appropriate age group “without causing distress to younger women” (p.263) (339).
Medical decision-making can be viewed from two perspectives; a prescriptive view based on probability and rates, and a descriptive view highlighting the influence of unrelated social factors, i.e., consideration of “who the patient is as much as what the patient has” (p.769) (282).

2.5 Conclusion
The literature describes the burden of cancer worldwide and in Ireland. Cancer incidence in Ireland is higher than the EU average, with mortality lower than the EU average.

The epidemiology of breast cancer outlines the risk factors and prognosis of this disease. The National Cancer Registry predicts that breast cancer in Ireland will increase by approximately 130% between 2010 and 2040 signifying the need for service planning, early detection and prevention.

The evidence for centralisation and specialisation of cancer services has underpinned cancer policy and organisational change in many countries, including Ireland.

The literature outlines many factors influencing GP referrals to specialist care, including social factors, clinical factors, GP factors and health system factors, which consist of both medical and non-medical reasons.

Some of the more recent literature e.g. personal and public involvement (PPI) and implementation science has not yet been implemented and evaluated widely and evidence of its efficacy is lacking. Other literature, such as the health belief model is quite old. There were gaps in the literature in relation to national reorganisation of cancer services, such as in Ireland. Many of the studies investigating cancer services were single-site or regional studies or single method (qualitative or qualitative) studies. While considerable research has been undertaken with GPs in the UK regarding cancer referrals, the primary care structure in the UK has little application in a health system like our own.
The combination of evidence based healthcare and patient values needs to be considered by clinicians. Shared decision making also needs to be debated alongside value for money and the possible iatrogenic side effects of unnecessary treatment. The literature outlines many approaches to GP referral, however, the context is not always comparable to Ireland e.g. GPs in the UK are employed by the NHS and the US does not have a population based national breast screening service.

GP referrals from primary to secondary care will be explored in this thesis in the context of symptomatic breast services in Ireland.

This literature review highlighted that there is a gap in the evidence relating to national reorganisation of cancer services and referral patterns in a similar health care system to Ireland using a mixed methods approach. There is also a lack of research with GPs in Ireland using a random sample regarding factors influencing their referrals. This gap analysis led to the choice of methods for this thesis which are discussed in detail in Chapter 6.

Chapter 3 will outline the relevant health-care structures, strategies and systems in Ireland and provide a summary of previous research and recent policy developments in the area of breast cancer referral patterns.
Chapter 3: Breast Cancer Services:  
The Irish Context

3.1 Introduction
The healthcare system in Ireland is delivered through primary care services in the community (GPs and primary care teams) and secondary care in acute hospitals (both public and private). The Health Service Executive (HSE) is responsible for the public health services and contracts certain services from independent contractors, such as GPs. The organisation of health services in Ireland has gone through a number of reconfigurations in recent decades, moving from eight autonomous health boards to a national health system under the HSE. The HSE, with four administrative regions, was established by the Health Act, 2004, and came into official operation on January 1st, 2005. These configurations are shown in figure 3.1 below.

![Figure 3.1: Health service reconfiguration in Ireland
Health Boards 1-8
HSE regions A-D](image)
Further hospital reconfiguration is currently underway, with the establishment of six hospital groups and a paediatric group within the HSE in 2013 and 2014.

Cancer services in Ireland have also undergone significant change and development since the publication of the first National Cancer Strategy in Ireland in 1996 (146) and the second National Cancer Strategy in 2006 (11). Prior to the first cancer strategy, there had been limited targeted investment in cancer services in Ireland. Cancer services, along with the other health services in Ireland, were originally delivered by the eight autonomous health boards, each to be self-sufficient for the needs of its population. Currently, delivery of cancer services is the responsibility of the HSE, through the National Cancer Control Programme (NCCP), based on the recommendations of the 2006 National Cancer Strategy. Prior to the 2006 strategy, there was a lack of national evidence-based guidelines, standards, quality indicators or quality assurance processes for cancer services. The Eurocare-4 report on cancer outcomes at that time (2000-2002) also showed that Ireland lagged behind other European countries in relation to cancer outcomes (25). This fragmented system of cancer service delivery provided the opportunity for the NCCP to standardise cancer care across the country.

The National Cancer Control Programme was established to implement a comprehensive cancer control programme in Ireland, based on the recommendations of the 2006 cancer strategy. The NCCP designated four geographical cancer networks and eight designated cancer centres to deliver a full range of cancer services. The essential components of the designated cancer centres included:

- Each cancer centre to serve a population at least 500,000
- Rare and complex cancers to be treated by a subset of the eight cancer centres, consistent with incidence of disease and evidence based practice
- Multidisciplinary teams (340)
The Kingdon model of agenda setting (64) can be effectively used to describe the accelerated progress of cancer control in Ireland. The Kingdon model describes how a policy window can emerge when 3 streams collide - the problem stream, the policy stream and the political stream. A policy window in cancer services in Ireland resulted from the convergence of the problem stream, the policy stream and the political stream in 2006. The problem stream was highlighted through a series of high-profile cancer cases of missed diagnosis, delayed diagnosis and unopened GP referrals in hospitals in Ireland (62, 63, 341). The 2006 Cancer Strategy (11) constituted the policy stream and the strong support from the Minister for Health and Government at the time (Mary Harney TD) provided the political stream. This Kingdon model of agenda setting provided optimal opportunity for development of cancer services in Ireland.

3.2 Healthcare structures, strategies and systems
A series of reports and strategy documents have been published on the structure and integration of health services in Ireland, which have been described in the literature review chapter (Chapter 2). While these reports are not focused on cancer services specifically, they formed the basis for the planning of specialist services and integration of primary and secondary care. The key strategy documents which influenced the healthcare system in Ireland were outlined in Chapter 2 and include the following:

The Fitzgerald report in 1968 (91) initiated the debate about hospital location in Ireland.

- The first national health strategy ‘Shaping a Healthier Future’ in 1994 (93) and the second national health strategy ‘Quality and Fairness – A Health System for You’ in 2001 (94) built on the previous recommendations made in the Fitzgerald report of establishing hospital networks.
• The Primary Care Strategy ‘Primary Care: a new direction’ (13), also in 2001, outlined plans to strengthen the primary care system through establishment of primary care teams.

• The Value for Money report (2001) (95) and the Prospectus report (2003) (100) also endorsed the model of hospital networks to ensure high quality services and value for money.

• The Hanly report on Medical Staffing (2003) (97) outlined the benefits of centralising services, with specialist staffing, in terms of benefits for patients and cost-effectiveness.

In tandem with the numerous reports on developing and improving the quality of Irish healthcare in general, there were also focussed developments in relation to cancer care, resulting in the development of specific cancer strategy documents and reports.

3.3 Cancer strategy and development

While cancer services were highlighted in broader health strategies in Ireland such as the national health strategy in 1994 (93), the first national strategy focussing exclusively on cancer services in Ireland was published in 1996.

**National Cancer Strategy (DoH 1996)**

The first National Health Strategy ‘Shaping a Healthier Future’ (1994) (93) prioritised areas of premature mortality in Ireland, including cancer, cardiovascular disease and accidents, which led to the development of specific national strategies in these areas (146, 342, 343).

The first national cancer strategy in Ireland ‘Cancer services in Ireland: A National Strategy’ (146) was published in 1996 and aimed to review the existing range of preventive, treatment and palliative services relating to cancer in Ireland, and to set out a plan for their further development and improvement, including staffing. Specialist cancer posts received
government funding through this strategy, including 85 consultant posts and 245 clinical nurse specialists. The target for this cancer strategy was to reduce the death rate from cancer in the under-65 age group by 15% within 10 years. This first national cancer strategy was evaluated in 2003 and the evaluation concluded that the target of reducing the death rate from cancer in the under-65 age group by 15% had been achieved. The report recommended the development of a second cancer strategy, focusing on reconfiguration of existing services, enhanced coordination, redefining of work practices and service management (16).

Second National Cancer Strategy (DoH 2006)
The second National Cancer Strategy in 2006 (11) reported on the improvement in capacity resulting from the first cancer strategy. However, the delivery of cancer services was still fragmented and spread across 35 hospitals. Many services were provided in small volumes, without a full multidisciplinary team approach, which was not in accordance with international best practice. The strategy built on the second national health strategy ‘Quality and Fairness – A Health System for You’ (2001) (94) and the primary care strategy ‘Primary Care: a new direction’ (2001) (13). Key recommendations were outlined in relation to centralisation and standardisation of cancer services as follows (see Appendix C for the full list of recommendations from the 2006 cancer strategy):

- Recommendation 12: the HSE should put in place arrangements to monitor inequalities in cancer risks, cancer occurrence, cancer services and cancer outcomes.
- Recommendation 19: opportunistic testing of asymptomatic individuals for cancer is not recommended.
- Recommendation 20: the HSE should develop specific programmes that promote early detection of cancer.
- Recommendation 21: All cancer care should be delivered through a national system of four managed cancer control networks, each serving a population of approximately one million people.
• Recommendation 23: A lead clinician for each cancer centre should be appointed. In addition a clinician should be appointed to lead the development of cancer care pathways for each major site-specific cancer (e.g., breast cancer) in partnership with all stakeholders in the network.

• Recommendation 24: The HSE should develop care pathways for cancer care to link primary care services, hospital services and other relevant services.

• Recommendation 25: Improved cancer information services should be available to primary care.

• Recommendation 31: Patients should have their diagnosis established and their treatment planned by site-specific multidisciplinary teams.

• Recommendation 32: The HSE should conduct a review of the number of centres required for the management of symptomatic breast disease to bring them into line with designated cancer centres.

• Recommendation 41: The Health Information and Quality Authority (HIQA) should establish site-specific multidisciplinary groups at a national level to develop guidelines for quality in major cancers.

• Recommendation 47: General Practitioners should have comprehensive information that enables informed referral and other management decisions.

Review of the 2006 cancer strategy (NCCP 2014)
The National Cancer Control Programme published a report in 2014 on the implementation of the 2006 cancer strategy (4). Significant progress was seen in the areas of cancer prevention, community oncology, screening, radiation oncology and the development of evidence-based tumour guidelines. Challenges were outlined in the areas of increased incidence and prevalence of cancer, fiscal and recruitment constraints and the need for further investment in IT infrastructure. The rise in benign referral to Symptomatic Breast Units was noted and recent developments to address this trend were described.
This report will assist the development of a third national cancer strategy. This has been identified as a Ministerial priority and is due for publication in 2016.

**National Cancer Control Programme 2007**

Based on the recommendations of the second *National Cancer Strategy* (2006) (11), the National Cancer Control Programme (NCCP) was established in 2007 to manage, organise and deliver cancer services on a whole-population basis. This set in motion a series of fundamental changes to the delivery of cancer care in the Republic of Ireland which remains ongoing.

In addition to recommending centralisation of cancer services, the *National Cancer Strategy* (11) recommended that GPs should have comprehensive information available to enable them assess a patient with suspicious symptoms and findings, and to make an informed referral for specialist assessment. GP referral guidelines with standardised referral forms for suspected cancers (breast, prostate and lung cancers) were introduced nationally by the NCCP in 2009, with comprehensive education for GPs, through a collaborative process with the Irish College of General Practitioners (3).

**National Quality Assurance Standards for Symptomatic Breast Disease Services, HIQA 2007**

In 2007, the Health Information and Quality Authority (HIQA) adopted the National Quality Assurance Standards for Symptomatic Breast Disease Services (167) developed by an expert group in 2006. These standards define what is expected of the providers of symptomatic breast disease services and provided the basis for service planning, development and continuous improvement. They describe the essential elements that are fundamental to providing safe care for individual patients on a day-to-day basis and others that are important for the sustainable and consistent delivery of quality care to patients over time. This set of Quality Standards outlined a total of 297 recommendations, which formed the basis for the
NCCP Key Performance Indicators for Symptomatic Breast Disease in the designated cancer centres.

Framework to implement the National Cancer Strategy (NCCP 2007)
In line with the recommendations of the National Cancer Strategy, the HSE developed a framework for the ‘Establishment of Managed Cancer Control Networks and Designation of Eight Cancer Centres’ in September of 2007 (340). This framework defined the criteria for the delivery of cancer services, based on the recommendations of the National Cancer Strategy (11). The report recommended that the treatment of symptomatic breast disease should be delivered at eight Cancer Centres nationally, with Letterkenny (County Donegal) providing a satellite service for Galway in the North West of the country.

The report mandated that breast services be withdrawn sequentially from hospitals which did not meet the defined criteria for delivery of symptomatic breast care, commencing with the lowest-volume hospitals and ultimately including all hospitals which did not meet the guideline standards. Hospitals with low case volumes were directed to no longer provide symptomatic breast services and surgical treatment with immediate effect. The centralisation of Symptomatic Breast Disease services from 35 acute hospitals into 8 designated cancer centres (and a satellite unit at Letterkenny General Hospital) took place during 2009. Since centralisation of publicly-provided breast cancer services, all patients attending the SBD Units in Ireland are treated by cancer specialists in multidisciplinary teams.

Professor Tom Keane from Canada was appointed as the first Director of the National Cancer Control Programme in 2007 and Dr. Susan O’Reilly took over as Director from 2010 – 2014. Concerted efforts to manage a fundamental reconfiguration of services ensued, with a radical change in the centralisation of cancer surgical services, followed by considerable expansion of radiation oncology and medical oncology services. Strong leadership, with political and financial support, was instrumental in the successful implementation of the second national cancer strategy.
Development of Key Performance Indicators (KPIs) for breast disease, 2009

The 2006 National Cancer Strategy recommended that ‘the HSE should put in place arrangements to monitor inequalities in cancer risks, cancer occurrence, cancer services and cancer outcomes’ (recommendation 12).

A suite of Key Performance Indicators (KPIs) for breast disease was developed by the NCCP in 2009, along with data definitions, based on the HIQA national standards for Symptomatic Breast Disease (167). Data collection of KPIs commenced in 2010, with a total of 28 KPIs for breast disease across the areas of: access, imaging, diagnosis, multidisciplinary working, time to treatment (surgery, chemotherapy, radiation therapy) and pathology.

Each public cancer centre reports on this set of Key Performance Indicators (KPIs) monthly, which continue to be published on the NCCP website. These KPIs are designed to assist patients, staff and the NCCP in assuring themselves that all designated cancer centres are adhering to the required standards of practice. Prompt access to cancer services has been one of the key deliverables for this service.

HIQA National Quality Review of Symptomatic Breast Disease Services, 2009

In 2009, the Health Information and Quality Authority (HIQA) carried out a national quality review of Symptomatic Breast Disease Services in the public system. Individual reports were published for each breast unit in addition to an overall national report; ‘Report of the National Quality Review of Symptomatic Breast Disease Services in Ireland’ (6). The HIQA national report set out 18 recommendations on clinical governance, standards, audit, system assurance and the role of the Clinical Lead for Symptomatic Breast Disease services in each centre. The NCCP worked with each of the designated centres to implement the individual hospital recommendations and the overall national recommendations. The recommendations of the HIQA Quality Review are outlined in Table 2.2 in Chapter 2. The majority of recommendations were implemented by 2014, while others are ongoing. The
recommendation which was particularly relevant to this thesis was that the HSE should coordinate “a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians” (p.75)(6). The HIQA review found that an average of 17 patients with benign breast disease were seen for every one patient diagnosed with breast cancer. There was wide variation found across cancer centres, with a range of 14 to 37 (6).

Establishment of a national governance model for Symptomatic Breast Disease, 2010

In 2010, the NCCP held a Governance Forum for Symptomatic Breast Disease with the Chief Executive Officers (CEOs), clinicians and clinical directors of the designated cancer centres. This forum developed a national governance model for breast services, based on the recommendations of the National Quality Review of Symptomatic Breast Services (6). This governance model recommended the establishment of a national group of lead clinicians for Symptomatic Breast Disease and the establishment of a national tumour group for the development of clinical guidelines. These groups are now established. The clinical leads group meet quarterly and also host an annual audit quality and risk forum. National guidelines for the diagnosis, staging and treatment of breast cancer were completed by the Tumour Group in 2014.

3.4 Recent developments in national policy

Several publications since the centralisation of cancer surgery have recommended a similar approach for the wider health system, such as integration with primary care, specialisation within hospital groups and guidelines for evidence-based practice.
Following a change in Government in Ireland in 2011, the programme for Government announced major reform of the health services. A new strategy was launched entitled; *Future Health – A Strategic Framework for Reform of the Health Service 2012 – 2015* (2012)(108). It outlines the reform agenda, which includes:

- Focus on waiting lists and inequitable access to care
- Better integrated delivery systems based on multidisciplinary care
- Models of shared care which set out the roles and responsibilities of primary care and specialist services
- Clinical protocols and guidelines for use in primary care and specialist services
- More responsive and equitable access to vital services for all patients
- Enable quality and safety through indemnity: The Department of Health, with the HSE and the State Claims Agency are working to ensure that the indemnity provided to clinical services aligns with health systems policy. For example, if it is deemed appropriate that all specialised surgery for a given cancer be provided in identified centres, then indemnity will not extend for that service to be provided in other locations.

The priorities for implementation of Future Health in 2015 are the formation of hospital groups, activity-based funding (money follows the patient) and access to primary care, as announced by the Minister for Health in January 2015 (344).

**Review of referral and triage processes in Symptomatic Breast Units 2012**

The HIQA review of SBD services in 2009 found significant hospital and regional variation in referral patterns. HIQA made several key recommendations with regard to cancer referral practices, including that a review should be carried out of referral and triage processes.
This review of referral processes in Symptomatic Breast Units was conducted in 2012 as one component of this thesis (Study 2: qualitative study with hospitals).

**National Standards for Safer Better Healthcare, HIQA 2012**

In 2012, the Health and Information Quality Authority (HIQA) in Ireland published the *National Standards for Safer Better Healthcare* (80). These describe the means by which a public healthcare service provides high quality, safe and reliable care, centred on the service user, and are structured around eight themes for quality and safety as seen in Figure 3.2 below, including:

- Person-centred care and support
- Effective care and support
- Safe care and support

The National Standards provide a basis for those planning, funding or providing healthcare services to work towards achieving and maintaining high quality, safe and reliable care. Safer Better Healthcare has been used as a framework for quality assurance in cancer programmes, including guideline development and implementation (79, 345).

![Figure 3.2: Safer Better Healthcare (HIQA, 2012). Source: HIQA, Safer Better HealthCare, 2012 (80)](image)
Cancer Projections (NCRI, 2014)

The National Cancer Registry in Ireland (NCRI) published projections for cancer in Ireland in 2014 up to the year 2040 (23). These projections show an increase in incidence and prevalence of breast cancer. Based on demographic trends alone, the NCRI predict an 84% increase in breast cancer incidence in females and a 107% increase in males by 2040. The NCRI has also reported the number of breast cancers requiring treatment in 2010, and the estimated number requiring treatment in 2025, for the first year following patient diagnosis, as shown in Table 3.1 below. These projections estimate a 36% increase in surgery, chemotherapy and radiotherapy by 2025.

Table 3.1: Breast cancer projections in Ireland

<table>
<thead>
<tr>
<th>Female breast</th>
<th>2010</th>
<th>2025 projections (Based on demography only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>2,541</td>
<td>3,461</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1,388</td>
<td>1,890</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2,058</td>
<td>2,803</td>
</tr>
</tbody>
</table>

Source: Cancer Projections for Ireland 2015-2040, NCRI, 2014 (23)

National clinical guidelines for diagnosis, staging and treatment of breast cancers, NCCP 2014

The 2006 Cancer Strategy (11) recommended that HIQA should establish national multidisciplinary groups to develop guidelines for major cancers. The NCCP completed the development of national evidence-based clinical guidelines for the diagnosis, staging and treatment of breast cancers in 2014 (345). These guidelines include recommendations relating to the patient pathway in acute services in the areas of radiology, surgery, medical oncology and radiation oncology. Referral pathways from primary care had already been completed in 2009.


In 2014, the Department of Health commissioned an international review of the implementation of the 2006 Cancer Strategy. A report on the
implementation of the 2006 cancer strategy was published by the NCCP as part of the external review (4).

HSE and hospital restructuring 2013 - 2014
The eight designated specialist cancer centres were originally located and networked within each of four administration regions in the HSE (Dublin North-East, Dublin mid-Leinster, West, South), each centre serving a minimum population of 500,000.

In 2013, a fundamental reconfiguration of Irish hospital services was announced. This reconfiguration is the implementation of a report to the then Minister for Health (Dr. James Reilly TD) in 2013 entitled ‘The establishment of hospital groups as a transition to independent hospital trusts’, also known as the Higgins report (109). These hospital groups have been established as a transition to the eventual establishment of independent hospital trusts. Interim boards have been established to oversee the delivery of high quality, safe patient care and these boards report to the Director General of the HSE. Governance of the hospital groups is outlined in the Higgins report, which includes the main functions of the hospital boards; strategic planning, policy making, supervision and challenge of executive management and accountability to stakeholders (109).

The introduction of hospital groups in 2013 has resulted in a change in the governance of these cancer centres to the hospital groups. Standards and policy remain the responsibility of the NCCP.

Additional structural changes at primary care and community level such as primary care networks and Community Healthcare Organisations (CHOs) do not impact on the restructuring of cancer services.

Collaborative links have been established between the Northern Ireland Cancer Registry (NICR) and the National Cancer Registry of Ireland (NCRI) for all-Ireland research activities. The Cancer Consortium has also been established with the National Cancer Institute (NCI) in the USA, as part of an
all-Ireland initiative to facilitate interaction among the US, Ireland, and Northern Ireland cancer-control communities and provide educational programmes in cancer control.

3.5 Previous health services research on cancer

The following section will outline previous health services research related to cancer referral patterns which are of particular relevance to this thesis. These include both Irish and international studies which have provided the context and evidence-base for this thesis to build upon.

3.5.1 Irish College of General Practitioners (ICGP)

In 2006, the Irish College of General Practitioners (ICGP) carried out a needs assessment of General Practitioners for the early detection of cancer in primary care (260). The aim of the study was to identify the barriers experienced by GPs to early diagnosis of cancer in order to improve early detection, increase the number of patients diagnosed at an early stage and maximise potential for cure. The needs assessment included five focus groups (n = 47 participants) and a postal survey. A total of 950 GPs (47% of the ICGP membership) responded to this survey. This study was conducted for all cancers and not breast cancer specifically.

The findings of the qualitative study component of this needs assessment showed that barriers to early detection of cancer identified by GPs in 2006 were predominantly:

- Delay in patient presentation
- Lack of GP direct access to radiological and endoscopic investigation
- Difficulty with referral of patients to hospital services for investigations and/or assessment
- Lack of clear recommendations for cancer screening
- Poor communication with hospital staff
- Inequitable access, with long waiting lists for investigations and referral for patients who cannot afford to pay privately
In the ICGP quantitative postal survey, the factors identified which would assist GPs in the early detection of cancer were listed, commencing with those of highest importance to the GPs, as:

- Agreed criteria for screening high-risk individuals
- Agreed referral criteria for suspected cancers
- A ring-fenced budget for community diagnostic services
- Increased public awareness of early cancer symptoms
- Earlier patient presentation/increased patient awareness
- Further GP education on identification of early-stage cancer
- Clinical practice guidelines
- Appropriate investigative pathways
- Hospital-based GP liaison nurse
- Meaningful GP representation at senior level of local hospitals

Areas of cancer in the 2006 study, which GPs wished to receive further education and clinical practice guidelines included; identification of early-stage cancer; appropriate investigative pathways for suspected cancer; referral criteria for suspected cancer; hospital cancer treatment care pathways; familial cancers; identification of high-risk individuals; and targeted cancer screening for high-risk individuals.

This current thesis assesses whether the priorities for early detection of cancer identified by GPs in the 2006 study, have been addressed. The researcher (NO'R) has collaborated with the ICGP since the inception of this study to optimise the relevance of the study and its findings to health services research, policy and practice.

3.5.2 Audit of GP referral guidelines
An audit of local GP referral guidelines for suspected cancer was carried out in Ireland in 2009 (346) in the East Coast Area Health Board (a sub-division of the HSE in South Dublin and Wicklow, now subsumed into a larger region.
following reconfiguration in 2005). The majority of GPs reported that they usually or sometimes use the guidelines, found them useful, usually adhered to the agreed guideline referral criteria and considered their compliance with the guidelines was good or reasonable. They recommended that guidelines be developed on a national basis to provide streamlined referral pathways. The authors found that whilst GPs welcomed national referral guidelines, they wished to retain independence to act on clinical judgement.

There are also a number of international strategic documents and reports that identify current and future issues that need to be addressed to enable efficient referral of suspected cancers from primary to secondary care, which are summarised below.

3.5.3 The Institute of Medicine (IOM)
The Institute of Medicine (IOM) in the USA describes how primary care clinicians are often the first clinician that patients see when they have signs or symptoms of cancer. Access to care, or “the timely use of personal health services to achieve the best possible health outcomes” (p.4)(347) is an important aspect of high quality cancer care (348). Recent IOM recommendations identify a vision for accessible cancer care. This vision involves evidence-based cancer care, coordinated team-based cancer care, accessible affordable cancer care and quality measurement (14).

3.5.4 OECD cancer policy study
This OECD policy study Cancer Care: Assuring Quality to improve Survival (19) makes recommendations on health systems and cancer policy in the fight against cancer. It identifies three main policy areas that help improve the quality of cancer care:

- Resources (drugs, equipment, institutions and workforce)
- Practices (timely and affordable access to evidence-based care)
- Governance (national plans setting out targets, guidelines for care and means for monitoring progress)
Key recommendations from the OECD include ensuring that cancer care is of high quality and is rapidly accessible. The OECD report considers the most critical element influencing cancer survival is diagnosing the cancer at an earlier stage of disease and starting treatment quickly. In particular, breast, colorectal and cervical cancers are considered curable if they are detected early enough.

As a policy priority, the OECD indicate that “countries should develop a clear understanding of the pattern of excessive or inequitable waiting times for cancer care in their population and respond with policies suited to the local context” (p.142).

3.5.5 National Health Service UK: 2-week rule
The experience of reorganisation of breast cancer services in other jurisdictions, such as the UK, has been described in the literature review (Chapter 2). In the UK, the ‘2-week wait rule’ for cancer referrals from primary to secondary care became effective in December 2000 for all cancers treated by the National Health Service, whereby urgent cancer referrals were guaranteed to be seen within 2 weeks. The aim of this initiative was to improve access to specialist services, thus facilitating early diagnosis and treatment (5). Whilst improvement in waiting times for urgent referrals have been reported in the UK, GPs have reported a loss of autonomy and have “acknowledged an element of over-referral under this rule due to the effects of clinical uncertainty and patient pressure” (p.82)(227). Potter and colleagues (5) questioned the scientific foundation of the 2-week rule: “the poor predictive value of fast track referral guidelines, together with poor adherence in primary care, has flooded one-stop clinics with large numbers of inappropriate referrals” (p.288). This had been predicted several years earlier by Fentiman (315) who warned that “if GPs do not act as a screen but as an open gateway there is a risk that specialist one-stop clinics will become overrun by the worried well” (p.1251).

Increases in overall volume of referrals were reported in the UK following the introduction of this rule (5, 339). An increase of 9% in breast referrals was
found in one study (5). However, this increase was seen mostly for those referred under the 2-week rule (urgent referrals), which increased by 42%, while routine referrals decreased by 24%. The total number of cancers detected remained fairly constant. The UK National Audit Office reported an increase of 51% in urgent GP referrals for suspected cancer between 2009-10 and 2013-14 (318). Concerns have been expressed that this restructuring of referral pathways has resulted in longer waiting times for non-urgent referrals, some of which had cancers diagnosed (5, 162, 339).

3.6 Summary
The convergence of the problem, policy and political streams in 2006 described in the Kingdon model (64) resulted in a policy window in Ireland, which provided an excellent opportunity for successful implementation of the national cancer strategy.

The National Cancer Control Programme was established to implement the recommendations of the 2006 cancer strategy. In relation to breast cancer this resulted in the centralisation of breast cancer surgery into eight designated cancer centres with GP referral guidelines to rapid access breast clinics. Since the establishment of the specialist centres and GP referral guidelines, there has been a sizable increase in GP referrals to breast clinics.

This thesis will examine the impact of this process on breast cancer referral patterns, focussing on access to services and patient outcomes.
Chapter 4: The Current Study

4.1 Introduction

Whilst the initial focus of this thesis was to determine the impact of centralisation of breast cancer services in Ireland on breast cancer referral patterns – a ‘natural experiment’ in the Irish healthcare system, the literature identified additional factors influencing GP referrals and hence the research was broadened to examine the wider influences on GP referral patterns.

4.2 Structure

Based on the multi-factorial nature of the factors influencing referrals to breast cancer units described in the literature, a mixed-methods research design was chosen for this study.

This thesis comprises 4 individual studies as part of an iterative sequential mixed-methods design, as described by Teddlie and Tashakkori (349). The findings of each individual study informed the development of the subsequent study. These four distinct components each build on the evidence base, while seeking to answer one common overarching research question “What are the factors influencing GP referrals to symptomatic breast units in Ireland?” Key developments in the Irish healthcare system such as centralisation of cancer services and adherence to GP referral guidelines were examined to assess their impact on breast cancer referral patterns.

An overview of the thesis structure is provided in Figure 4.1 below.
What are the factors influencing GP referrals to SBD units in Ireland?

Aim: to determine the impact of centralisation policy on breast cancer referral patterns

Methodology
- Examine the pattern of GP referrals to SBD units.
- Examine diagnostic yield.
- Determine the proportion of GP referrals for family history of breast cancer.
- Determine the proportion of GP referrals for mastalgia.
- Determine if there is evidence of seasonal variation in GP referrals to SBD units.

Study 1
- Mapping study
- Descriptive statistics
- Preparatory developmental stage

SBD: Symptomatic Breast Disease

Overall methodology: Mixed-methods iterative sequential study

Figure 4.1: Thesis overview.
4.3 Thesis aim
This thesis sought to identify the factors influencing GP referrals to SBD units in Ireland and to make recommendations regarding future delivery of services, to ensure that those with urgent symptoms are seen quickly and those with non-urgent symptoms are seen in the most appropriate setting.

4.4 Thesis objectives
The objectives of the overall thesis were as follows:

- To identify the factors influencing GP referrals to Symptomatic Breast Disease (SBD) units in Ireland.
- To investigate the impact of centralisation on breast cancer referral patterns in Ireland.
- To describe the implications of referral patterns for quality health service provision, including implications for current service provision, and recommendations for improvement and policy implications.

In order to explore comprehensively the study objectives, four interconnected studies were conducted, as follows:

**Study 1: Mapping study**

**Aim:**
To examine GP referral patterns to Symptomatic Breast Disease units in Ireland.

**Objectives:**
1. To examine the pattern of GP referrals to SBD units in Ireland over time (volume of referrals, triage categorisation, cancers detected).
2. To examine diagnostic yield (proportion of GP referrals diagnosed as breast cancer) over time (pre- and post-centralisation).
Secondary objectives:
During the pilot hospital interview, additional phenomena were raised which warranted further investigation. A decision was made to expand this mapping study to include an exploration of certain types of referral, as these particular referral patterns had not heretofore been investigated on a national basis in Ireland. The following objectives were therefore added:

- To determine the proportion of GP referrals to SBD units for family history of breast cancer.
- To determine the proportion of GP referrals to SBD units for mastalgia (breast pain).
- To determine if there is evidence of seasonal variation in GP referrals to SBD units.

Study 2: Qualitative study with hospital SBD units

Aim:
To explore the perceptions of hospital SBD staff on the factors influencing GP referrals to Symptomatic Breast Disease Units in Ireland.

Objectives:
1. To explore perceptions of hospital SBD teams on the factors contributing to the increase in GP referrals to SBD units in Ireland.
2. To explore potential reasons for the decrease in proportion of GP referrals diagnosed with cancer.
3. To ascertain the views of hospital SBD teams on the accuracy and adequacy of GP referrals.
Study 3: Qualitative study with GPs

**Aim:**
To explore the perceptions of GPs on factors influencing GP referrals to Symptomatic Breast Disease Units in Ireland.

**Objectives:**
1. To explore perceptions of GPs on the factors contributing to the increase in GP referrals to SBD units in Ireland.
2. To explore potential barriers and facilitators to implementation of evidence-based GP referral guidelines.
3. To investigate whether centralisation of cancer services has impacted on individual GP referral practices/behaviour.

Study 4: Impact of centralisation on cancer referral patterns

**Aim:**
The aim of this study is to determine the impact of the policy of centralisation of cancer services on breast cancer referral patterns in Ireland and to ascertain if this policy has achieved early indicators of success.

**Objectives:**
1. To identify referral route (method of presentation) of patients with breast cancer in Ireland (e.g., screening programme, GP referral).
2. To determine proportion of patients with breast cancer being diagnosed and treated at designated cancer centres vs. non-cancer centres, since service centralisation.
3. To compare breast cancers referred before and after centralisation, in terms of patient, tumour and hospital characteristics.
4. To determine if patients with breast cancer are being referred and diagnosed at an earlier stage of disease since service centralisation.
5. To determine if waiting times from GP referral to diagnosis and treatment (biopsy, surgery, chemotherapy) have changed since the centralisation policy.
4.5 Research impact

Research impact refers to the contribution research makes “to achieve desired societal outcomes” (p.1)(350). Using citation analysis on its own is not sufficient for assessing research impact and “is not predictive of subsequent clinical applications resulting in meaningful health outcomes”. (p.17)(351). The research conducted for this thesis provides important data and information to both policy-makers and service providers in relation to optimising referral patterns for breast cancer to maximise patient outcomes, in addition to efficiency and effectiveness of the service. To capture the potential impact of this thesis, the Kuruvilla Research Impact Framework (352) was used, as seen in Table 4.1 below. This framework was developed to assist researchers to identify and describe research impacts and has previously been used in the areas of surgical audit, healthcare financing, public health implications of climate change and public health implications of the trafficking of women and adolescents (353). It is used here to outline areas where this research thesis is likely to have an impact, under the following headings:

- Research-related impacts
- Policy impacts
- Societal impacts
- Service impacts
Table 4.1: Expected research outcomes

<table>
<thead>
<tr>
<th>Area of Impact</th>
<th>Expected research outcomes from this study (based on Kuruvilla et al., 2006) (352)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>• Establish baseline data to enable monitoring of referral trends over time.</td>
</tr>
<tr>
<td></td>
<td>• Establish if changes are required to current GP referral guidelines.</td>
</tr>
<tr>
<td></td>
<td>• Build the evidence-base to inform policy.</td>
</tr>
<tr>
<td></td>
<td>• Identify non-medical factors influencing GP referrals.</td>
</tr>
<tr>
<td></td>
<td>• Contribute to the evaluation of the policy of centralisation of cancer services in Ireland.</td>
</tr>
<tr>
<td>Policy</td>
<td>• Contribute to policy development in cancer control.</td>
</tr>
<tr>
<td></td>
<td>• Contribute to development of policy to integrate primary and secondary care.</td>
</tr>
<tr>
<td></td>
<td>• Evaluation of the policy of centralisation of cancer services in Ireland.</td>
</tr>
<tr>
<td></td>
<td>• Contribute towards the review of the implementation of the 2006 cancer strategy and development of the 2016 cancer strategy.</td>
</tr>
<tr>
<td>Societal</td>
<td>• Patient centred: Identify and address the need for additional patient information on breast disease.</td>
</tr>
<tr>
<td></td>
<td>• Examination of patient pathways which may contribute to improvement of services for the patient.</td>
</tr>
<tr>
<td>Service</td>
<td>• Identification and prioritisation of service needs for resource allocation.</td>
</tr>
<tr>
<td></td>
<td>• Identification of variation in referral practices between designated centres and their referring clinicians.</td>
</tr>
<tr>
<td></td>
<td>• Identification of education and training needs for targeted GP education/awareness where necessary.</td>
</tr>
</tbody>
</table>

*Source: Developed by the author for this study, based on Kuruvilla et al., 2006 (352)*
4.6 Summary

The four components of this research explore referral patterns from a number of perspectives, while addressing one common overarching research question: ‘What are the factors influencing GP referrals to symptomatic breast units in Ireland?’

The research findings will be discussed in terms of research impact in the areas of research, policy, societal and health service impact. Chapter 5 will explore the theoretical frameworks considered to underpin this study.
Chapter 5: Conceptual Framework

5.1 Introduction

Chapter 4 summarised the aims and objectives of the thesis and the expected outcomes in relation to research impact, policy impact, societal impact and service impact. A key challenge in healthcare is implementing new initiatives. Theoretical frameworks to design interventions and understand facilitators and barriers to implementation are recommended for use in implementation research. This chapter will present the models and frameworks considered to underpin this research.

In implementation science, the ‘implementation gap’ refers to the difference between the evidence of what works in theory and what is delivered in practice. Implementation of evidence-based healthcare has had varied success (354). Michie advises that “improving implementation depends on changing the behaviour of health professionals, managers, commissioners and others working within and with the health care system” (p.9)(354). Theory can assist in the identification of the mechanisms of behaviour change in clinical practice, allowing programmes and health systems to focus on the areas requiring change in order to implement an intervention. The use of theory can assist the development and tailoring of more effective interventions, based on a better understanding of the causal mechanisms by which interventions work (355).

The UK Medical Research Council (MRC) has produced guidance on developing and evaluating complex interventions (356). The MRC recommends that when designing and implementing an intervention, organisations should develop a theoretical understanding of the likely process of change by drawing on existing evidence and theory (357). Key elements of the development and evaluation process of complex interventions include development, feasibility and piloting, evaluation and implementation (356). For developing and evaluating complex intervention studies, the MRC guidance recommends that a good theoretical
understanding is needed of how the intervention causes change, so that weak links in the causal chain can be identified and strengthened (356). The guidance recommends developing interventions systematically, using the best available evidence and appropriate theory (357).

Michie et al. (358) found that, for implementation of clinical guidelines, changing clinical behaviour is more likely if the behaviour is identified and specified precisely in the implementation plan. In this study, the impact of clinical guidelines on GP referrals is explored as one of the potential factors influencing referral.

5.2 Background
Centralisation of breast cancer services in Ireland was completed in December 2009. In tandem with centralising services, GP referral guidelines were developed to inform referral from primary care to specialist services in the area of breast cancer.

Health behaviour change by healthcare professionals is the crucial outcome variable in most health interventions and implementation of evidence-based practice in healthcare depends on “changing multiple behaviours of multiple types of people” including managers, administrators and health professionals (p.1) (245). However, changing behaviour is a challenging and complex task. The provision of information alone is not an effective way to change behaviour (359). The National Institute for Health and Care Excellence (NICE) in the UK has published guidance on behaviour change for individuals and for broader population interventions (360, 361).

The House of Lords Behaviour Change report (362) in the UK looked at evidence for effectiveness of interventions based on principles of behavioural economics. This report described the ‘nudge’ approach (363-365) and the ‘intervention ladder’ from the Nuffield Council on Bioethics (366), as approaches to intervention implementation.
In an overview of systematic reviews of interventions, Grimshaw et al. (367) concluded that multifaceted interventions targeting different barriers to change are more likely to be effective than single interventions. Increasing recognition of the failure to translate research findings into practice “has led to a greater awareness of the importance of using active dissemination and implementation strategies” to maximise translation (p.2) (367).

In a systematic review of the use of theory in the design of guideline dissemination and implementation strategies (250), only 6% of the 235 studies reviewed explicitly used theory to underpin their guideline implementation strategy. Michie (354) recommended that, to achieve and maintain behaviour change as part of evidence-based medicine, an intervention requires the following steps:

- “A systematic method for analyzing the target behaviours in their context as a starting point for designing an intervention
- selecting interventions that are most likely to be effective given this analysis
- specifying the intervention in sufficient detail in trial protocols and published reports to allow accurate replication and evidence syntheses
- drawing on relevant theory to guide both the intervention design and evaluation” (p.9)

5.3 Overview of models and frameworks

The following models and frameworks were considered to underpin this research:

- Bayesian theory (278) (279)
- Institute of Medicine (IOM) USA. Aims for the 21st century healthcare system (75)
- Safer Better Healthcare (HIQA), Ireland (80)
Bayes' theorem

Bayes' theorem of diagnostic reasoning, which is based on the probability of disease, was considered and compared with the Social Constructivist Model of Medicine, which looks at non-medical influences on medical decision making.

Bayes' theorem, published by Thomas Bayes (an English clergyman and mathematician) in 1763 is a mathematical formula used for calculating conditional probabilities. Bayes' theorem of diagnostic reasoning undertakes a statistical diagnostic decision, considering the patient's clinical information in the context of the probability of the disease. The post-test probability of disease is a function of the pre-test probability, which is measured by the likelihood ratio (278). Decision making is made in the light of external evidence and prior plausibility of hypothesis (277).

The rule is defined as “a mathematical relationship between conditional probabilities that relates the posterior probability of parameter values, on the one hand, to the probability of the data given the parameter values, and the prior probability of the parameter values, on the other hand” (p.293) (279).

Summerton (280) examined the likelihood of disease in identical patients presenting in primary and in secondary care. Applying Bayes' theorem, the probability of disease in secondary care will be higher, as the interpretation of the clinical presentation should depend on the prior probability of disease (281).
Alternatively, medical decision making can also be viewed as a social construct, with factors other than biomedical factors influencing decision making. In this context, variability in medical decision making cannot be explained purely by Bayesian inference (282).

Bayes’ theorem of diagnostic reasoning, while contributing to the understanding of medical decision making, was not chosen as the theoretical model for this thesis as a deeper understanding and interpretation of GP referrals than the dichotomy of Bayesian reasoning was required.

Medical Research Council

The UK Medical Research Council has produced guidance on developing and evaluating complex interventions (357). The Medical Council recommends that when designing and implementing an intervention, organisations should develop a theoretical understanding of the likely process of change by drawing on existing evidence and theory (357).

Key elements of the development and evaluation process of complex interventions include development, feasibility and piloting, evaluation and implementation (356).

The MRC model was considered as a potential theoretical framework for this study as it linked the theoretical basis with implementation of interventions. However, this research thesis examined an intervention which had already been implemented and sought to understand the barriers and facilitators to implementation retrospectively. Craig et al. (356) recommend that theory and evidence should ideally be identified before an intervention is designed to have the greatest chance of success.

Institute of Medicine

The US Institute of Medicine’s (IOM) aims for a 21st century health care system (75) state that health care should be safe, effective, patient centred, timely, efficient and equitable. Whilst this model contributes to the assessment of quality of health services and would have been considered in
the development of the policy of centralisation, it was not chosen as a model for this thesis as it does not provide an explanatory framework for the development or implementation of health service interventions.

**Safer Better Healthcare**

In 2012, the Health and Information Quality Authority (HIQA) in Ireland published the National Standards for Safer Better Healthcare (80). These standards describe how a service provides high quality, safe and reliable care, centred on the service user. Safer Better Healthcare has been used as a framework for quality assurance in cancer programmes in Ireland, including guideline development and implementation (345) and quality assurance (79) but was not considered broad enough for use as a model for this thesis as it focuses exclusively on standards.

**Health Belief Model**

The health belief model (HBM) (180) (181) explains risk reducing behaviour in health and predicts the likelihood of patients taking recommended action to avoid a health threat or disease (369). This model of behaviour change proposes that demographic factors and a person’s beliefs such as perception of threat and behavioural evaluation will influence the likelihood that individuals will engage in particular health behaviours (370). Cues to action (371) was added to the model in 1975 and health motivation was added in 1977 (372) to further develop this model.

The health belief model has been used for studies on attendance for breast cancer screening (182) and for predicting self-breast examination (373) (374). Limitations of the Health Belief Model include that there are several versions available, the manner in which the different variables interact are not specified, it assumes that people are rational decision makers, it may overestimate the role of threat and it takes limited account of social factors in behaviour change (370).
While the Health Belief Model has been used as a useful predictor of prevention activities, in particular cues to action to attend screening, the HBM has been criticised for its failure to address contextual constraints influencing behaviour (375).

The Health Belief Model was not used to underpin this research as this study focussed on the behaviour of health professionals in relation to making referrals to hospital and the area of social influences was a key area to be investigated.

**Theory of Planned Behaviour**

The theory of reasoned action and the subsequent theory of planned behaviour are social cognition models which “assume that social behaviour is determined by a person’s beliefs about behaviour in given social contexts and by their social perceptions and expectations” (p.127) (370). The Theory of Planned Behaviour (TPB) (368) has also been used to explore the uptake of cancer screening (376) and for patients with breast symptoms (377) to examine predictors of the patient’s intention to seek help from their GP. The TPB has also been used in implementation science to study the determinants of clinical behaviour change (287). Limitations of the Theory of Planned Behaviour include that prediction of behaviour using this model is lower than prediction of intentions and the need to incorporate the influence of other variables such as anticipatory regret, moral norms, self identity and implementation intention (370).

While the Theory of Planned Behaviour was considered for use in this research, based on its inclusion of social context, it was not used to underpin this research as this study focussed on the behaviour of health professionals in relation to making referrals to hospital and the area of anticipatory regret / beliefs about consequences was a key area to be investigated.
5.3.1 Behaviour Change Wheel

The behaviour change wheel (251) was developed in 2011 as a tool for designing and evaluating behaviour change interventions. “Improving the design and implementation of evidence-based practice depends on successful behaviour change interventions. This requires an appropriate method for characterising interventions and linking them to an analysis of the targeted behaviour” (p.1) (251). The authors assessed existing frameworks of intervention functions and policies to enable their implementation. The Behaviour Change Wheel (BCW) is a synthesis of those frameworks.

The Behaviour Change Wheel approach is based on a comprehensive causal analysis of behaviour and starts with the question; “what conditions internal to individuals and in their social and physical environment need to be in place for a specified behavioural target to be achieved?” (p.9) (251).

The BCW is used for characterising and designing behaviour change interventions, using the COM-B system (capability, opportunity, motivation, behaviour) (251). The COM-B model is at the hub of the BCW and is a model to understand behaviour in context, a principle that has been used in US criminal law (287). This model, with its components of capability, opportunity and motivation is shown in Figure 5.1 below and is used to understand behaviour in context.

![Figure 5.1: The COM-B model. Source: Michie et al., 2011 (251)]
The components of the COM-B model associated with capability, opportunity and motivation, along with their definitions are shown in Table 5.1.

Table 5.1: COM-B model components

<table>
<thead>
<tr>
<th>COM-B</th>
<th>Capability</th>
<th>Motivation</th>
<th>Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physical Capability</td>
<td>Reflective Motivation</td>
<td>Physical Opportunity</td>
</tr>
<tr>
<td></td>
<td>Physical skill</td>
<td>Reflective processes, involving</td>
<td>Opportunity afforded</td>
</tr>
<tr>
<td></td>
<td>Psychological Capability</td>
<td>evaluations and plans; beliefs</td>
<td>opportunity by the</td>
</tr>
<tr>
<td></td>
<td>The capacity to engage in</td>
<td>about what is good and bad;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the necessary thought</td>
<td>conscious intentions; decisions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>processes: comprehension,</td>
<td>and plans.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>reasoning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Automatic Motivation</td>
<td>Automatic processes involving</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>emotions and impulses that arise</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>from associative learning and/or</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>innate dispositions. Emotional</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>responses, desires, impulses and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>habits resulting from</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>associative learning and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>physiological states.</td>
<td></td>
</tr>
</tbody>
</table>

Source: Michie et al., 2011 (251)

Figure 5.2 below, shows the sources of behaviour, intervention functions and policy categories in the Behaviour Change Wheel.

Figure 5.2: The Behaviour Change Wheel.
Each component can be mapped onto nine different intervention functions, which are activities aimed at changing behaviour. Intervention functions and their definitions are shown in Table 5.2 below.

Table 5.2: Intervention functions

<table>
<thead>
<tr>
<th>Intervention function</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Increase knowledge or understanding</td>
</tr>
<tr>
<td>Persuasion</td>
<td>Using communication to induce positive or negative feelings or stimulate action</td>
</tr>
<tr>
<td>Incentivisation</td>
<td>Creating expectation of reward</td>
</tr>
<tr>
<td>Coercion</td>
<td>Creating expectation of punishment or cost</td>
</tr>
<tr>
<td>Training</td>
<td>Imparting skills</td>
</tr>
<tr>
<td>Restriction</td>
<td>Using rules that limit engagement in the target behaviour or competing or supporting behaviour</td>
</tr>
<tr>
<td>Environmental</td>
<td>Changing the physical or social context</td>
</tr>
<tr>
<td>Restructuring</td>
<td></td>
</tr>
<tr>
<td>Modelling</td>
<td>Providing an example for people to aspire to or imitate</td>
</tr>
<tr>
<td>Enablement</td>
<td>Increasing means/reducing barriers to increase capability or opportunity</td>
</tr>
</tbody>
</table>

Source: Michie et al., 2011 (251)
Examples of these interventions in breast cancer services could include provision of information on cancer risk (education), skills to deal with patient expectations (training), confidence in referral decisions (enablement), reorganisation of cancer clinics (environmental restructuring), sanctions for inappropriate referral (coercion), reporting/rewarding areas of good practice (incentivisation) and advice on appropriate referral from a representative body (persuasion).

Using this framework can assist intervention designers and policy makers to identify and consider all potential options, including the behaviour change of individuals and external influences. The context of the intervention can be considered in the choice of intervention functions, thereby increasing the effectiveness of design and implementation of the intervention (251).

The COM-B model links to these interventions through its component parts, as indicated in Figure 5.3.
These intervention functions can then be mapped onto seven possible policy categories to enable or support their delivery: guidelines, environmental/social planning, communications/marketing, legislation, service provision, regulation and fiscal measures. These policies are defined in Table 5.3.

Improving implementation of evidence-based practice depends on channelling the behaviour of health professionals, managers and other health care staff. Using the COM-B approach, behaviour change techniques can be selected to deliver the intervention based on the intervention strategy (354).
Table 5.3: Policy categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines</td>
<td>Creating documents that recommend or mandate practice. This includes all changes to service provision</td>
</tr>
<tr>
<td>Environmental / social planning</td>
<td>Designing and/or controlling the physical or social environment</td>
</tr>
<tr>
<td>Communications / marketing</td>
<td>Using print, electronic, telephonic or broadcast media</td>
</tr>
<tr>
<td>Legislation</td>
<td>Making or changing laws</td>
</tr>
<tr>
<td>Service provision</td>
<td>Delivering a service</td>
</tr>
<tr>
<td>Regulation</td>
<td>Establishing rules or principles of behaviour or practice</td>
</tr>
<tr>
<td>Fiscal measures</td>
<td>Using the tax system to reduce or increase the financial cost</td>
</tr>
</tbody>
</table>

*Source: Michie et al., 2011 (251)*

Examples of these policy functions include evidence-based guidelines for cancer (guidelines), breast cancer awareness campaigns or activities (communications/marketing), development of specialist breast services (service provision) and regulation through professional bodies (regulation).

5.3.2 Theoretical Domains Framework (TDF)

The Theoretical Domains Framework (TDF) can be used as an elaboration of the COM-B model. Michie *et al.* (244) developed a theoretical framework for use in implementation research of evidence-based practice. This model was developed in the UK by inviting three groups of experts to contribute to the project:

- Health psychology theorists with an interest in the theoretical approaches to behaviour change and implementation research.
- Health services researchers who were involved in implementation research.
- Health psychologists who did not have specific expertise in theory, behavioural change or implementation research were included as a validation group.

The purpose of this project was to “simplify psychological theory relevant to behaviour change and to make it accessible to those involved in EBM implementation” (p.29) (244).
The groups identified psychological theories and theoretical frameworks relevant to the implementation of evidence-based practice. Relevant psychological theories were identified in motivational theory, action theory and organisational theory. A total of 33 psychological theories and 123 explanatory constructs were identified (244). Constructs particularly relevant to changing the behaviour of healthcare professionals were then selected. The domain list was validated through backward validation to ensure that the domains identified reflected the underlying theoretical constructs.

Twelve domains were initially identified as a framework for studying the implementation of evidence-based practice. The theoretical domains framework was refined in 2012 (245) and extended to 14 domains. The group separated the original domain of ‘motivation and goals’ into two domains of ‘intentions’ and ‘goals’ and added two new domains of ‘reinforcement’ and ‘optimism’. The domain ‘nature of the behaviour’ was dropped by the group as the influences on behaviour were being examined, as opposed to the nature of the behaviour.

The fourteen domains of the revised Theoretical Domains Framework are as follows: physical skills/cognitive and interpersonal skills, knowledge, memory attention and decision processes, behavioural regulation, environmental context and resources, social influences, professional/social role and identity, beliefs about capabilities, optimism, beliefs about consequences, intentions, goals, reinforcement and emotion.

The Theoretical Domains Framework (TDF), as an elaboration of the COM-B model, can be used to identify problems with intervention implementation and to aid implementation design. The validity of the TDF framework was investigated by Cane et al. (245). This validation study resulted in a refinement of the framework with 14 domains. The authors outlined three advantages of the TDF framework:
• Comprehensive coverage of the possible influences on behaviour
• Components of each domain are specified, providing clarity
• Links are made between behaviour change theories and behaviour change techniques to tackle implementation problems

The authors concluded that the TDF is a useful framework to inform interventions to improve implementation (245).

Figure 5.4 shows the behaviour change wheel incorporating both the COM-B components and the theoretical domains framework.

Figure 5.4: The Behaviour Change Wheel and Theoretical Domains Framework.
Source: Behaviour Change Summer School, Centre for Behaviour Change, University College London, August 2014.
A number of criteria have been identified to support the Behaviour Change Wheel, known as the APEASE criteria (affordability, practicability, effectiveness, acceptability, side effects/safety and equity) (378). These criteria are used to assess the appropriateness of intervention functions, policy categories and behaviour change techniques for proposed interventions, under the headings of affordability, practicability, effectiveness and cost effectiveness, acceptability, side effects/safety and equity.

The Behaviour Change Taxonomy (BCT) (251), (379), (378) has been developed to standardise the content and reporting of intervention studies and is used in this study to describe the specific components of proposed interventions based on the findings of this research (Appendix D).

Michie et al.’s COM-B model with its Theoretical Domains Framework (244) was chosen as the theoretical framework for this study. This framework was considered appropriate, given the context of implementation of an evidence-based policy of centralisation of breast cancer services in Ireland which included evidence-based GP referral guidelines. Behaviour change is a key component required for the uptake of evidence based practice in healthcare (380). The TDF has been used to assess barriers and facilitators to guideline development and implementation in a range of studies, such as pregnancy weight management and obesity guidelines (381); diagnosis, management and implementation of guidelines for dementia (249); theory-informed behaviour change for low back pain (248); and using psychological theory to investigate difficulties implementing a mental health guideline (382).

The TDF has been used to advance the science of implementation research by theoretically assessing implementation problems, identifying barriers and facilitators to implementation and identifying intervention components to overcome the modifiable barriers and enhance the enablers (245, 248, 380). The TDF can also be used as a coding framework for analysis (380).
A review of the Theoretical Domains Framework (380) concluded that its strength was its theoretical coverage and ability to elicit beliefs signifying key mediators of behaviour change.

The use of the TDF as an interview topic guide has been criticised as being too focussed and constraining. However, a study on hand hygiene (383) compared results using TDF and atheoretical methods and concluded that the TDF methodology was both comprehensive and inclusive. A limitation of the TDF is that it is a framework rather than a theory and as such, the relationships between the domains are not specified (380). Inter-coder agreement has also been reported as low in interview studies using the TDF (384).

The authors concluded that the TDF provided “a useful conceptual basis for assessing implementation problems, designing interventions to enhance healthcare practice and understanding behaviour-change processes” (p.35) (380).

The TDF has been used widely to investigate the behaviour of health professionals, with several recent studies designed specifically to identify barriers and levers to uptake of a guideline (249) (385) (386) (387) (388) (389) (390) (391) (392) (393). The TDF is cross disciplinary and has been used to examine behaviour in wide range of health care settings (380). The TDF is used in this thesis to explain GP referral patterns and inform implementation interventions.

The TDF has been described as “the most comprehensive framework for designing implementation interventions as it offers broad coverage of potential change pathways” (p.6) (248). However, the authors recommend further research examining the links between theoretical assessment and behaviour change techniques.
5.4 Summary

Through identification of barriers and facilitators in relation to implementation of national policy of cancer centralisation, referral practice and use of guidelines, this study sought to explain implementation facilitators and problems and inform implementation intervention.

The mapping study (Study 1) and quantitative analysis of national cancer registry data (Study 4) assessed the level of compliance with and the impact of the policy of centralisation of breast cancer services in Ireland. The qualitative research component of this research sought to understand and explain professional and social processes of referral patterns from the perspective of the hospital consultant or their nominee (Study 2) and to explore GP’s self-reported referral practice (Study 3) to describe the reasons for adherence or non-adherence to evidence-based referral guidelines, using theory of behaviour change. The interaction of capability, opportunity and motivation in supporting behaviour change was explored. The Theoretical Domains Framework (TDF) supported the description of these factors in more detail to identify implementation problems and aid future implementation design.

In the development of the current research, a number of models and frameworks were considered as potential theoretical frameworks to underpin this study. These models included the Institute of Medicine (IOM) aims for the 21st century healthcare system (75), Bayesian theory (278, 279), Health Belief Model (180) (181), Theory of Planned Behaviour (368), the Behaviour Change Wheel (251) and the Theoretical Domains Framework (244).

Davis et al. (394) conducted a review of theories of behaviour change across the social and behavioural sciences. The authors found that most theories used in public health interventions had limited reference to social and contextual factors and recommended drawing on a wider range of theories to increase intervention effectiveness.
The model deemed most relevant and applicable to this study was the Theoretical Domains Framework (TDF) (244, 251). The TDF is useful in the context of the current study as it can be used to identify problems with intervention implementation and aid implementation design and has previously been used to assess barriers and facilitators to guideline development and implementation (381) (249) (248) (382). The TDF has also been used in this study as a coding framework for analysis.

This theoretical approach can assist the identification of the mechanisms of behaviour change in clinical practice, thus allowing programmes and health systems to focus on the areas requiring change in order to implement an intervention successfully. While theories of behaviour change have more generally been used to examine individual behaviours, or possibly organisational levels, the Theoretical Domains Framework identified domains particularly relevant to changing the behaviour of healthcare professionals. This facilitates a deeper insight into macro-level forces which affect health service provision and enables intervention planning based on the specific behavioural components which need to change.

A psychological framework has been chosen to underpin this research. The next chapter (Chapter 6) builds on this model to describe the overall research methodology used for this thesis.
Chapter 6: Methodology

6.1 Introduction
This chapter presents the research methodology chosen for this thesis. As described in the previous chapter on models and frameworks, this is a health services research project using a psychological framework. The professional and academic background of the researcher in nursing and health services management has informed the research interests and research approach.

This research was originally planned to investigate the impact of the policy of centralisation of cancer services on GP breast cancer referral patterns. A review of the literature found that many factors, including centralisation, can affect GP referral patterns. In addition, reports on a national review of the Symptomatic Breast Disease Services by the Health Information and Quality Authority (HIQA) in 2010 (6) and from the National Breast Cancer Audit, Quality and Risk Conference in 2011 (1) and 2012 (2) identified a need to explore the factors influencing breast referrals from primary to secondary care in Ireland. The scope of the study was broadened accordingly.

As discussed in Chapter 2, the choice of methods was informed by a review of the literature and the gaps in the current evidence.

6.2 Research methodology
Researcher reflexivity is important in the overall quality of a study (395) and in assessing whether the researcher has interacted with the phenomenon under investigation (396). In line with this view, it is important to articulate the researcher’s position as an integral element of reflexivity within the research project. With a professional and academic background in nursing, public health medicine and health services management, this researcher’s PhD topic was influenced by her work as an employee of the National Cancer Control Programme (NCCP) from 2010 – 2014. While the researcher was working in the area of cancer control, she had not formed relationships with prospective participants at the time of the study, as the researcher was new
to this post. In terms of other potential conflicts of interest, self-reflection was used to assess possible biases between the dual roles of researcher and health service employee, for example, in discussions with consultants and GPs on health service impacts.

As described in the previous chapter, this research uses a psychological framework (the Theoretical Domains Framework). With a background and work area (cancer control) in which quantitative methods are often the instrument of choice for data collection, this researcher chose to adopt a mixed-methods approach for this PhD research in order to incorporate qualitative methods which can bring richness, depth and broader findings, while allowing the researcher to consider different realities articulated by research participants. During this research project it became evident that factors influencing GP breast cancer referrals are multi-level, spanning macro, meso and micro levels. This research methodology thus sought to take account of the multi-factorial nature of the phenomenon under study, including micro-level influences.

Issues of objectivity and subjectivity go to the core of differences between quantitative and qualitative research and these two investigative approaches were amalgamated within this research project in the form of mixed-methods. The utilisation of mixed-methods within this project are discussed in detail in the next section, yet it is important to acknowledge from the outset that some debate surrounds the use of mixed-methods, as qualitative and quantitative research are derived from “opposing philosophical backgrounds” (p.433) (397). As Creswell and Plano Clarke (398) explain, all research has a philosophical foundation that encapsulates certain assumptions about knowledge, which in turn shapes the research process.

6.3 Overview of mixed-methods research
The underlying logic of mixed-methods research is that neither quantitative nor qualitative methods may be sufficient on their own (399). When used in combination, this approach facilitates a better understanding of a research phenomenon than either approach in isolation and yields a more
comprehensive analysis (398, 399). The findings from mixed-methods research integrate to create “a whole more than the sum of the parts” (p.40) (400).

Using mixed-methods, the inherent limitations in one approach can be tackled through an additional different methodological approach. Creswell and Plano-Clarke (398) outline the weaknesses of single-approach methodology – it is considered difficult to explore context and setting in quantitative research, and the voice of the participants can be lost. Qualitative research, on the other hand, has been criticised for its lack of generalisability and its subjective interpretations. Creswell and Plano-Clarke recommend mixed-methods research to offer strengths that offset these individual weaknesses (398).

The complexity of health-care requires a range of methodologies for assessment and a mixed-methods approach is often used in health services research for comprehensiveness (401) (402) (396). Mixed-methods can be used “in a series of studies that investigate the same underlying phenomenon” (p.267)(403), to conduct both exploratory and confirmatory research (404), particularly in real-world settings. The quality criteria for good reporting of a mixed-methods study (GRAMMS) (405) were used for this study.

6.4 Philosophical paradigms
Creswell (p.6) (406) highlights how different philosophical approaches can be understood as ‘paradigms’ or ‘worldviews’, which he refers to as a “general philosophical orientation of the world and the nature of research that a researcher brings to a study”. Guba and Lincoln describe how paradigms define the world view of the researcher (407). Creswell identifies four main worldviews evident in social science research; post-positivism, constructivism, transformative, and pragmatism, and points out that “pragmatism is not committed to any one system of philosophy or reality” and it allows the researcher to draw from both qualitative and quantitative assumptions, providing a “freedom of choice” (p.11) (406). For these
reasons, in the current study the researcher chose to adopt a pragmatist approach, using qualitative and quantitative methods as tools to serve the questions pursued, rather than allowing the methods to “constrict the range of inquiry” (p.4)(408). Furthermore, mixed-methods can be used to answer research questions that could not be answered by a single paradigm alone (403).

6.4.1 Pragmatist paradigm
Mixed-methods research has its primary philosophy in pragmatism and “attempts to consider multiple viewpoints, perspectives, positions and standpoints” (p.113)(409). Pragmatism gives primacy to the importance of the research question (410) and values both objective and subjective knowledge.

The benefits of pragmatism include the following:

- The flexibility to use the method which best answers the question (402) (411)
- Solving practical problems in the real world (412)
- Methodological pluralism leads to more effective research (413)

Pragmatism is based on “situational responsiveness and a commitment to an empirical perspective” (p.9) (411), providing an innovative approach to address contemporary issues in the health services (402).

Morgan (410) discusses the theory-driven deductive mode and the data-driven inductive mode and describes the pragmatic approach as “abductive reasoning that moves back and forth between induction and deduction – first converting observations into theories and then assessing those theories through action” (p.71) (410). This approach has been used in this research by using data in the initial quantitative study to design the qualitative deductive phase and assessing the theories generated using another data-driven inductive study. Feilzer describes pragmatism as a commitment to
uncertainty (412), offering an alternative worldview and a focus on the research, and solving practical problems in the real world.

6.5  Choice of study design for this thesis

There are four distinct components to the research conducted for this thesis, each building iteratively on the previous studies, while seeking to answer one common overarching research question “What are the factors influencing GP referral patterns to Symptomatic Breast Units in Ireland?” Based on the multi-dimensional nature of the factors influencing breast cancer referrals described in the literature, a mixed-methods research design was chosen for this study. The phenomenon being studied is a health service research issue which was examined before and after major restructuring of the cancer services in Ireland. The referral practices of GPs in the context of changes in evidence-based practice, referral guidelines and centralisation policy were examined. This, in effect, constituted a natural experiment in the Irish healthcare system. Mixed-methods have been central to the design of this study, due to the complex nature of both medical and psychosocial influences on cancer referral patterns.

Mixed-methods research has several structural designs, mostly based on the sequence or the prominency of the individual components. In a sequential approach, quantitative or qualitative data collection serves as a basis for the next data collection and analysis stage (399). This structure has been used in this study, whereby using an iterative design, results from one study were used for the development of the next study. “With multiple iterations, the study enables a progressive reconfiguration of substantive findings and interpretations in a pattern of increasing insight and sophistication” (p.23) (414). Explanatory and exploratory mixed methods are described by Creswell and Plano Clarke (398) and are shown in Figure 6.1 below. The explanatory sequential design commences with the collection and analysis of quantitative data, which is followed by the subsequent collection and analysis of qualitative data. The qualitative data builds on the quantitative results. The exploratory sequential design begins with and prioritises the collection of qualitative data. Building on the results of this qualitative data, the
researcher then conducts a second quantitative phase to test or generalise the initial findings.

The model chosen for this study is the iterative sequential mixed design. This design is described by Teddlie and Tashakkori (349) as a more complex design with more than two phases. This iterative sequential model facilitates research evolving as new salient events occur. In this study, this particular approach facilitated the addition of sub-studies in this research, which were added to the study in response to initial early findings.

Convergence coding has been used in this study to report the yield of the integrated approach used. Convergence coding was used to assess to what extent the different findings show convergence (meaning and prominence of themes presented), complementarity (multiple dimensions for the same research question to ensure completeness in perspective), dissonance (disagreement/divergence) or silence (one set of findings is silent on a theme (415, 416).
Palinkas (404) investigated the role of mixed-methods in implementation research. In this area of research, qualitative methods are often used to explore reasons for success or failure in implementation of evidence-based practice, while quantitative methods are used to test and confirm hypotheses. Mixed-methods have also been used in implementation research “to develop a science base for understanding and overcoming barriers to implementation” (p.44)(404), in particular in the area of evidence-based medicine.

The Theoretical Domains Framework (TDF), as described in Chapter 5, is the framework upon which this study is based and is used in this study to identify barriers to implementation of evidence-based practice in cancer control, and to make recommendations to aid implementation of cancer policy. Whilst theories of behaviour change have been used more commonly in studies relating to individual behaviours, or organisational level change, the TDF has been used to include macro level forces which affect health service provision, including a meta-synthesis of barriers and facilitators to implementation of pregnancy weight management and obesity guidelines (381); understanding diagnosis and management of dementia (249); development of interventions to implement evidence into practice for acute low back pain (248); and investigation into difficulties associated with implementing a mental health guideline using psychological theory (382). It's use in examining the behaviour of health professionals is of particular relevance to this study.

Using a mixed-methods approach facilitated the exploration of breast cancer referral patterns at various levels, from a micro and meso level to a macro level. The use of the Behaviour Change Wheel (BCW) and the Theoretical Domains Framework (TDF) as the analytical framework provided a model to identify the sources of behaviour (capability, opportunity and motivation), and link these to the relevant intervention functions and policy categories to address these. This broad approach to both methods and models facilitated the exploration of a ‘real world’ problem in the Irish health services and the development of an implementation plan to address the issues identified.
As this research focussed on GP referrals from primary care to symptomatic breast units in secondary care, interviews with both primary and secondary care providers were included in this research.

A summary of the methodological approach for this thesis is outlined in Figure 4.1 (Chapter 4).

6.6 Summary of methodological approach
The methodological approach used for the different study components of this thesis is outlined below. A detailed methodology for each study is contained in the chapters presenting the results for each study (Chapter 7 – 10).

6.6.1 Study 1: Mapping study
The initial exploratory study was conducted to review breast cancer referral patterns in Ireland. Existing routine data from the Symptomatic Breast Disease Units were analysed for patterns and trends in breast cancer referrals. The mapping study was expanded to include data on family risk, mastalgia and seasonal variation following the pilot hospital interview. Conducting this preparatory mapping phase allowed the quantitative findings to inform the development of the qualitative phases. This strategy ensured that the focus of the qualitative phase was underpinned by national and local data, which facilitated in-depth focused discussion on possible influencing factors. Morse’s taxonomy of mixed-methods design (417) describes this approach as a ‘development’ function in mixed-methods research.

The exploratory mapping study provided national data on referral patterns. In order to explore the factors influencing these referral patterns and to provide richness to the quantitative data, two qualitative studies were designed as the next phases of this study.
6.6.2 Study 2: Qualitative study with hospital SBD units
This first of the qualitative studies was conducted with the lead SBD consultant or their nominee in each of the 8 cancer centres and the satellite centre, to explore the data trends generated in Study 1 and to identify potential factors influencing referrals. Interviews are considered the most suitable method to investigate opinions, values and motivations (418). The data from Study 1 were circulated to the interviewees in advance to stimulate discussion. While this data was already in the public domain, it helped to focus the discussions in the limited time available. The Theoretical Domains Framework (244) was used in analysis of the interviews to identify factors influencing referral patterns. Although some of the observed quantitative trends were explained by the hospital interviews, the majority of consultants concluded that many factors influencing referrals to the cancer centres originated at General Practice level. This required further qualitative research with referring GPs.

6.6.3 Study 3: Qualitative study with GPs
The second qualitative study was conducted with a random sample of 24 GPs across the four HSE geographical networks to explore factors influencing their referral decisions. The Theoretical Domains Framework (244, 245) was used in analysis of the interviews to identify barriers and facilitators to referral practices. The findings from the consultant and GP interviews were then compared to address completeness, convergence and dissonance of key themes (415). A number of additional factors were raised by consultants and GPs in relation to factors influencing referral patterns, for which data had not previously been collected on a national basis in Ireland. An assessment of these factors (family risk of breast cancer, mastalgia and seasonal variation) were subsequently added to the quantitative component of the study.
6.6.4 Study 4: Impact of centralisation on breast cancer referral patterns
Secondary data analysis of the National Cancer Registry database was used to investigate the impact of centralisation on breast cancer referral patterns. Both the consultants and GPs highlighted the impact of centralisation of cancer services on referral patterns, but this had not yet been quantified in Ireland, as the centralisation process was only completed in 2009. Whilst it is too early to show a difference in survival rates following the policy of centralisation (5-year survival rates for patients referred from 2010 onwards will be available after 2015), it is possible that stage of disease at diagnosis and a number of process outcomes may be seen at this early stage. To broaden the range and depth of the research, secondary data analysis was conducted with anonymised datasets from the National Cancer Registry of Ireland (NCRI) to compare breast cancers diagnosed in 2008 (pre-centralisation) with those diagnosed in 2010 (immediately post-centralisation), in relation to method of presentation, proportion of patients who were treated in cancer centres, stage of disease at diagnosis and waiting times for diagnosis and treatment.

6.7 Analysis of findings
In the interpretation of the overall results, convergence assessment was used to review the level of convergence across all studies, i.e., to what extent does a coherent picture about causal relationships emerge from the data. Completeness assessment was conducted by comparing each data source, highlighting similar and unique contributions to the research question and examining what is missing from the analysis (415).

A visual model of the points of integration in this mixed-methods study can be seen in Figure 6.2 below. The initial exploratory study (Study 1) was used to develop the qualitative studies (Study 2 and 3). Initial findings in Study 2 resulted in expansion of the mapping exercise in Study 1 to include additional parameters to answer the questions raised. Hypotheses were generated in Study 2 with hospitals consultants, which were elaborated on in Study 3 with GPs. The results of the two qualitative studies were also compared for agreement, partial agreement, silence or dissonance. There
was complementarity between studies, in that findings from several perspectives addressed the research question. The hypotheses generated in the qualitative studies (Study 2 and 3) were tested in Study 4 with a national quantitative dataset. The results of Study 4 confirmed the initial trends mapped in Study 1 and expanded on the interpretation of referral trends discussed at the qualitative stages. The overall interpretation of results used convergence assessment and completeness assessment to assess the level of convergence across all studies.

![Figure 6.2: Integration of studies in a mixed methods design.](image)

Figure 6.2: Integration of studies in a mixed methods design.
The research question for this thesis could not be answered using a single method alone. Nor did it lend itself a simple left to right flow. The individual studies related an organic way e.g. Study 4 was not interpretable without reference to other studies. The iterative sequential mixed method design chosen for this thesis added an additional layer of meaning, facilitating the completion of the loop.

6.8 Summary

Examination of the National Cancer Registry data was the most comprehensive method of investigating trends in diagnosed breast cancers. However, this approach alone would not explain the reasons for referral, in particular the benign referrals, where the biggest changes had occurred. Interviews with hospital consultants were chosen as the research method to elicit the broad factors influencing referrals to hospital breast clinics from the hospital viewpoint and interviews with GPs were carried out to examine the factors influencing GP referral decisions.

A number of patient factors have been described in the literature which can affect GP referral decisions, in addition to the patient’s medical condition e.g. age, anxiety, socio-economic group. Patient interviews did not form part of this research as the phenomenon under investigation was the GP referral to specialist units, as opposed to the patient presentation to primary care. Interviewing patients would have provided an insight into patients’ perceptions of why the GP did or did not refer them to specialist centres but would have not have addressed the research question as to the actual factors influencing GP referrals.

Factors influencing patient presentation to primary care has been researched previously for cancer in general (419-424) and for breast cancer specifically (425-431). Using a meta-ethnographic approach, Khakbazan et al. (432) investigated the factors influencing patient delay in patients with breast cancer symptoms. Eight key concepts were identified, which included symptom detection, interpretation and monitoring, emotional reaction, social reaction, priority of medical help, personal-environmental factors and
appraisal of health services in terms of accessibility and acceptability. Whilst the focus of this thesis was on factors influencing the GP referral, any delay in presentation to the GP will have an impact on subsequent decisions, treatment options and prognosis.

Given the complex and ‘real world’ nature of the study, a pragmatic approach was used for the research design. The dual role of the researcher as PhD candidate and health service employee was both challenging and useful. Researcher reflexivity was employed to address the challenge of potential biases arising from this dual role. The advantages of working in the health services at the time of the research included:

- the identification of an existing issue in the health service which required investigation
- the design of a study which was feasible in relation to availability of data and required minimal time and input from overstretched health personnel
- the enhanced possibility of research outcomes in the areas of research impact, policy impact and service impact, as health service personnel advised on the process and key areas requiring investigation throughout the process

Mixed-methods were chosen as the most appropriate and comprehensive method to answer the research question. Based on the rationale and overall methodological approach described in this chapter, the next chapters (Chapters 7 – 10) detail the methodology and results of each of the four inter-connected studies of this thesis.
Chapter 7: Study 1: Referral Patterns

7.1 Introduction
This thesis, based on a recommendation from the Health Information and Quality Authority (HIQA), aimed to explore the referral and triage patterns in the Symptomatic Breast Disease (SBD) units in Ireland.

In 2009, HIQA conducted a national review of Symptomatic Breast Disease (SBD) services in Ireland (6) which found significant hospital and regional variation in referral patterns from primary to secondary care. HIQA made a specific recommendation to investigate referral processes in SBD clinics “aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians” (6) (p.75).

The centralisation of breast cancer surgery in Ireland was completed in 2009.

7.2 Aim and objectives

**Aim:**
To examine GP referral patterns to SBD units in Ireland

**Objectives:**
- To examine the pattern of GP referrals to SBD units in Ireland over time (volume of referrals, triage categorisation, cancers detected)
- To examine diagnostic yield (proportion of GP referrals diagnosed as breast cancer), over time (pre- and post-centralisation)

7.3 Study design
This study was an exploratory mapping study to examine breast cancer referral patterns in Ireland and constitutes one component of the mixed-methods approach used for this thesis.
Data from the Symptomatic Breast Disease units (n = 9) were analysed for patterns and trends in GP referrals. The results of this initial mapping study were used to inform the development of the subsequent qualitative studies. This strategy ensured that the qualitative interviews were underpinned by local and national data, which helped to identify tangible reasons for variation in referral and triage patterns, as identified in the HIQA report. Morse’s taxonomy of mixed-methods design (417) describes this approach as a ‘development’ function in mixed-methods research.

During the pilot qualitative studies with hospitals, additional phenomena relating to referrals which warranted further investigation were raised in the interviews. A decision was made to expand this mapping study to include an exploration of certain types of referral, as these particular referral patterns had not heretofore been investigated on a national basis in Ireland. These data were obtained through the lead clinicians participating in the qualitative interviews. For clarity of presentation, the methods and results for these additional components are reported with the findings of this initial mapping exercise. Additional data were collected to explore the following issues raised by hospital consultants as part of an iterative approach to this research:

- Reported increase in referrals for family history of breast cancer
- Reported increase in referrals for mastalgia (breast pain)
- Reported increase in referrals during breast cancer awareness month in October each year

Secondary objectives were added to the study as follows:

Objective 3:
- To determine the proportion of GP referrals to SBD units for family history of breast cancer
Objective 4:
• To determine the proportion of GP referrals to SBD units for mastalgia

Objective 5:
• To determine if there is evidence of seasonal variation in breast cancer referrals

7.4 Sample

7.4.1 Data sources
Data from the National Cancer Control Programme were used to map existing breast cancer referral patterns to identify trends (Table 7.1). The data used were routine data submitted by the cancer centres to the National Cancer Control Programme for the purposes of performance monitoring and assurance of compliance with the HIQA standards for Symptomatic Breast Disease (167). These data are identified by hospital but do not contain any patient-identifiable data. The data are available to the public and are reported on the Health Service Executive (HSE) website as part of routine HSE performance monitoring. Each cancer centre reports Key Performance Indicator (KPI) data for all patients referred to the Symptomatic Breast Disease service. These are reported in the HSE performance monitoring reports on the HSE website www.hse.ie and also in the NCCP annual reports for Symptomatic Breast Disease on the NCCP website www.cancercontrol.hse.ie

Table 7.1: Data sources

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>2006 data: NCCP review of activity in breast clinics (NCCP, 2009)(48)</td>
</tr>
<tr>
<td>b</td>
<td>2009 HIQA: HIQA national quality review of the SBD service (HIQA, 2010)(6)</td>
</tr>
<tr>
<td>c</td>
<td>2009 NCCP: NCCP KPI data (NCCP, 2012)(3)</td>
</tr>
<tr>
<td>d</td>
<td>2010 NCCP: NCCP KPI data (NCCP, 2011)(12)</td>
</tr>
</tbody>
</table>

7.4.2 Data variables
Data variables included in this study were as follows:
Objective 1:
- To examine the pattern of GP referrals to SBD units in Ireland

Variables:
- Number of breast referrals (to each cancer centre and nationally)
- Number of referrals triaged as urgent and as non-urgent (to each cancer centre and nationally)
- Number of breast cancers detected (in each cancer centre and nationally)

Objective 2:
- To examine diagnostic yield (proportion of referrals diagnosed as breast cancer)

Variables:
- Number of referrals diagnosed as malignant (cancer)
- Number of referrals diagnosed as benign (non-cancerous)

These data were mapped for the years 2009 and 2010, and were presented both as national data and hospital-level data (Appendix E). These referral trends were provided to the participants in the hospital and GP interviews by post or by e-mail in advance of their interviews to facilitate the discussion on referral patterns.

7.5 Analysis

Objective 1: To examine the pattern of GP referrals to SBD units in Ireland (volume of referrals, triage categorisation, cancers detected).

Descriptive statistical analysis was conducted to examine the following:
7.5.1 Volume of referrals
The data on number of new attendances every month to each of the cancer centres have been collected nationally by the NCCP since 2009. These data
were obtained from routine NCCP KPI data for the years 2009 and 2010 for this study. In order to compare to referral patterns prior to centralisation, 2006 data were obtained from a review of activity in the SBD units (48).

7.5.2 Triage categorisation
The NCCP dataset includes the triage category for all referrals and is divided into urgent and non-urgent referrals. Referrals are triaged as urgent (to be seen in SBD clinic within 2 weeks) or non-urgent (to be seen within 12 weeks), based on their presenting features. Categories of urgent and non-urgent (early/routine) symptoms are outlined in the NCCP referral guidelines for GPs, as seen in Figure 7.1 below. A copy of the full GP referral guideline can be seen in Appendix A.

![Figure 7.1: Referral categories: GP referral guideline for breast referrals. Source: National Cancer Control Programme, GP referral guideline](image)

7.5.3 Cancers detected and diagnostic yield

Objective 2: To examine diagnostic yield (proportion of referrals diagnosed as breast cancer), over time.

Studies in the UK have reported rates of diagnostic yield (proportion of referrals with a cancer diagnosis), also referred to as positive detection rates, of 6% to 10% (5, 43-46). Imkampe (47) compared diagnostic yields before and after the introduction of the 2-week rule for cancer referrals in the UK and found that the proportion of referrals diagnosed with breast cancer dropped from 10% in 1999 to 7% in 2003-2004, after the introduction of the
rule. The diagnostic yield in each cancer centre and nationally in Ireland was examined during this exploratory phase.

HIQA reported emerging evidence of a decrease in diagnostic yields and also found geographic variation in diagnostic yields in their national audit carried out in 2009 (6). In order to examine this phenomenon over time, NCCP full-year data for 2009 and 2010 for diagnostic yield were examined. The numbers of breast cancers detected each month in each of the cancer centres were obtained from these data.

7.5.4 Family history of breast cancer

| Objective 3: To determine the proportion of referrals due to family history of breast cancer. |

Hospital consultants reported an increase in the numbers of patients referred for assessment of their family risk of breast cancer post-centralisation of services. The volume of referrals in this category had not heretofore been quantified on a national basis in Ireland. An Irish study (179)(p.2961) reported that, while rapid-access breast clinics experienced “cluttering by low-risk women”, 10% of those with a benign diagnosis had a significant family risk and required assessment of future risk. Inheritance of a mutated susceptibility gene is the underlying cause of 12% of breast cancers. Strict adherence to referral guidelines is recommended for referral of patients with a family history of breast cancer (190).

To investigate referral to SBD units for family risk, data were collected from hospitals on the proportion of GP referrals received for family history of breast cancer. A chart review was conducted in the SBD units of one month’s GP referrals to the breast units in 2011, to determine the proportion of referrals with family history of breast cancer as their primary reason for referral. Data were collected prospectively, as the reason for referral had not been routinely and consistently recorded in previous years.
7.5.5 Mastalgia

**Objective 4:** To determine the proportion of referrals for mastalgia.

Hospital consultants reported an increase in the numbers of patients referred for assessment of mastalgia post-centralisation of services. Similar to family risk, the volume of referrals in this category had not previously been quantified on a national basis in Ireland.

The risk of cancer in a woman presenting with breast pain as her only symptom is extremely low (433). An audit of GP referrals for breast pain to rapid-access breast clinics in North Cheshire in the UK found that 23% of their referrals were for breast pain but there were no malignancies detected in this group (434). Joyce *et al.* (186) recommended that women in Ireland under the age of 35 with mastalgia could be suitable for management in the primary care setting and outlined the resources in terms of time and cost of assessing these women in the hospital setting.

To investigate this phenomenon, data were collected from hospitals on the proportion of GP referrals received for mastalgia. A prospective chart review was conducted in 8 hospitals of one month’s GP referrals to the breast units in 2011, to determine the proportion of referrals with mastalgia as the primary reason for referral.

7.5.6 Seasonal variation

**Objective 5:** To determine if there is evidence of seasonal variation in breast cancer referrals.

Hospital consultants reported an increase in the number of GP referrals around the time of breast cancer awareness month in October each year, but this had not been examined on a national basis in Ireland. The Cardiff Breast group noted some seasonal variation in their breast cancer referrals, with peaks observed in the spring and autumn (43).
In order to explore this hypothesis, the number of referrals and number of new breast cancers detected by month were examined using NCCP KPI data.

7.6 Results
The results from this study (Study 1) have been published as a report ‘Review of Referral Patterns and Triage Processes in Symptomatic Breast Units’ in 2012 and is available on the NCCP website (3).

**Objective 1:** To examine the pattern of GP referrals to SBD units in Ireland (volume of referrals, triage categorisation, cancers detected).

7.6.1 Volume of referrals
Figure 7.2 shows the total number of new attendances nationally to symptomatic breast units in 2006 (prior to centralisation), 2009 (during centralisation) and 2010 (immediately post centralisation). This includes referrals to all public hospitals for symptomatic breast disease, excluding patients who did not attend for their appointment (DNAs). The outcome in relation to benign diagnosis and breast cancers detected is also shown.

These data represent the patients attending symptomatic breast services in the public hospitals and do not include the National Breast Screening Programme (BreastCheck) or the private hospitals. The Breast screening service and the symptomatic service are two separate but parallel services in the Irish health care system. This study examines GP referrals to the symptomatic service.

National data collection on referrals to the SBD Units commenced in 2009. Data from 2006 is from an audit of symptomatic breast clinic activity in public hospitals undertaking primary surgical treatment of breast cancer (48).
Figure 7.2: GP referrals to symptomatic breast clinics.

Figure 7.2 shows that new referrals to the symptomatic breast disease units in Ireland have increased rapidly, without a corresponding increase in breast cancer incidence. There were 23,575 new referrals for breast disease in 2006, which increased to 32,249 new referrals in 2009 (48) and to 37,631 new referrals in 2010, an increase of almost 60% in five years (12). The small decline in breast cancer incidence in the symptomatic service coincides with the national roll-out of the breast screening programme which is a separate service and is not included in this data. The reasons for the
overall increase in GP referrals to the symptomatic service and the proportionate reduction in diagnostic yield were explored in this study.

Table 7.2: Referrals to symptomatic service and breast cancers detected

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancers detected</td>
<td>2,137</td>
<td>1,879</td>
<td>2,012</td>
</tr>
<tr>
<td>Benign diagnosis</td>
<td>21,438</td>
<td>30,370</td>
<td>35,619</td>
</tr>
<tr>
<td>Total referrals to symptomatic service</td>
<td><strong>23,575</strong></td>
<td><strong>32,249</strong></td>
<td><strong>37,631</strong></td>
</tr>
</tbody>
</table>


Table 7.2 shows the total number of referrals to the symptomatic breast service, the number of breast cancers detected and the number of benign referrals. The number of hospitals providing symptomatic breast clinics decreased to nine designated units in 2010 as part of the centralisation process in the public hospitals. In individual symptomatic breast units, the highest number of annual referrals was 4,913 referrals to Beaumont Hospital in 2009 and 5,738 referrals to Galway University Hospital in 2010.

7.6.2 Triage categorisation

Figure 7.3 displays the proportion of referrals to symptomatic units triaged as urgent and non-urgent across all centers. While the total number of referrals to the symptomatic service increased nationally, the proportion of urgent referrals remained stable at 33% in both 2009 and 2010. These data were not available in previous years.
There was some variation in the proportion of urgent and non-urgent referrals between hospitals with a range of 17% – 54% urgent referrals from GPs in 2009 and 15% – 47% urgent referrals in 2010. This may be due to variation in the population who present to each GP or may be due to the referral practices of individual GPs. There are currently no defined catchment areas for these hospitals and GPs can refer to any of the cancer centres. As the triaging of patient referrals by GPs occurs outside of the hospital, controlling for inter-hospital variation was not applicable and therefore clustering by hospital site was not applied.

7.6.3 Diagnostic yields

Objective 2: To examine diagnostic yield (proportion of referrals diagnosed as breast cancer).

The HIQA review of Symptomatic Breast Disease (SBD) Services (6) highlighted significant variation between hospitals in the proportion of breast cancers detected.
Table 7.3: Diagnostic yield in breast referrals to symptomatic service

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2009</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of new referrals with breast cancer detected</td>
<td>9.1%</td>
<td>5.6%</td>
<td>5.8%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Data source</td>
<td>NCCP audit</td>
<td>HIQA audit (7 months)</td>
<td>NCCP</td>
<td>NCCP</td>
</tr>
</tbody>
</table>

Table 7.3 shows the proportion of new referrals to the symptomatic breast service with breast cancer diagnosed. An NCCP audit found that, in 2006, prior to centralisation of breast cancer services in Ireland, the proportion of referrals for breast disease that had breast cancer detected was 9.1% (48).

In 2009, during the seven months of the HIQA review, 17 benign referrals were seen for every one cancer diagnosed (i.e., the proportion of referrals diagnosed with breast cancer was 5.6%, with a range between hospitals of 2.6% - 7.1%). The remaining referrals were seen and diagnosed as having benign conditions (6). Full-year 2009 data from the NCCP found a similar proportion of 5.8% (3).

By 2010, the proportion of referrals diagnosed with breast cancer was 5.3% (12), with a range between hospitals of 4.2% - 7.1%, showing that while the proportion of cancers detected has fallen, the variation between hospitals reported in the 2009 HIQA review has reduced considerably.

7.6.4 Cancers detected

The number of new cancers detected was examined across SBD units. Of the 32,249 new attendances to SBD Units nationally in 2009, 1,879 had a primary breast cancer diagnosed. Of the 37,631 new attendances in 2010, 2,012 had a primary breast cancer diagnosed (12) (see Table 7.2). The number of new cancers diagnosed in individual cancer centres was highest in University Hospital Galway in 2009 (319 cases) and Cork University Hospital in 2010 (336 cases).
7.6.5 Family history of breast cancer

Objective 3: To determine the proportion of referrals due to family history of breast cancer.

To investigate specific referral patterns in relation to family history, a chart review was conducted to assess GP referrals for one month to the Symptomatic Breast Disease Units (n = 2,980 referrals). All SBD units except Galway agreed to participate in the study on family history referrals.

![Proportion of patients referred to SBD clinics for assessment of family history](image)

Figure 7.4: Proportion of referrals for assessment of family history. Source: Review of referral patterns and triage processes in Symptomatic breast units. O’Rourke (2012) (3).

LGH: Letterkenny Regional Hospital
ULH: University of Limerick Hospital
WUH: Waterford University Hospital
CUH: Cork University Hospital
MMUH: Mater Misericordiae University Hospital
BH: Beaumont Hospital
SJH: St James’ Hospital
SVUH: St Vincent’s University Hospital
Findings indicated that an average of 9.1% of GP referrals were for assessment of family history of breast cancer as the primary reason for referral, ranging from 3.9% to 14.2% between hospitals. Clustering by hospital site was not applied, as the reason for referral (family history) is based on the GP referral, which can be to any one of the SBD units nationally. Figure 7.4 shows that the highest proportion of referrals for assessment of family history was seen in St Vincent’s University Hospital (Dublin) and Cork University Hospital, with the lowest in Waterford and Limerick.

For the data on family risk and mastalgia, patients were allocated to these categories if mastalgia or family risk was their primary reason for referral. E.g. if a patient presented with family risk and a breast lump, they were not included as a family risk referral for this research. Therefore the number of patients presenting with family history or mastalgia is likely to be higher.

7.6.6 Mastalgia

Objective 4: To determine the proportion of referrals for mastalgia (breast pain).

The chart review also assessed GP referrals for mastalgia for the same month to the SBD Units (n = 2,980 referrals). All SBD units except Galway agreed to participate in the study on mastalgia referrals.
Findings indicated that an average of 15.3% of GP referrals were for mastalgia as their primary reason for referral, ranging from 10% to 18.6% between hospitals. Inter-hospital variation was not examined, as the reason for referral (mastalgia) is based on the GP referral, therefore clustering by hospital site was not applied, for reasons detailed earlier.

Figure 7.5 shows that the highest proportion of referrals for mastalgia was seen in St Vincent’s (Dublin), Letterkenny (satellite unit in Donegal) and Limerick, with the lowest in Waterford.

7.6.7 Seasonal variation

Objective 5: To determine if there is evidence of seasonal variation in breast cancer referral patterns.

Figure 7.6 shows the total number of referrals (urgent and non-urgent) seen in the SBD units, by month, over the 3 years 2009 - 2011.
In 2009, the highest number of referrals was seen in October, which corresponds with reports of an increase in referrals during Breast Cancer Awareness Month (annually in October). In 2010, there were several peaks and troughs throughout the year. Data for 2011 shows peaks in March, May and November. When all three years are examined together, the month in which most referrals are seen is November (average 3,396 referrals), followed by March (average 3,355 referrals). There does not appear to be a marked increase in October.

An alternative explanation for the perceived ‘October surge’ could be that breast clinics may have been quieter during the summer months due to patients and staff being away on holidays. The month the patient is seen may not be the same month as they are referred eg. patients may be referred at the end of one month and are seen the following month if they are referred urgently or possibly later if they are non-urgent referrals.

Statistical analysis using time series analysis (Poisson segmented regression) is recommended to examine this phenomenon in more detail. Interrupted time series analysis is the strongest quasi-experimental study
design to analyse longitudinal effects of interventions (435-437), including natural experiments or ‘real world events’, such as this study.

A minimum number of data points and a sufficient number of observations at each data point is recommended. Detecting cyclical patterns of seasonal variation requires a baseline series that spans enough time periods. A minimum of 50 time points is recommended for using these models (435). Therefore, as the data available did not reach this minimum criterion, this analysis was not possible with the data available. It is recommended that additional statistical analysis is carried out on this phenomenon when over four years national data is available.

ARIMA (autoregressive integrated moving averages) models could also be used to smooth out curves and test for trend. However, this would require an increased number of data points, not currently available.

Figure 7.7: Number of newly-diagnosed breast cancers, by month. Source: Review of referral patterns and triage processes in Symptomatic breast units. O’Rourke (2012) (3).
Figure 7.7 shows the number of newly-diagnosed breast cancers in the Symptomatic Breast Units by month. This is based on the date of the histology report, which is normally within 10 days of attendance. For patients attending the Triple Assessment Clinic (TAC), the biopsy is normally taken on the day of attendance. Triple Assessment Clinics provide clinical examination, diagnostic imaging (e.g., mammogram) and biopsy for patients referred to the clinic requiring triple assessment.

In 2009, the months in which the highest numbers of breast cancers were diagnosed were July (184) and November (176). In 2010, there were several peaks in numbers of cancers diagnosed, in April (188), July (185) and September (186). Data for 2011 show the highest peak in November (212). When all three years are examined together, the month in which most cancers are diagnosed is July, followed by September and November. Overall, there does not appear to be a seasonal trend or seasonal variation in the detection of breast cancers in the SBD units in Ireland. Further analysis with longer-term data is required.

7.7 Summary
The pattern of referrals to the SBD units shows an increase in referrals but without a corresponding increase in breast cancers detected, i.e., the increase in referrals is comprised of predominantly benign (non-cancerous) referrals. The factors influencing this trend were explored in the qualitative studies presented in the next chapters.

In 2011, of the total of 37,955 referrals to the SBD units in Ireland, approximately 3,454 patients were referred for assessment of breast cancer family risk (9.1%), with an additional 5,807 referrals for mastalgia (15.3%). Management of these women in primary care would significantly reduce the number of referrals to Symptomatic Breast Units. Factors influencing these types of referrals and recommendations for interventions were explored in the qualitative studies with both hospital consultants and GPs.
While increases in referrals were seen in some years in the months following breast cancer awareness campaigns, this was not consistent across all years. Statistical analysis using time series analysis over a longer time frame is recommended to analyse seasonal variation in more detail.

The HIQA report recommended a review of referral and triage processes to assess variation in referral patterns (6). This current review of referral patterns has established that the level of variation between hospitals found in the 2009 HIQA review has decreased considerably by 2010. The HIQA review was based on data for the first 7 months of 2009, before national availability of breast cancer screening and before centralisation of breast cancer surgery was complete. The interventions which have been implemented since this time include:

- the completion of centralisation of breast cancer surgery (December 2009)
- the development of GP referral guidelines and standardised referral forms (2009)
- the completion of the national roll-out of the national breast screening programme (December 2011)

Since the implementation of these initiatives, the major geographical variation in referral patterns seen in 2009 has declined substantially. However, the volume of referrals continues to increase. To investigate this phenomenon, an in-depth qualitative study with consultants in the cancer centres was designed as the second study (Study 2) in this thesis to explore their views on the rapid increase in referrals to SBD units, in the absence of an increase in cancers detected.

In addition, a before-and-after study was carried out using the National Cancer Registry database of breast cancers diagnosed pre-centralisation (2008) and post-centralisation (2010) to examine the impact of centralisation. This study is described in Chapter 10.
For the qualitative studies (Study 2 and 3), the data generated in Study 1 was circulated to all participants in advance of the interviews, to facilitate targeted discussion (Appendix E). Participants were asked at interview to comment on the data on breast cancer referral patterns and to identify local and national factors influencing referrals.
8.1 Introduction
Hospital consultants have expressed concerns about the increasing volume of GP referrals to symptomatic breast clinics in Ireland (1, 2). The first of the qualitative studies (Study 2) for this thesis was conducted with hospital consultants in the symptomatic breast units, or their nominee, to explore the data trends of referrals generated in Study 1. Participants were asked their views on local and national factors influencing GP referrals and for recommendations on interventions which could be implemented to address these.

The HIQA national review of the Symptomatic Breast Services in 2009 found variation in referral patterns from primary to secondary care and recommended that the HSE review referral processes to examine variations in referral practices between the designated centres and their referring clinicians (6). Study 1 of this thesis investigated whether these variations persisted post-centralisation of cancer services. Although the variation was not as pronounced as previously, some variation persisted. The trend of increasing numbers of referrals to the breast units was mapped in Study 1, showing an increase in GP referrals of almost 60% in 5 years. The reasons for this increase formed the focus of enquiry for this qualitative study with hospital consultants.

8.2 Aim and objectives
This qualitative study sought to identify factors influencing referral patterns by examining both the medical and non-medical influences on referrals from GPs to Symptomatic Breast Disease (SBD) Units in Ireland, from the perspective of SBD unit consultants (or their nominee).
Aim:

- The aim of this study was to explore the perceptions of hospital staff on the factors influencing GP referrals to Symptomatic Breast Disease Units in Ireland.

Objectives:

Primary objectives:

- To explore perceptions of hospital SBD teams on the factors contributing to the increase in GP referrals to SBD units in Ireland.
- To explore potential reasons for the decrease in proportion of GP referrals diagnosed with cancer.
- To ascertain the views of hospital SBD teams on the accuracy and adequacy of GP referrals.

8.3 Design

The research with hospitals was qualitative in design, using in-depth semi-structured interviews. This method was chosen as detailed exploration of the views and experiences of participants was required. Interviews are considered the most suitable for this exploratory research, investigating opinions, values and motivations (418). Semi-structured interviews were conducted with the hospital consultant or his/her nominee in each of the eight specialist cancer centres and the satellite centre in Letterkenny, Co Donegal (See Figure 8.1).

8.3.1 Study participants

All SBD Units were invited to participate in the study – the eight designated cancer centres and the unit in Letterkenny, Co Donegal, which is a satellite of the SBD Unit in Galway University Hospital. The key informant in each hospital was the Lead Clinician for Symptomatic Breast Services or their nominee. Figure 8.1 shows the location of these hospitals within the four HSE regional networks.
These 9 hospitals are located in the four HSE geographical regions (networks), as outlined in Table 8.1 below.
Table 8.1: HSE Cancer Networks

<table>
<thead>
<tr>
<th>HSE Region / Network</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dublin North East (DNE)</td>
<td>Beaumont Hospital (BH), Dublin</td>
</tr>
<tr>
<td></td>
<td>Mater Misericordiae University Hospital (MMUH), Dublin</td>
</tr>
<tr>
<td>Dublin mid Leinster (DML)</td>
<td>St James’s Hospital (SJH), Dublin</td>
</tr>
<tr>
<td></td>
<td>St Vincent’s University Hospital (SVUH), Dublin</td>
</tr>
<tr>
<td>South</td>
<td>Cork University Hospital (CUH)</td>
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<tr>
<td></td>
<td>University Hospital Waterford (UHW)</td>
</tr>
<tr>
<td>West</td>
<td>University of Limerick Hospital (ULH)</td>
</tr>
<tr>
<td></td>
<td>University Hospital Galway (UHG)</td>
</tr>
<tr>
<td></td>
<td>Letterkenny General Hospital (satellite unit) (LGH)</td>
</tr>
</tbody>
</table>

8.3.2 Recruitment and response rate
A letter of invitation was sent to each clinical lead for SBD services in the 9 hospitals. This was followed up with a phone call where necessary. All units agreed to participate in the study.

8.4 Procedure
The principles outlined by Kvale (438) for qualitative research interviewing were employed, including questions which were introductory, follow-up, prompts and probes, direct and indirect. The use of silences was also used to encourage the participants to elaborate on points raised (439).

To facilitate targeted discussion on trends and variances, national and hospital-level data from Study 1 was circulated to participants in advance of the qualitative interviews (Appendix E). This helped to avoid or move beyond ‘talk tracks’ focussed on participant’s own areas of interest (438). At interview, the participants were asked to comment on the possible reasons for the upward trend in referrals both locally and nationally. This approach served to overcome the lack of depth of the quantitative data available and provide richness through a qualitative approach. Where data were presented by hospital, each hospital was given the identity code for their
hospital only and asked at interview to comment on any variation between their hospital and others, and on possible reasons for this variation, if known.

The hospital interviews were conducted between December 2010 and May 2011. The Lead Consultant for each SBD Unit was invited to participate in a Key Informant Interview lasting approximately 40 minutes. The interview was based on a topic guide (Appendix F), which was circulated to participants in advance of the interview, along with a participant information leaflet and consent form (Appendix G, H).

Interviews were conducted either face-to-face (n = 7) or by telephone (n = 2), based on the preference of the individual clinicians. Telephone interviews can be used productively in qualitative research and the method of interviewing (telephone vs. face-to-face) has been shown not to influence responses (440, 441). They are considered a more practical approach for more geographically-dispersed participants and for reluctant respondents.

Telephone interviewing allows participants to feel relaxed and can facilitate disclosure of sensitive information (442), with considerable value to health services research (443).

There are a number of limitations with telephone interviewing. Irvine (444) found that the duration of telephone interviews was generally shorter than face-to-face, as a result of participants speaking for less time and providing more succinct responses, with less detail or elaboration. The absence of visual cues may also affect the depth of meaning (445). However a number of studies have found the quality of data from telephone interviews not to be noticeably different from face to face interviews (446) (447) and evidence is lacking that telephone interviews produce lower quality data (442) (443).

One pilot interview was conducted prior to commencement of the study and this interview was included in the study as there was no change to the study instrument. The same interviewer (NO’R) conducted all interviews. Written consent was obtained from all participants.
The interviews were arranged at a time and place to suit the interviewee and were digitally recorded with the consent of the participants and transcribed verbatim. Field notes and attributes such as gender and HSE network were also recorded and linked to each case using NVivo software. Typed transcripts were returned to participants to check for accuracy. The identity of the participants was kept confidential – a participant study number was allocated to each hospital at the point of data collection. Any information which could identify the respondent or hospital was removed and stored in a secure codebook (see section 8.4.3). The presentation of the results was anonymous; management of data was through use of codes. Interviews ranged from 28 to 58 minutes, averaging 42 minutes.

The lead clinicians who participated were six Consultant Breast Surgeons and one Consultant Radiologist. In the remaining two hospitals, the Cancer Nurse Specialist was nominated by the lead consultant to represent them. The participants who took part by telephone interview were two consultant breast surgeons.

8.4.1 Interview topic guide
The review of the literature found that variances in referrals, which are not as a result of clinical need, may be as a result of patient/clinical, provider or health service factors (15, 183, 206). Additional factors such as media and publicity are also known to impact on referral patterns (5, 46, 210, 227, 329). These broad categories were used to develop the interview topic guide.

Figure 8.2 shows a conceptual map for the study instrument, which was informed by the literature.
Open-ended questions were used in the interviews and, if required, prompts were also used, as shown in Table 8.2 below. The interview topic guide and participant information leaflet are contained in Appendix F and G.

Table 8.2: Summary of interview topic guide

- GP referral patterns to Symptomatic Breast Disease Units.
- Factors influencing local referral patterns:
  - health service factors
  - patient factors
  - provider factors
- Possible actions/solutions

8.4.2 Research ethics

Research ethics applications were made to the Research Ethics Committee in each of the 9 participating hospitals. Research ethics approval was received from the 9 hospitals between December 2010 and May 2011. Copies of approval letters can be found in Appendix I.
8.4.3 Data handling and data confidentiality
Data storage procedures are in accordance with the RCSI Division of Population Health Sciences Data Handling Guidelines. Interviews were digitally recorded, transcribed and stored electronically on a password-protected computer. Details which could be identifiable from individual interviews were anonymised in any reports and recorded in a codebook. A participant study number was allocated at the point of data collection. As there are only two cancer centres in most of the regional networks, the network has not been identified in the results.

The measures to ensure confidentiality of collected data also complied with the HSE Information Security Policy (V2.0 Nov 2010), the HSE Data Protection Breach Management Policy (2010), the National Hospitals Office Code of Practice for HealthCare Records Management (2007) and the HSE Standards and Recommended Practices for Healthcare Records Management (V3.0 2011).

8.5 Data Analysis
8.5.1 Analytic structure
Qualitative thematic analysis was carried out using NVivo10 to identify emerging themes. Credibility and interpretation was established through the ‘constant comparative method’ (448, 449) involving constant and repeated checking and interpretation of data (450). Two people checked the de-identified interview transcripts for accuracy. The second person (HM) was a breast cancer nurse specialist familiar with the structure of the breast service. Using analytic software such as NVivo facilitates an audit trail which ensures that the results and recommendations are routed in the data (451).

The analytic strategy for this study is based on the principles of thematic analysis (452) and is adapted from a QDA NVivo training workshop (453). There were eight discrete cycles of analysis for this study. These cycles involved three separate cycles of coding, two cycles of managing codes, one for data reduction through consolidating codes into a more abstract theoretical framework and three using writing itself as a tool to prompt
deeper thinking of the data (451), leading to findings from which conclusions could be drawn.

**Phase 1: Generating initial ideas**

Each transcript was read several times for data familiarisation and transcribed verbatim. Broad open coding of each transcript was conducted in QSR NVivo10 to deconstruct the data into general themes, using thematic analysis. The constant comparative method (448, 449) or ‘accuracy of fit’ (454) was used by comparing themes across different cases. The data were broken down into discrete incidents (454) or units (455), which were then coded into thematic categories. These categories were not pre-defined but, rather, derived from the data, through a process of inductive reasoning.

Clear labels and definitions were assigned to each theme as rules for inclusion (449). Researchers should stay “as close to the construction of the world as the participants originally experience it” (p.18) (449), therefore participant’s own terms and language were used to construct initial themes. These definitions were recorded and stored in NVivo to ensure consistency in coding throughout the process. The same person (NO’R) carried out the coding for all phases.

Coding was independently reviewed by a Breast Care Nurse Specialist (HM) from the National Cancer Control Programme who assisted the study through interpretation of observations and confirmation of findings. HM attended four of the hospital interviews and listened to all of the audio recordings. The coding structure was reviewed with this independent reviewer and any differences were discussed and resolved. These steps were taken to enhance the validity of the study.

**Phase 2: Categorisation of codes into potential themes**

Themes identified and coded in Phase 1 were re-ordered into categories of themes by grouping related themes under these categories and organising them into a framework. In this phase, smaller related categories were merged and some larger categories were distilled into several themes and re-labelled where necessary. Each coding phase was saved in the NVivo
programme to allow for review and revision. This also served as a tool for transparency and audit.

**Phase 3: Reviewing themes**
The restructured themes were broken down into sub-themes to offer more in-depth understanding of the highly qualitative aspects under scrutiny such as attitudes, beliefs and behaviours coded to these categories, and to offer clearer insights into the meanings embedded therein, a process referred to as ‘coding on’. Divergent views and negative cases were used to challenge generalisations (451). As Taylor and Bogdan (456) describe “the researcher refines these concepts, identifies their properties, explores their relationships to one another and integrates them into a coherent explanatory model” (p.126).

**Phase 4: Data reduction**
This involved consolidating the codes into a more abstract and conceptual map of a final framework of codes. The Theoretical Domains Framework (TDF) (244) was used to further analyse the data following the initial identification of themes. This framework was not applied *a priori*. This approach was chosen to ensure that the initial analysis did not become ‘hijacked by a method’ or ‘writing to the method’ as described by Bazeley (451). This allowed the data to speak for itself, without a predefined framework and facilitated the emergence of additional unprompted themes (450). Once the initial themes and sub-themes developed in Phase 3 were completed, these were also mapped onto the 14 domains of the Theoretical Domains Framework, Version 2 (244, 245), as described in Chapter 5. This double coding framework can be seen in Appendix J.

The fourteen domains of the Theoretical Domains Framework are as follows; skills; knowledge; memory attention and decision processes; behavioural regulation; environmental context and resources; social influences; professional/social role and identity; beliefs about capabilities; optimism; beliefs about consequences; intentions; goals; reinforcement; and emotion.
Coding reliability was checked by a second coder trained in the Theoretical Domains Framework (AF).

**Phase 5: Summary statements**

Summary statements were written against smaller sub-themes to offer a synthesis of the coded content they contained; using writing itself as a tool to prompt deeper thinking about the data (451).

**Phase 6: Analytical memos**

Analytical memos were written against the major themes, to summarise the content of each category and its codes, and to propose empirical findings against such categories. These memos considered key areas such as content of coding clusters, coding patterns and linking data to participant attributes, using matrices. Themes were situated in the storyboard – the relatedness of individual themes to other themes and their relevance to the research question were considered. Field notes and demographics were reviewed to examine any patterns linked to participant’s profiles. Findings were considered in the context of the current literature and gaps in the literature were also identified.

**Phase 7: Cross tabulation with attributes**

This phase included testing, validating and revising analytical memos to self-audit proposed findings by seeking evidence in the data beyond textual quotes to support the stated findings and seeking to expand on deeper meanings embedded in the data. This process involved interrogation of data, drawing on relationships across and between categories and cross-tabulation with demographics. This phase resulted in evidence-based findings, as there is a clear audit trail linking each finding with the data. Lincoln and Guba describe how “The process of comparative analysis stimulates thought that leads to both descriptive and explanatory categories” (p.341)(455).
Phase 8: Findings and discussion

This final phase involved the synthesis of analytical memos into a coherent, cohesive and well-supported outcome statement or findings report. “Themes only attain full significance when they are linked to form a coordinated picture or an explanatory model” (p.9) (457).

One weakness of qualitative research identified by Bazeley (457) is that researchers can rely simply on the presentation of key themes supported by quotes. She recommends that the first draft of qualitative results is written without quotes to ensure that the results are based on the wider evidence, rather than superficial reporting of themes using segments of text as evidence. This approach was used for this research and verbatim examples from the transcribed interviews were identified for inclusion only after the identification of key themes and writing up of initial findings.

8.5.2 Research quality

A number of the steps taken to ensure the rigour and validity of this research have been outlined in the analytic strategy above. Confirmability of findings, trustworthiness, consistency and dependability are all terms used to describe reliability in qualitative research (450). The use of in-depth interviewing as the study method increased the richness of the data, thus increasing credibility and internal validity (458).

The documenting of each phase of analysis in NVivo provided an audit trail throughout the analytical process (451). Memos, field notes and attributes were documented and linked to the cases in NVivo. Deviant case analysis was used to ensure that outliers were not ignored (459). Quotes were used to illustrate findings and provide validity (460). As recommended by Barbour (461), a second individual reviewed the coding framework at two stages during the process, firstly a breast care nurse (HM) reviewed the initial Phase 1 coding of the transcripts and secondly a PhD scholar familiar with the TDF framework (AF) reviewing the Phase 4 coding, where the codes were mapped onto the theoretical framework.
With regard to transferability, every symptomatic breast unit in the country participated in this research. A theoretical framework was used for the analysis to enable the transfer of findings at a theoretical level. The development and circulation of a report on the findings to the SBD unit consultants was used to enable a discussion of findings and recommendations at policy and strategy level (Review of Referral Patterns and Triage Processes in Symptomatic Breast Units – a hospital perspective, 2012)(3).

8.5.3 Models and frameworks
Michie’s COM-B model with its Theoretical Domains Framework (244) was used as the theoretical framework for this study, as described in Chapter 5. Informed thematic analysis was conducted with reference to the Theory of Behaviour Change. This model, with its components of capability, opportunity and motivation, was developed as a tool for designing and evaluating behaviour change interventions (251). The TDF framework was considered appropriate to this study given the context of implementation of an evidence-based policy of centralisation of breast cancer services in Ireland which included GP referral guidelines.

Theory can assist the identification of the mechanisms of behaviour change in clinical practice, allowing programmes and health systems to focus on the areas requiring change in order to implement an intervention. The development of effective intervention strategies using behaviour change theories has been shown to be effective (355). This qualitative research sought to understand and explain professional and social processes of referral patterns from the perspective of the hospital SBD unit consultant or his/her nominee.

8.6 Results
Table 8.3 shows the domains identified in hospital interviews, ranked in order of the frequency with which they were discussed. The main TDF domains emerging from the hospital interviews were environmental context and resources (volume of referrals, ease of access, diagnostic imaging),
knowledge (knowledge, education) and social influences (media and publicity, patient expectations). Domains which did not emerge as prominent during the hospital interviews were intentions, goals and emotion. The results are presented in order of decreasing prominence.

A small number of comments in one hospital interview were retracted during the transcript review stage. These were deleted from the transcripts and were not used in the analysis. Based on this learning and feedback from participants on the time required to review the transcripts, a decision was made not to use transcript review for the subsequent GP qualitative study. However, GPs were given the option of reviewing the transcript if they wished.

Table 8.3: Ranking of theoretical domains: hospital interviews

<table>
<thead>
<tr>
<th>Primary TDF domain</th>
<th>References from hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Environmental context &amp; resources</td>
<td>219</td>
</tr>
<tr>
<td>2: Knowledge</td>
<td>80</td>
</tr>
<tr>
<td>3: Social influences</td>
<td>73</td>
</tr>
<tr>
<td>4: Memory, attention &amp; decision processes</td>
<td>61</td>
</tr>
<tr>
<td>5: Skills</td>
<td>59</td>
</tr>
<tr>
<td>6: Behavioural regulation</td>
<td>44</td>
</tr>
<tr>
<td>7: Beliefs about consequences</td>
<td>28</td>
</tr>
<tr>
<td>8: Social/Professional role and identity</td>
<td>21</td>
</tr>
<tr>
<td>9: Beliefs about capabilities</td>
<td>20</td>
</tr>
<tr>
<td>10: Emotion</td>
<td>15</td>
</tr>
<tr>
<td>11: Reinforcement</td>
<td>4</td>
</tr>
<tr>
<td>12: Optimism</td>
<td>0</td>
</tr>
<tr>
<td>13: Intentions</td>
<td>0</td>
</tr>
<tr>
<td>14: Goals</td>
<td>0</td>
</tr>
</tbody>
</table>

Definitions of domains are taken from the TDF validation study by Cane et al. (245) and are based on definitions from the American Psychological Association’s Dictionary of Psychology (243).

As the TDF framework was applied after initial coding was carried out, this framework did not inhibit the transcription and analysis of the transcripts.
A number of themes arose which did not fit the TDF domains which included:

- Other cancers: participants spoke about service developments required for other cancers such as colorectal, testicular and gynaecological cancers, commenting that these were not as well developed as breast cancer services.
- Mode of referral: the mode of referral (letter, fax, electronic) and the benefits and challenges associated with these modes of referral were discussed.

These additional themes were not directly applicable to this study. The themes were coded but were not reported in the results.

In presenting the results, quotes are included to provide validity for the findings (460).

8.6.1 Environmental context and resources

| Definition: Any circumstance of a person’s situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour. |

Themes mapped to this domain included:

- Centralisation/reconfiguration
- Public vs. private health services
- Volume of referrals
- Geographical factors
- Health service factors: access to breast units, access to diagnostic imaging, breast screening, hospital-GP interface, resources and costs.

A screen shot from NVivo in Figure 8.3 below shows the coding framework for the domain or ‘tree node’ of ‘environmental context and resources’, with its component ‘child nodes’.

Centralisation / reconfiguration

The centralisation of cancer services by the NCCP into eight designated cancer centres was seen as a positive development and participants shared a view that members of the public appear to have greater confidence in the new centralised service with specialist multidisciplinary teams. However, the overall decrease in number of units as part of the centralisation process has transferred additional referrals to the remaining units.

“There has been a great turn-around since the NCCP.” (Hospital A)

“I think the NCCP is doing a very good job. When this all started, we were all looking over our shoulders. We’ve much more ownership of the process now, we’re much more empowered.” (Hospital I)

“When Hospital X closed in 2009, we started getting more referrals from Hospital X catchment area – it had an impact on our referral patterns as well.” (Hospital G)
Public vs. private services
A proportion of patients are having their breast surgery carried out in private hospitals. However, participants noticed a shift back to the public system since the designated cancer centres were established. Consultants felt this was due to confidence in the service and efficiency of the service. This phenomenon was observed by consultants in relation to patients who had private health care insurance but still wished to attend the public breast service. Thus, this phenomenon did not appear to be linked to austerity or recession. It was also remarked that the cancer service in the public system was more comprehensive than in the private sector. Consultants expressed pride in the service they provided.

“There is now confidence in public care with NCCP.” (Hospital A)

“Because we’re so efficient with the public system, most of the patients are coming through the public system.” (Hospital H)

“The other negative side of going private....they don’t actually get to see a breast nurse specialist, they don’t get the support systems in the private sector.” (Hospital B)

Volume of referrals
The increase in numbers being referred to the SBD Units was a common concern, with some participants expressing hope that the numbers will eventually level off. The increase in demand was also seen by some to be as a result of the quality of the service.

“The current monthly referrals are at about 500, and that’s really exploded in the last 6 months.” (Hospital H)

“It’s increased significantly over the last number of years. There is a steady increase in referrals constantly.” (Hospital C)

“We are victims of our own success.” (Hospital I)
This research was conducted at a time when budgetary constraints were being introduced in hospitals and a moratorium had been placed on staff recruitment, placing additional pressures on existing staff. It is possible that staff perceived their overall workload to be greater. Alternative agendas may also have influenced responses, to support proposals for additional resources for their units. However, the increase in numbers of patients referred to the individual clinics is validated by the quantitative data from hospital Key Performance Indicators (KPIs).

Geographical factors
Geography, distance to travel and physical location were seen as factors influencing GP referral patterns. Motorway infrastructure and availability of public transport were also seen to influence the hospital of choice. The referral process of the National Cancer Control Programme facilitates referrals to any of the 8 designated cancer centres, giving GPs and patients a choice of where to be referred to. However, there was a belief that some patients attended several different units in order to get a second opinion. Some participants commented on the distance the patients had to travel to the breast units, particularly in rural areas. However, there were no concerns raised by consultants about other negative impacts on patients, such as removal from family support systems.

“The highly rural population and the great distance for a lot of patients to travel to hospital......The road with the new motorway actually makes a huge difference.” (Hospital E) (in relation to local factors affecting referral patterns)

“Public transport influences where patients go. 600 GPs are referring to us.” (Hospital A)

“The phenomenon that we refer to as the ‘breast tourist’.” (Hospital I)

“It depends on what part of the county you’re living in. Some places are very remote from here – it can take an hour and 15 minutes from some of the places to get here.” (Hospital G)
Health service factors
Health service factors included access to breast units, access to diagnostic imaging, breast screening, hospital-GP interface, resources and costs.

Access to clinics
Ease of access to the SBD units was identified as a major factor influencing referrals. Consultants felt that access was perhaps too easy now and this was fuelling the rise in referrals.

“There is very good access now.” (Hospital A)

“I think perhaps because it’s so quick, and it happens so quickly, no effort involved, that it’s not a problem.” (Hospital B)

“I also think we have made this incredibly easy for the patient and incredibly easy for the GP and so there’s no requirement to be selective about who you refer, because you can refer everybody and we all bend over backwards to see them.” (Hospital I)

Access to diagnostic imaging (mammography, ultrasound)
The availability of local breast imaging (mammography) through GP referral was cited as a factor influencing GP referral decisions. Hospitals not providing this service felt that in the absence of GP direct access to imaging, GPs refer all patients to the Symptomatic Breast Service to rule out cancer and to reassure their patients. Access to private mammography varied, with some units having private service providers in the area and others not. Access to mammography was recommended, where this is required.

“There’s no GP access, lots of these women are the ones the GP gets to send in here for screening mammogram.” (referring to GP access to mammography) (Hospital H)

“The worried well and the need for mammography, that would be a large proportion of it.” (Hospital E)

“They would just send them in. It’s the only way patients can actually be seen, because we don’t have the direct access.” (referring to GP access to mammography) (Hospital G)
Breast Screening (BreastCheck)

The National Breast Screening Programme (BreastCheck) commenced in Ireland in 2000 and provides free mammography to women aged 50 – 64, every two years. At the time of the interviews there was regional variation in availability of BreastCheck, such that first-round screening had not yet been completed in all areas of the country and this was reflected in the interviews. First-round screening had been completed in all areas nationally by December 2011.

BreastCheck was cited as a factor influencing local referral patterns for a number of reasons. In areas where BreastCheck was not yet fully rolled out at the time of the study, hospitals cited the absence of BreastCheck as being a factor which increased referrals to their unit, as patients had nowhere else to go. Full rollout of the BreastCheck screening programme was recommended. A reduction in referrals had been noted in other areas where the BreastCheck programme had already commenced.

“We didn’t have BreastCheck in the region. It only came late 2010, so a lot of patients had no other way of getting seen unless they came through the symptomatic service.” (Hospital G)

“It’s a lot to do with the screening process not being really in place fully.” (Hospital E)

“There’s a significant cohort of patients that might otherwise have been coming to us that are captured by the screening programme and are reassured by their mammogram and they don’t come I suppose.” (Hospital I)

BreastCheck is currently provided for women aged 50-64. Emerging cohorts of ‘post-BreastCheck women’ are now seeking regular screening mammography in the SBD Units following their discharge from BreastCheck at the age of 65. Participants in one hospital voiced their concern about the perception among some women that they cannot get breast cancer after the age of 65. Extension of the BreastCheck programme beyond age 65 was recommended.
“There’s a phenomenon that we are starting to see now because of increased awareness and education is the post-BreastCheck patient, and increasingly we’re getting referrals now, you know, ‘this woman was having BreastCheck screening and she’s now past the screening age, please arrange routine mammography’ so that’s something that’s going to need to have to be looked at……most women say “sure, I can’t get breast cancer, I’m 66” - they actually believe that. It’s very worrying.” (Hospital I)

Hospital - GP interface
Consultants felt there was a good working relationship with the local GPs and felt GPs could contact them directly if they had concerns about their patients.

“We have a good relationship with GPs...they would ring us if they’re concerned about somebody.” (Hospital F)

“They don’t need to refer everybody, and they need to be sure that they will be backed up. We’ve been very good to the GPs, we give a fabulous service.” (Hospital I)

“We try to engage a lot more with GPs in the last couple of years.” (Hospital B)

Resources and costs
The cost of providing Triple Assessment Clinics (TAC) was also raised, although only by one unit. Triple Assessment Clinics provide clinical examination, diagnostic imaging (e.g., mammogram) and biopsy for patients referred to the clinic requiring triple assessment. The costs resulting from patients who did not attend (DNA) for their out-patient appointment was also raised.

(Referring to TAC clinics) “The cost per patient in TAC clinic is absolutely phenomenal. It has to be the most expensive activity in the hospital. ......we need to have some fiscal responsibility in this.....Not only do we have to be efficient clinically, we also have to be cost effective in what we’re doing.” (Hospital F)

“We estimate that a DNA costs about €80. There seems to be very little value out there perceived by the patient.” (Hospital B)
Interestingly, although ‘environmental context and resources’ was the domain most frequently referred to, key issues such as centralisation and reconfiguration were not discussed critically and participants did not problematise these issues, as this process was considered a successful policy intervention. However, this study only included the designated cancer centres and the views of the breast teams working there – the views of hospital staff working in hospitals which are not designated cancer centres may be different.

Only one hospital referred to the cost of providing a Triple Assessment Clinic. Additional references to resources were that perhaps the breast service had received too much funding, which could have been used in other less resourced sectors of the health service.

8.6.2 Knowledge

Definition: An awareness of the existence of something.

Themes which were mapped to this domain included:

- GP knowledge/education
- Electronic referral

Knowledge and education

Increased information, education and training for GPs in the areas of mastalgia, family risk and breast examination was recommended by participants, to assist GPs in the management of mastalgia and benign breast disease in primary care. In order to include as many GPs as possible, it was recommended that all GPs should be offered additional training and support. No education needs were identified by the consultants for the hospital staff.
“We’re waiting on the mastalgia materials [from NCCP], which will be fantastic, because even if it doesn’t discourage people from coming in, at least it puts them off for 3 months and they realise, actually, you know, I have to get on with this, there’s no magic answer to it.” (Hospital H)

“GP education, giving them the confidence and competence.” (Hospital E)

“I think GPs really do need to be given a bit of ownership over what symptoms are a worry and what ones aren’t.” (Hospital I)

Electronic referral
Participants encouraged the promotion of the Healthlink electronic referral system and questioned whether all GPs were aware of this system. Consultants recommended the inclusion of mandatory fields on the electronic referral form to ensure all relevant information was included. The integration of Healthlink electronic referral into the GP software systems was strongly recommended and was in the process of being implemented at the time of this study. The benefits of the electronic referrals were seen by hospitals in terms of level of information received, legibility of information, efficiency of the process and tracking of referrals.

“The Healthlink system, it’s fantastic when it’s used.” (Hospital B)

“If they were all Healthlink it would be much easier, it would be readable.” (Hospital I)

“The NCCP development of electronic referral has made the system more efficient. Proper electronic tracking is now in place for both the breast unit and the GP.” (Hospital A)

Participants questioned whether it was the type of GP using electronic referral which resulted in improved referrals and suggested that it may be the more informed GPs that have been the early adopters of this system.
“The electronic are better but I’m not sure if that’s a reflection of the fact that GPs that use it are more proactive.” (Hospital C)

“I think the users of Healthlink are perhaps the more innovative and informed people.” (Hospital I)

8.6.3 Social influences

**Definition:** Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours.

Themes mapped onto this domain included:

- Patient anxiety
- Media and publicity
- Patient awareness and education
- Patient expectations
- The ‘worried well’
- Seasonal variation

A screen shot from NVivo in Figure 8.4 below shows the coding framework for the domain or ‘tree node’ of Social Influences, with its component ‘child nodes’.
Patient anxiety
Consultants discussed the sources of patient anxiety and perceived that in addition to the time of diagnosis, much anxiety was generated from media and awareness campaigns. There were some repercussions from historic high-profile cases which took place before the current reorganisation of cancer services.

“There is a lot of education for breast, but the problem sometimes it’s hysteria; sometimes it’s too high sometimes.” (Hospital I)

“There’s a lot of panic, isn’t there, particularly here locally because of what happened with X.” (Hospital E)

“People tend to come, you know, worrying about things they really shouldn’t be worrying about.” (Hospital G)
Media and publicity

As outlined in the literature review chapter (Chapter 2), media and publicity are known to impact on referral patterns (5, 46, 210, 227, 328, 329). Participants commented on the power of the media and publicity, and the impact of media and publicity on referrals to the breast clinics.

One factor which influenced referral patterns through impacting individual’s behaviour was the visit of a celebrity singer with a history of breast cancer (Kylie Minogue). This also affected the age profile of patients referred. This was consistent with the finding of a UK study on ‘Kylie Minogue’s breast cancer: effects on referral to a rapid access breast clinic in the UK’ (329), which found that despite increased referrals there was no increase in the number of malignant diagnoses.

“We do get quite a few younger women whenever Kylie Minogue comes to the country, for whatever reason. She’s just been and the profile of the clinics was quite young.” (Hospital H)

“It’s lovely to say that we haven’t had Kylie or any other celebrities since, no more celebrities so we haven’t had the Kylie factor, it’s amazing.” (Hospital I)

The power and impact of publicity was discussed. Some participants felt that some of the messages were not suitable for all age-groups and tended to heighten anxieties, e.g., the message that 1 in 10 or 11 women will get breast cancer. More measured and appropriate messages were recommended. The impact of publicity was highlighted, both for its positive and negative effects. Consultants discussed the reputational damage done to the entire service based on a few heavily-reported cases which took place before the reorganisation of the cancer services.

“I really think that until the whole country settles and goes ‘OK breast cancer is being properly managed’, that will be the only time that people will be comfortable enough to say “I won’t send you into the clinic, you’re fine.” (Hospital H)
“We all know the publicity around the process, whether that is good publicity, i.e., increased patient awareness through advertising etc., or negative publicity through media hype and reporting of events, adverse events and incidences.” (Hospital I)

“I think we’re just suffering an awful lot from the damage that was done in the media to breast services. I think hopefully it will begin to turn around.” (Hospital F)

In relation to public health campaigns, there was recognition among participants about macro level processes and policies which impact on micro and meso level behaviours. It was recommended that an age-specific message be given for the annual Breast Cancer Awareness Campaign in October, so that people know that the risk of breast cancer increases with age. Education of helpline staff was also recommended.

“In the October campaign you will hear “one woman in 11 will get breast cancer”. There will be a group of teenagers sitting around in college thinking “which one of us has it”. It needs to be said that it is age-specific and that there is a much smaller risk in younger women compared to those over 70.” (Hospital A)

“A lot of people are ringing help-lines, so you don’t just educate the GPs; you’ve got to educate all those at the end of help-lines as well. They just want the responsibility gone from the end of their phone on to the next step.” (Hospital F)

“The older women aren’t being targeted at all.” (Hospital I)

Patient awareness
Awareness of breast cancer and awareness of the breast services was perceived to increase demand for the service. However, it was felt that the level of breast self-examination in women was lower than expected.

“I think women are quite aware, although I would say you would be surprised the amount of people who don’t examine.” (Hospital H)

“People are so much more aware now, aren’t they? And I think if anyone kind of gets any sort of a little niggling pain, they automatically go. I suppose from a GPs point of view, there’s easy access. The other side of it is it’s important that they are referred if they do have a
symptom......it's hard to know what the right thing to do is.” (Hospital G)

“There is undoubtedly a hugely increased level of consumer awareness, i.e., patient or women’s awareness, I think at one level there is a huge increase in the demand from women for breast assessment.” (Hospital I)

Patient education
Information for patients was recommended in relation to breast pain, breast self-examination and when to visit their GP. Clear information for patients on what to expect in the Symptomatic Breast Unit such as appointment scheduling, investigations and waiting times was also suggested. Information for older patients, particularly advice for those who have been discharged from BreastCheck at the age of 65 was seen as an emerging and growing need. The role of the Practice Nurse in patient education was identified as an opportunity.

“Key messages for patients – when to worry and when really not to worry. When you should really go to the doctor and when you don’t need to go to the doctor.” (Hospital G)

“The problem with patient education is, the people who are aware are the young patients and actually, the post BreastCheck age are not aware ......when they are being discharged from BreastCheck, they need to be told that the incidence of Breast Cancer increases with age, because I can’t tell you the number of women I had to tell last week “you can still get breast cancer after the age of 65” and they are horrified, so education, it seems to be at the younger patient level. They need to be informed, but actually the BreastCheck age and the older women, education is not hitting them.” (Hospital I)

“The majority of lumps you feel are not cancer, that’s a huge message.” (Hospital E)

Patient expectations
Hospitals perceived that patient expectations and patient demand, as well as an increased awareness of the breast service and an increased confidence in the public system had increased the number of referrals.
“Public are aware of the centres of excellence – they are good for urgent, but for routine, there is now an expectation that Triple Assessment will be provided for everyone in one day, including breast pain. Expectations have been raised.” (Hospital A)

“It’s about expectations.” (Hospital D)

“It’s too easy and we’re all very proud of what we do, but I just think, there are no obstacles to every single woman in the country who wants some form of breast assessment, just for a check-up, to be referred to the symptomatic breast unit and furthermore, being guaranteed an appointment within 12 weeks, and I think that’s the problem.” (Hospital I)

The worried well
The ‘worried well’ was a term generally used to describe a cohort of people without any symptoms who wished to undergo breast assessment as a form of regular screening for reassurance. This group were perceived to account for a large proportion of referrals to the SBD units.

“I think when GPs hear ‘rapid access’ they suddenly think this is their way to get their patients seen, and so I do think that they are sending in a lot of worried well.” (Hospital H)

“The worried well and the need for mammography, they would be a large proportion of it all right.” (Hospital E)

“I think we’re not responding to a clinical requirement, we’re responding to a kind of perceived need.” (Hospital I)

Seasonal variation
Concerns were expressed about seasonal variation in the autumn, corresponding with the traditional Breast Cancer Awareness Month in October each year. Participants felt that although there was an increase in referrals resulting from this campaign, there weren’t any additional cancers detected.

“We would see a huge increase in referrals from October, all the way through January / February would just be a surge. I don’t think there’s an increase in cancer over those months, no increases in actual
cancers during those months, it’s more an increase in referrals”. (Hospital E)

“Breast awareness month would have had an impact.” (Hospital F)

“We used to say “oh my God, here it comes, breast cancer awareness month”. We were already so swamped, it wasn’t possible to increase the referrals, you would always see it around October, as you know, but I think it’s maxed out at this stage, we see it all the time!” (Hospital I)

8.6.4 Memory, attention and decision processes

<table>
<thead>
<tr>
<th>Definition: The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.</th>
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Themes mapped to this domain included:

- Family history of breast cancer
- Mastalgia (Breast pain)

**Family history of breast cancer**

Participants reported an increase in patients referred for review of their family history of breast cancer, and felt many of these referrals did not require referral to the specialist units. Two units had dedicated family risk clinics, with the remaining units seeing these patients in the general SBD clinics. The absence of dedicated family risk clinics was seen as a deficit. The introduction of these clinics was recommended in areas where these were not established.

“I think we should be encouraging the GPs to hold on to all their family history, unless there’s more than one first degree relative.” (Hospital F)

“There’s no dedicated family history clinics in the centres. We would get a lot of family history referrals.” (Hospital G)

“A deficit in the breast referral patterns is the absence of established family history clinics and funding for those.” (Hospital D)
Clear information for GPs and patients on what constitutes a family risk of breast cancer was considered necessary. The development and circulation of guidelines from the NCCP was recommended.

“There wouldn’t be an accurate family history or certainly what you wouldn’t call a family history, maybe a first cousin or something like that ... People think that if they had an aunt who died in her eighties that they have a family history and a cousin or whatever, and I suppose they don’t know what the true family history is.” (Hospital G)

“If we could draw up guidelines to inform GPs as to what exactly constitutes a family history requiring referral.” (Hospital H)

“I know ye (NCCP) are working on a national referral guideline and form. And that will be great if that could be rolled out. It would divert a lot of what would take up a large amount in our triple assessment clinics.” (Hospital E)

Mastalgia
Participants reported a sizable number of referrals with mastalgia and felt many of these patients could be managed by GPs in Primary Care. The number of referrals with mastalgia was reported to be increasing. Consultants concluded this was partly due to ease of access to the breast services and partly due to patient anxiety.

“Our cancer services have been taken over by benign disease, by mastalgia. We’ve the best mastalgia service in the world, which is an unintended side effect of developing a cancer programme.” (Hospital C)

“Breast pain – we understand it, but the patients think they have cancer until proven otherwise. Patients need education and written information about breast pain to allay their anxiety, as many patients think breast pain may mean cancer. If GPs could look after mastalgia, it would reduce our clinics by approx. 900 patients in one year.” (Hospital A)

“We have to go back and think of some sort of public health initiative, which I think will re-educate women that breast pain the week before your period does not mean you have breast cancer.” (Hospital I)
8.6.5 Skills (Cognitive and interpersonal skills, physical skills)

Definition: An ability or proficiency acquired through practice.

Themes mapped to this domain included:

- Skills and training
- Accuracy of referrals
- Patient reassurance

Skills and Training
When discussing educational needs, additional training for GPs in clinical breast examination was recommended by participants. On-site training in a breast unit was suggested, which was already happening in some units. Participants did not identify any skills training required for the hospital team.

“The GPs also need to be happy doing the breast exam. Breast examination, the interpretation of symptoms, obviously the clinical assessment of the patient, the clinical assessment of the breast.” (Hospital I)

“The GPs have commented that asymmetric nodularity, lumps, fibrous tissue and cysts are difficult for GPs to differentiate.” (Hospital A)

“I think there needs to be some training for GPs in terms of using the NCCP referral form.” (Hospital B)

Accuracy of referrals
Hospitals reported the quality and accuracy of referrals received from GPs to be varied. Referrals using the official referral form were generally better than a GP letter.

“The form, when it’s used, is the best. Often the letter just says “thank you for seeing patient x who is complaining of…” and that’s it.” (Hospital E)

“Generally, I would have to say that more often than not, it’s pretty accurate what the GP has referred as urgent.” (Hospital D)
The level of urgency GPs assigned to referrals was also discussed. Consultants questioned whether individual GPs were ‘gaming the system’ to get their patients referred earlier.

“They know exactly when they say urgent on the triage; they know they’ll get an appointment within 2 weeks.” (Hospital E)

“All these TAC forms that say they have a lump and they never have a lump... We need to prove to the GPs that we know they are bluffing the request forms and we can’t keep this up nationally.” (Hospital F)

“GPs understand there is no screening now, so they are giving, I think some patients are getting symptoms they don’t have, just to get into the clinic.” (Hospital H)

“GPs sometimes refer patients with symptoms and when they arrive they don’t have the symptoms that they have said they had. And obviously it’s because they want them to be seen at the clinic.” (Hospital G)

“Regarding the information, we wouldn’t have triaged it as urgent, so it’s not accurate, no.” (Hospital B)

Patient reassurance
Hospitals alluded to the additional time required to reassure patients and the need to enable GPs to take on this role. The skills required to provide patient reassurance were not raised.

“The amount of time it takes the girls to reassure these patients.” (Hospital F)

“We need to try and empower the primary care physician to take more ownership in terms of reassuring them.” (Hospital I)

“They get sent in for a second opinion and for reassurance and that has impacted hugely on us; we’ve seen a lot of that.” (Hospital H)
8.6.6 Behavioural regulation

Definition: Anything aimed at managing or changing objectively observed or measured actions.

Themes mapped to this domain included:
- GP referral practices
- Referral form and guideline
- Protocols and compliance

GP referral practices / patterns
Participants commented on the alleged GP practice of sending a referral to several hospitals simultaneously, with the intention of taking the earliest appointment offered. There was also evidence of some patients attending several SBD units. Participants also believed that some GPs were ticking the box marked ‘breast lump’ in order to get an urgent appointment.

“They know that if they put the word lump down, that it’s automatic. If you are going to put everybody down as a lump, this system is not going to work.” (Hospital F)

“Breast tourists, these people, I don’t know whether it’s the patient or the GP or both, but they send the letter to whatever number of centres, and they may take the first appointment but some of them actually go to two centres.” (Hospital I)

“Whichever hospital gets the first appointment, it’s common practice with GPs.” (Hospital B)

Referral form and guideline
The GP referral guideline and form were regarded as useful, with a high level of sensitivity. There were suggestions made in relation to the specificity and format of the GP referral form, with some changes recommended to the indicators for referrals, such as mastalgia.
“I think it works pretty well for most of the GPs. Again, it’s user dependent.” (Hospital I)

“I think we should remove breast pain as an indicator for referral completely.” (Hospital C)

Protocols and compliance
The success of the National Cancer Control Programme and the HIQA review of the Symptomatic Breast Services were acknowledged. It was also noted that breast cancer has the most comprehensive set of standards of all the cancers.

“HIQA has been a good thing. We are all measuring our performance now and this has a direct effect on patient care......everything in the unit is done according to protocol.” (Hospital A)

“Prof O’Higgins and his colleagues produced that fantastic set of recommendations which is what informed the HIQA standards. There’s no other cancer that has those standards, so they will have to do a lot more work.” (Hospital I)

8.6.7 Beliefs about consequences

Definition: Acceptance of the truth, reality or validity about outcomes of a behaviour in a given situation.

Themes mapped on to this domain included:

- Risk
- Reliance on diagnostic imaging
- GP reassurance

Risk
Discussion on risk focused on cautious management of breast referrals in primary care, risk aversion and medico-legal implications. Consultants recognised that GPs do not wish to take a risk in the area of breast disease. This was seen to be partly due to the media coverage of investigations into individual cases. Consultants understood that GPs were referring patients for fear of missing a cancer.
“GPs have said ‘we are afraid not to send them in.’” (Hospital A)

“It impacts on the amount of referrals we get in because nobody is willing to take a chance.” (Hospital H)

“I think with the whole media perception and the number of investigations and difficulties has led general practitioners taking a decision to step back.” (Hospital C)

Reliance on diagnostic imaging
Participants commented on the perceived patient and GP dependence on diagnostic imaging for reassurance, with many women being referred for mammography imaging in the absence of any symptoms.

“If I was a GP and a woman came to me whose mother had breast cancer, there is no way in the world I’d send that women home without a mammogram, because that’s your patient, you want to do the best for her.” (Hospital F)

“They just say, ‘I know she’s OK but I’ll just send her in and just be sure, and let her have her mammogram and ultrasound done’.” (Hospital E)

GP reassurance
Hospitals acknowledged that some referrals were made to provide reassurance for the GP. Whilst consultants were happy to review any patients the GP was concerned about, they were cognisant of the impact on referral numbers.

“I don’t mind the GPs sending in anyone they are genuinely worried about.” (Hospital F)

“They are going to be told by their GP ‘I’m sending you in just in case. I’m happy, but just in case, just to be sure’. ” (Hospital I)

“They get sent in for a second opinion and for reassurance and that has impacted hugely on us; we’ve seen a lot of that.” (Hospital H)
8.6.8 Social/Professional role and identity

Definition: A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.

Themes mapped to this domain included:
- GP responsibility and ownership
- Gatekeeping

**GP responsibility and ownership**
Consultants perceived a current lack of ownership of breast disease in primary care and discussed the need to give some ownership back to GPs, especially as the GPs know the patients so well.

“Here the GPs know everybody and they know what they had for breakfast and they know when they are not at mass on Sunday that there’s a big problem, they know people so much better.” (Hospital H)

“I don’t think General Practice currently is prepared to take any ownership of the process... I do think that if we in some way give some ownership back to the GPs in this process, that would have an impact.” (Hospital I)

“The perception in the units would be that primary care has abdicated pretty much all interest in symptomatic breast disease and every patient gets referred.” (Hospital C)

**Gatekeeping**
Participants believed a gatekeeping process was required and that this was the role of the GP. Consultants felt there was a certain proportion of referrals which did not require specialist review and could be managed by the GP in primary care. Consultants focussed on changing individual GP referral behaviour as opposed to systematic changes such as increasing the capacity of the hospital SBD clinics.

“I think we need to educate the consumer, we need to give the GP some help in terms of managing these women in primary care and I think we actually need to make it a bit more difficult, we need to put in a bit of a gatekeeping process.” (Hospital I)
“I think we should be encouraging GPs to hold on to all their breast pains, all their bilateral nodularities unless there’s something particularly worrying.” (Hospital F)

8.6.9 Beliefs about capabilities

Definition: Acceptance of the truth, reality or validity about an ability, talent, or facility that a person can put to constructive use.

Themes mapped on to this domain included:

- Empowerment of GPs
- GP confidence

Empowerment of GPs

Participants discussed the role of the GP and empowerment of the GP to manage non-urgent cases in primary care. Participants discussed disempowerment of GPs in the management of breast disease. Referrals for a second opinion or for patient reassurance were seen as reasons for many referrals.

“I think we have disempowered our GPs in terms of decision making..... they get disenfranchised and they send them all to the clinic.” (Hospital I)

“We have to empower them; we haven’t empowered the GPs...I think we have to empower the GPs to keep some of their women in General Practice.” (Hospital F)

GP confidence

Many of the hospital respondents felt that there may be a lack of confidence in managing breast disease in primary care and that GP anxiety and GP level of experience in breast examination could be increasing the numbers of referrals received in the hospitals.

“The GPs need to be happy doing the breast exam. It’s the nodularity the GPs worry about.” (Hospital I)
I think if GPs were educated in treating mastalgia and had confidence in doing, treating it. I think it’s a confidence thing.” (Hospital B)

“They just have so many women coming in to them and they just, rather than take it on themselves, there are patients who could be managed in primary care, but they just feel they are safer, they’re just not confident.” (Hospital E)

8.6.10 Emotion

Definition: A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.

Themes mapped onto this domain included provider anxiety (GP/consultant anxiety).

Hospital participants acknowledged the anxiety of the GPs and understood that they were fearful of missing a cancer. There was less emphasis on consultant anxiety.

“Thereir fear is that they will miss a cancer.” (Hospital I)

“GPs have said ‘we are afraid not to send them in.’” (Hospital A)

“It’s just the GP worry factor.” (Hospital E)

“We do have a couple of BRCA\textsuperscript{1} families and other hereditary style breast cancers, so I’m more than anxious to keep an eye on all of them.” (Hospital H)

8.6.11 Reinforcement

Definition: Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.

Themes mapping onto this domain included HIQA.

\textsuperscript{1} BRCA is a human gene. Mutations in this gene are often found in breast and ovarian cancer.
The Health Information and Quality Authority (HIQA) and the National Cancer Control Programme (NCCP) were viewed as the enforcement bodies to which hospitals were accountable for maintaining the standards of the breast service. The success of the National Cancer Control Programme and the HIQA audit of the Symptomatic Breast Services were acknowledged. However, the unintended consequence of providing a successful service was also raised.

“HIQA has been a good thing. We are all measuring our performance now and this has a direct effect on patient care.” ....... “I wonder, are we victims of our own success?” (Hospital A)

“I think the 2-year audit process was a very useful and informative process at the time, but I don’t think it needs to be repeated again”. (Hospital I)

8.6.12 Optimism

Definition: The confidence that things will happen for the best or that desired goals will be attained.

There were no themes which mapped directly onto this domain as their primary focus. Related themes included NCCP and the cancer centralisation process. The success of the National Cancer Control Programme and the HIQA review of the Symptomatic Breast Services were acknowledged.

“There is now confidence in public care with NCCP......... There’s been a great turn-around since the NCCP, people know about the 9 centres. People are now phoning to come here and are well informed about the centres of excellence (public SBD unit) instead of private.” (Hospital A)

“I think that the NCCP is doing a very good job. When this all started, we were all looking over our shoulders. We’ve much more ownership of the process now, we’re much more empowered.” (Hospital I)
8.6.13 Intentions

Definition: A conscious decision to perform a behaviour or a resolve to act in a certain way.

There were no themes which mapped directly on to this domain as their primary focus. Related themes included protocols and compliance. Consultants acknowledged the NCCP Key Performance Indicators and reiterated their intentions to achieve these targets within their hospital.

“I think this process should inform improvement and change and enhance patient care.” (Hospital I)

8.6.14 Goals

Definition: Mental representations of outcomes or end states that an individual wants to achieve.

There were no themes which mapped directly on to this domain as their primary focus. Related themes included protocols and compliance.

Consultants and their teams wanted to provide the best possible care for their patients. Consultants acknowledged the success of the centralisation process and aimed to meet the quality standards and Key Performance Indicators (KPIs) set by HIQA and the NCCP.

“Meeting timelines has had a huge impact on service and the message out there.” (Hospital A)

“We’ve all settled down with our KPIs.” (Hospital I)

Content that was raised in the hospital interviews that was not included in this report related to discussions about other cancers (e.g., prostate, colorectal). Consultants felt that although breast services had been developed and enhanced, there was a need to replicate this level of service to other cancers.
8.7 Summary of findings
Participants focused attention on structural or macro level forces which affect health service provision, such as distribution of resources and use of evidence-based medicine. There were conflicting views on the management of benign breast conditions in primary care and only one hospital mentioned costs. Factors influencing referrals are summarised into health service factors, provider (consultant) factors, social and patient factors.

Health service factors
Consultants and their teams felt they provided a quality service, particularly since the establishment of the designated cancer centres. However, it was recognised that the health service would not be able to continue to provide this level of service, especially if the number of referrals continued to rise (environmental context and resources). This was considered by consultants to be a referral issue rather than a resource issue.

The scope of the Symptomatic Breast Service was questioned, as it accepts all breast referrals. The appropriate setting for treating patients with benign breast disease was an area of debate, with the view that the time and resources of Symptomatic Breast Clinics should be focussed on those with suspected cancers (environmental context and resources).

The efficiency and ease of access was seen as both complimentary and problematic and possibly fuelling the increase in referrals. The demand for the service has become greater than the capacity and consensus was that “we have become victims of our own success” (environmental context and resources, social influences).

Patient and social factors influencing GP referral
There was a perception among hospitals/consultants that increased patient information and awareness has led to increased patient expectations and perceived need (social influences). Whilst increased patient awareness was seen as positive in terms of patients recognising abnormal symptoms, there was a perception that media coverage and awareness campaigns appeared
to raise women’s anxiety and messages were currently aimed more at the younger age group, where there is a lower incidence of breast cancer (social influences). Although consultants reported a high level of patient confidence in the public cancer service, the need for reassurance through mammography imaging was a strong patient expectation noticed by respondents, particularly those patients outside the BreastCheck screening age (beliefs about consequences).

**Provider factors (hospital consultants)**

Participants in the hospital interviews articulated a great pride in the service they provide but questioned whether such ease of access to the service was appropriate or desirable (environmental context and resources). Consultants considered a system of gatekeeping necessary to ensure appropriate referral and optimum use of limited resources (professional role and identity/decision processes).

Consultants perceived that a variety of factors in primary care may have influenced the referral patterns, including GP anxiety (emotion); level of ownership in primary care (professional role and identity); and the need for enhanced training for GPs in breast examination (skills). The fear of missing a cancer and the cautious management of these patients was thought to increase referral numbers (beliefs about consequences). There were concerns from the hospital consultants about the possible disempowerment of GPs and an acknowledgement that GPs need to be supported in their role (beliefs about capabilities).

None of the emerging themes were coded to the TDF domains of optimism, intentions or goals as their primary domains and these appeared to be a poorer fit than other components in the framework. However, optimism was closely linked to the discussions around the cancer control programme, which was coded as ‘environment context and resources’ and the domains of intentions and goals were closely linked to the theme of ‘protocols and compliance’ which was coded as behavioural regulation. In these cases,
themes were allocated a secondary code in addition to a primary code, as seen in Appendix J.

The main recommendations made by the hospitals in relation to referrals to SBD units are listed below. As the interviews were conducted in 2010 and 2011, a number of these recommendations have already been initiated or implemented. These initiatives have been included in parentheses and are presented in more detail in the discussion chapter (Chapter 11).

- GP education, training and support – in the areas of breast examination, mastalgia, family risk and completeness of referral information (GP education programme commenced).
- Patient information on mastalgia, family risk and breast self-examination (patient information developed for mastalgia).
- Family risk – clear information for patients and clear guidelines for GPs on what constitutes a family risk for breast cancer. Consider the establishment of family risk clinics separate to the TAC clinics (GP referral guideline updated with advice on family risk).
- Mastalgia – information for GPs and patients on the management of breast pain. Consider the establishment of nurse-led clinics separate to the TAC clinics (Information developed for GPs and patients on mastalgia).
- Imaging – Clear national evidence-based guidelines on indicators for imaging and imaging requirements for asymptomatic women (breast cancer guidelines for diagnosis and staging developed).
- BreastCheck – continue national rollout of BreastCheck. Information for women being discharged from BreastCheck in relation to risk of breast cancer and access to services in the event of symptoms developing. Consider extending the BreastCheck age range above 65 (BreastCheck age-range to be extended in 2015).
- Integration of Healthlink (electronic referral) into ICGP accredited GP software management systems (Healthlink integrated into accredited GP software systems).
• Promotion of use of Healthlink and standard referral form by GPs (use of Healthlink promoted through CME, GP study days and articles in GP publications).

• Public information – Age-specific messages. Measured targeted messages for Breast Cancer Awareness Campaigns such as older age-group, symptomatic patients and post BreastCheck age-group (joint planning between NCCP and advocacy groups for awareness campaigns).

• Nurse training – training for nurses in the area of patient education (national training programme commenced for nurses caring for cancer patients).

The review of referral patterns in Study 1 established that the level of variation found in the 2009 HIQA review has decreased substantially. However, some variation between centres remained. Current geographical variances in cancer referral patterns may be as a result of patient, provider or health service factors. The finding of this qualitative study reflect a consensus in SBD units that patients should receive care in the most appropriate setting and should not be subjected to the stress of unnecessary investigation. Effective referral and triage processes should ensure the most effective use of available resources, better management of referrals and ultimately better outcomes for patients.

Participants in this qualitative study attributed this variation to several factors, including the remaining roll-out of the BreastCheck Screening service. BreastCheck is a population screening programme for women aged 50-65, with a structured call-recall system, separate to the Symptomatic Breast Service. According to participants, the BreastCheck service influenced referral patterns in several ways:

• In areas where BreastCheck was not yet fully rolled out, women in the BreastCheck age group of 50-64 were being referred to the Symptomatic Breast Unit as ‘there was nowhere else to go’.
Women who have been discharged from BreastCheck after the age of 65 are being referred back into the Symptomatic Breast Units to continue screening.

The overall increase in referrals nationally was perceived by the hospital consultants and their teams to be as a result of increased patient awareness, media-induced anxiety, ease of access to breast clinics and level of ownership in primary care.

Solutions recommended by the hospitals to address the volume of referrals included further education for GPs in breast examination; information for GPs and patients on mastalgia and family risk; and public information which is measured and targeted. Whilst acknowledging the anxiety of missing a cancer, the hospitals considered a gatekeeping process to be necessary. The opportunities to increase efficiencies through more accurate and complete referral information, electronic referral and the management of the patient in the most appropriate setting were widely endorsed. The cost of providing the TAC service was only alluded to by one hospital. However, the breast service was recommended as a system to be replicated for additional cancers and other diseases, which has resource implications for the health service if adopted.

The NCCP referral guidelines and referral form, with facility for electronic referral, were seen as positive developments, with a high level of sensitivity. There were some recommendations regarding specificity of the referral form. There was a high level of pride from health service personnel in the service they provided and they also remarked on the level of confidence of patients in the public breast cancer services. Hospital consultants and their teams contributed to the understanding of national and local factors influencing GP referrals to the breast clinics. However, this was from just one perspective, the hospital perspective. To ensure a more comprehensive understanding of factors influencing GP referrals, the third study in this thesis involved interviews with GPs referring to these breast clinics, to explore the factors influencing their referrals.
Chapter 9: Study 3: Qualitative Study with GPs

9.1 Introduction
Recent centralisation of cancer services in Ireland has streamlined the referral pathway for cancer patients, with the designation of eight specialist centres for cancer surgery and the introduction of GP referral guidelines and standardised referral forms. Referrals to Symptomatic Breast Disease (SBD) Units in Ireland have increased rapidly since this centralisation process, without a corresponding increase in breast cancer incidence. The reasons for this phenomenon were explored in this study.

The qualitative study with hospitals in Study 2 (Chapter 8) concluded that many factors influencing referrals to the cancer centres originated in General Practice, including adherence to referral guidelines, management of benign breast disease and seeking reassurance through specialist review and diagnostic imaging. Study 3, described in this chapter, presents research with referring GPs/family doctors who are central to this process. SBD units felt that existing national GP cancer referral guidelines were not being adhered to by referring GPs and that benign breast disease could be managed in primary care. Understanding the factors influencing GP referral practices could assist the development of effective health service interventions. In line with the Medical Research Council guidance on developing and evaluating complex interventions, stakeholder views and experiences can inform content and delivery of interventions (357).

This qualitative study with GPs sought to identify barriers and enablers to the implementation of evidence-based referral guidelines for breast cancer in order to explain referral patterns and inform future implementation interventions.
9.2 Background

GP referral guidelines for suspected cancers were introduced nationally by the National Cancer Control Programme (NCCP) in Ireland in 2009, with comprehensive education for GPs (3), as part of the centralisation of cancer services in Ireland.

Primary care is usually the first point of access for the patient into the healthcare system and the role of the General Practitioner as gatekeeper is widely acknowledged (13, 14). The GP role in the care of the patient with suspected cancer is key to early detection and referral at an early stage of disease (235).

9.3 Aim and objectives

This study aimed to determine the factors influencing referrals to Symptomatic Breast Disease (SBD) clinics in Ireland, by building on the issues raised in the hospital interviews, examining both the medical and non-medical influences on referrals from GPs to SBD Clinics.

Aim: To explore the perceptions of GPs on factors influencing GP referrals to Symptomatic Breast Disease Units in Ireland.

Objectives:

- To explore perceptions of GPs on the factors contributing to the increase in GP referrals to SBD units in Ireland.
- To explore potential barriers and facilitators to implementation of evidence-based GP referral guidelines.
- To investigate whether centralisation of cancer services has impacted on individual GP referral practices/behaviour.
9.4 Design

Current geographical variation, which are not as a result of clinical need, may result from patient, provider or health service factors (15). The research with GPs was qualitative in design, using in-depth semi-structured interviews to determine the factors influencing their referral decisions. This methodology was used as detailed exploration of the honest views and experiences of participants was required (418, 450). Vignettes were considered as an alternative methodology for the GP study. However, discussions by the researcher (NO’R) with six individual GPs concluded that GPs questioned considered vignettes to be a test of their knowledge rather than their intentions and they would seek to provide the ‘correct’ answers in these scenarios. This approach was not considered suitable for this study as the GP behaviour was being investigated.

Sampling was stratified across the four HSE regional cancer networks in Ireland (Figure 8.1) and included both urban and rural GPs, and male and female GPs. Sampling was designed as criterion-based stratified sampling – equal numbers of GPs were interviewed from the selection criteria (geographical location and GP gender). Contact details for GPs were obtained from an existing published list – the Irish Medical Directory (462). Sample size is discussed in Section 9.4.3.

9.4.1 Study participants

The random selection function in Stata (Version 10.1) was used to select 100 GPs from the 2,466 GPs listed in the Irish Medical Directory (2011-2012 edition)(462). 100 was chosen as the sampling frame in order to yield a minimum of 24 GPs to participate in the study. The ICGP database was considered as the sampling frame but was not used, as not all GPs are members of the ICGP and use of the ICGP database also has restrictions on number of reminders. GPs currently practicing in General Practice in the Republic of Ireland were eligible for inclusion in the study. Trainee GPs were excluded from the study.
Primary selection criteria were:

- Geographic location (HSE region/ cancer network)
- GP gender

These selection criteria were used to achieve ‘symbolic representation’ to ensure representativeness (463).

Attributes were recorded for each participant for type of GP practice (urban / rural); practice population (medical card\(^2\) / private); number of years practicing as a GP; structure of GP practice (single handed / group practice); and distance from the nearest cancer centre.

9.4.2 Recruitment and response rates

100 GPs were randomly selected and contacted. Twelve GPs were subsequently excluded as they had retired or were no longer working in the selected GP practice. From the remaining 88 GPs, 28 GPs accepted and further 15 GPs declined. The overall response rate was 49% (43/88) and acceptance rate was 32% (28/88) following one written reminder. 51% of GPs did not respond (Figure 9.1). This is similar to the 47% response rate in the ICGP postal survey of their members on a needs assessment for GPs for early detection of cancer in 2006 (260).

The last four GPs who agreed to participate in one geographical region (Dublin mid-Leinster) were not included in the analysis as the quota of GPs for this region had already been met and data saturation had been reached.

\(^2\) People who hold a Medical Card are entitled to a range of health services free of charge
Responders were more likely to be female from urban areas.

Twenty-eight GPs were interviewed in total and 24 were included in the analysis – six GPs from each of the four HSE cancer networks in Ireland (West, South, Dublin mid-Leinster and Dublin North-East).

9.4.3 Sample size
The proposed respondent sample size of 24 – 30 was an estimate of the number of qualitative interviews required in order to identify and thoroughly explore the key factors influencing GP referrals to cancer centres, i.e., to reach the point of data saturation – that is the point where an appropriate sample size has been reached with no additional perspectives or issues emerging from additional interviews (464). This is in keeping with estimate sizes of good practice for qualitative studies (465). The aim is to select participants based on their characteristics and not to generalise across the population, but to shed light on the range of issues and perspectives relevant to the research questions. Therefore, exact numbers are not rigidly fixed prior to the commencement of the study (464). The seven criteria for potential sample size described by Ritchie et al. (466) have been taken into consideration (heterogeneity of the population; number of selection criteria; nesting of criteria; special interest groups; multiple samples; data collection methods; budget and resources). Additional considerations in specifying sample size is the
richness of the data gathered and feasibility issues, given that qualitative research is a labour-intensive process including in-depth interviews, transcription, coding and analysis.

9.4.4 Recruitment

A letter of invitation, consent form and participant information leaflet with topic guide were sent to each GP being invited (Appendices K, L, M). One follow-up reminder letter was sent to non-responders. A minimum of six GPs from each of the four Cancer Networks was interviewed. Gender was nested in geographic location. Equal numbers of male and female GPs were interviewed. This reflects the ICGP database composition of 49.8% female and 50.2% male GPs (467). Additional characteristics of participating GPs are contained in Appendix N and are summarised in Table 9.1 below. Miles (1 mile=1.6 km) were chosen for measurement of distance to the nearest cancer centre to enable direct comparison with an ICGP study conducted in 2006 (260).

Table 9.1: Characteristics of participating GPs

<table>
<thead>
<tr>
<th>Catchment area</th>
<th>Distance from nearest cancer centre</th>
<th>Patient type</th>
<th>Practice type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban</td>
<td>&lt; 5 miles (8 km) 9 GPs</td>
<td>GMS (medical card) 6 GPs</td>
<td>Single handed 8 GPs</td>
</tr>
<tr>
<td>Rural</td>
<td>5 – 25 miles 6 GPs</td>
<td>Private only 3 GPs</td>
<td>Group practice 16 GPs</td>
</tr>
<tr>
<td>Urban + rural mixed</td>
<td>&gt;25 miles 9 GPs</td>
<td>GMS + private mixed 15 GPs</td>
<td></td>
</tr>
</tbody>
</table>

9.5 Procedure

The GP interviews commenced in March 2012 and took 5 months to complete. Interviews were conducted either face-to-face or by telephone, based on the preference of the individual GPs. Telephone interviews were used for the majority of the GP interviews (n = 21) and have been shown not to influence responses (440, 441). Pilot interviews were conducted with three GPs prior to commencement of the study and these were not included in the data for analysis as they were a purposive sample and not randomly
selected. There were no modifications to the study following the pilot phase. The same interviewer (NO’R) conducted all interviews.

The interviews were based on a topic guide, which was included in the participant information leaflet circulated to all participants in advance, along with the consent form (Appendices L, M). The data on national volume of referrals from Study 1 were also circulated in advance. Participants were prompted to elaborate on relevant issues (450). The duration of GP interviews ranged from 10 – 30 minutes, averaging 20 minutes and were arranged at a location and time to suit the participants. Interviews in the GP surgeries in the pilot phase and the main study enabled the researcher to gain a greater understanding of the referral process in context. Written consent was obtained from all participants. Participants who were interviewed by telephone submitted consent forms by post or fax. Interviews were digitally recorded with the consent of participants and transcribed verbatim. Field notes were documented during and after each interview. Copies of transcripts were available to participants on request.

A decision was made not to use transcript review and respondent validation for the GP study, based on learning gained from using this approach in the preceding hospital study and due to time pressure on participating GPs. The value of this approach has also been questioned. For example, Barbour found respondent validation useful to refine emerging findings but cautioned against the ‘collusion’ of accepting participant’s interpretations at face value (461). Similarly, Atkinson has cautioned on the dangers of ‘romanticising’ the accounts of respondents (468). Mays and Pope point out that while the process can be useful for error checking, respondents have individual opinions which may be discordant with the wider overall research findings (395). Barbour concluded that respondent validation can be useful in action research projects, but otherwise “may be more trouble than it is worth” (p.1117) (461).
9.5.1 Interview topic guide

The topic guide was developed based on the literature review, the consultant interviews and three GP focus groups held during GP training days (n = 52 GP participants in total) in Dublin. The focus groups concluded that GP referral decisions were based on more than medical factors alone. The conceptual approach used for this study builds on the approach used for the qualitative study with hospital consultants, outlined in Chapter 8 (Figure 8.2).

Factors influencing variation in GP referrals may be as a result of patient, provider or health service factors (15, 183, 206). These can also be triggered or enhanced by additional factors such as media and publicity (5, 46, 210, 227, 329). These topics were explored during the interviews and are summarised in Table 9.2. Where possible, the demographic information was documented in advance, where this information was already available in the public domain, e.g., in the Irish Medical Directory, websites of the GP practices or the registry of smear-takers established for the national cervical screening programme.

Table 9.2: Summary of interview topic guide

<table>
<thead>
<tr>
<th>Topic area</th>
<th>Prompts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic information</td>
<td>Gender.</td>
</tr>
<tr>
<td></td>
<td>Geographic location / HSE network.</td>
</tr>
<tr>
<td></td>
<td>Patient catchment area: urban/ rural / mixed.</td>
</tr>
<tr>
<td></td>
<td>Patient type/insurance cover: medical card/ private/mixed.</td>
</tr>
<tr>
<td></td>
<td>Number of years practicing as a GP.</td>
</tr>
<tr>
<td></td>
<td>Number of miles from nearest cancer centre.</td>
</tr>
<tr>
<td>Factors influencing GP referral decisions to cancer centres</td>
<td>Patient factors.</td>
</tr>
<tr>
<td></td>
<td>Provider factors (GP practice/individual GP).</td>
</tr>
<tr>
<td></td>
<td>Health service factors.</td>
</tr>
<tr>
<td>Impact of centralisation of cancer services and development of GP referral guidelines.</td>
<td>GP use of the national cancer referral guidelines, referral form, electronic referral.</td>
</tr>
<tr>
<td></td>
<td>Change in referring practice (if any) since introduction of the GP referral guidelines.</td>
</tr>
<tr>
<td></td>
<td>Change in referring practice (if any) since centralisation of cancer surgery.</td>
</tr>
<tr>
<td></td>
<td>Barriers / pressures relating to referral of patients with suspected cancer.</td>
</tr>
<tr>
<td>Recommendations from GPs</td>
<td>Additional services / training / support required by GPs.</td>
</tr>
<tr>
<td></td>
<td>Changes recommended to referral guidelines/forms.</td>
</tr>
<tr>
<td></td>
<td>Recommendations regarding additional information / support / services required by patients.</td>
</tr>
</tbody>
</table>
9.5.2 Research ethics
Research ethics approval was granted by the Irish College of General Practitioners in January 2012. A copy of the approval letter can be found in Appendix O.

9.5.3 Data handling and data confidentiality
Data handling procedures were in accordance with the RCSI and HSE data handling procedures used for the hospital study (detailed in section 8.5.3). A participant study number was allocated at the point of data collection which was not linked to identifiable details. Details which could be identifiable from individual GP interviews, such as place-names or hospital names, were anonymised in any reports.

9.6 Data analysis

9.6.1 Analytic structure
The analytic approach used for this study replicates the approach used for the qualitative study with hospital consultants and is detailed in Chapter 8. Qualitative thematic analysis was carried out using NVivo10 to identify emerging themes, with eight cycles of analysis. Two people checked the interview transcripts for accuracy. The same person (NO’R) carried out the coding for all phases and this coding was reviewed by a breast care nurse specialist (HM) who attended 20 of the interviews and listened to all of the GP interview audio-recordings. The inter-rater agreement of the coding was high and any differences were discussed and resolved.

9.6.2 Analytic strategy
The analytic strategy used for this study replicated the approach used for the qualitative study with hospital consultants and described in Chapter 8. The analytic plan has been described in detail in Chapter 8 and is summarised in Table 9.3 below (adapted from Braun and Clarke) (452).
Table 9.3: Analytic plan

<table>
<thead>
<tr>
<th>Analytic process</th>
<th>Practical application in NVivo</th>
<th>Strategic objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarising yourself with the data</td>
<td>Transcribing data, reading &amp; re-reading the data, noting down initial ideas.</td>
<td>Data management</td>
</tr>
<tr>
<td>Generating initial codes</td>
<td>Phase 1 – open coding of the transcripts</td>
<td>Descriptive accounts</td>
</tr>
<tr>
<td>Searching for themes</td>
<td>Phase 2 – categorization of codes into potential themes</td>
<td></td>
</tr>
<tr>
<td>Reviewing themes</td>
<td>Phase 3 – Coding on: More in-depth understanding of divergent views, negative cases, attitudes, beliefs and behaviours</td>
<td></td>
</tr>
<tr>
<td>Defining and naming themes</td>
<td>Phase 4 – data reduction: Consolidating codes into a more abstract and conceptual map</td>
<td>Explanatory accounts</td>
</tr>
<tr>
<td>Producing the report</td>
<td>Phase 5 – Summary statements Phase 6 – Analytical memos Phase 7 – Cross tabulation with attributes Phase 8 – Synthesising analytical memos into findings report.</td>
<td></td>
</tr>
</tbody>
</table>

9.6.3 Models and frameworks

As with the hospital interviews, thematic analysis was conducted with reference to Michie’s COM-B model and the Theoretical Domains Framework (TDF) (244, 245) as the theoretical framework for this study (described in Chapter 5). This model was chosen to explore GPs self-reported referral practice and to describe the reasons for adherence or non-adherence to evidence-based referral guidelines, using Theory of Behaviour Change.

Through identification of barriers and facilitators in relation to referral practice and use of guidelines, this study sought to explore implementation enablers and barriers, and inform future implementation of guidelines.
9.7 Results

The main TDF domains emerging from the GP interviews were; environmental context and resources, social influences, knowledge, and behavioural regulation, as seen in Table 9.4 below. Domains which did not emerge as prominent during the GP interviews were optimism, intentions and goals. Definitions of domains are taken from the TDF validation study by Cane et al. (245) and are based on definitions from the American Psychological Association’s Dictionary of Psychology (243).

Table 9.4: Ranking of theoretical domains, GP interviews

<table>
<thead>
<tr>
<th>Primary TDF domain</th>
<th>References from GPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Environmental context &amp; resources</td>
<td>481</td>
</tr>
<tr>
<td>2: Social influences</td>
<td>204</td>
</tr>
<tr>
<td>3: Knowledge</td>
<td>119</td>
</tr>
<tr>
<td>4: Behavioural regulation</td>
<td>114</td>
</tr>
<tr>
<td>5: Beliefs about Consequences</td>
<td>91</td>
</tr>
<tr>
<td>6: Memory, attention &amp; decision processes</td>
<td>88</td>
</tr>
<tr>
<td>7: Skills</td>
<td>86</td>
</tr>
<tr>
<td>8: Beliefs about capabilities</td>
<td>33</td>
</tr>
<tr>
<td>9: Social/Professional role and identity</td>
<td>18</td>
</tr>
<tr>
<td>10: Emotion</td>
<td>11</td>
</tr>
<tr>
<td>11: Reinforcement</td>
<td>0</td>
</tr>
<tr>
<td>12: Optimism</td>
<td>0</td>
</tr>
<tr>
<td>13: Intentions</td>
<td>0</td>
</tr>
<tr>
<td>14: Goals</td>
<td>0</td>
</tr>
</tbody>
</table>

Additional themes which emerged and were not included in the analysis were discussions on services for other cancers such as prostate, colorectal, testicular and gynaecological cancers.
9.7.1 Environmental context and resources

Definition: Any circumstance of a person’s situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.

Themes mapped to this domain included centralisation/reconfiguration, volume of referrals, geographical factors, public vs. private health services, access to services, mode of referral, scope of service, hospital-GP interface, resources, breast-screening service, GP access to diagnostic imaging and comparisons with services for other cancers.

Centralisation / reconfiguration of cancer services

Participants compared the new centralised structure of cancer services with the previous service and acknowledged that they were not sure initially if it was going to be a success. A number of factors acted as facilitators or enablers to GP referral, including confidence in the NCCP cancer services and ease of referral.

“When Centres of Excellence were starting, we didn’t know how they’d work out. I think they’re fantastic. I just think the Breast Clinics are fantastic.” (GP13, Female, HSE Dublin Mid-Leinster (DML)

“When we started off, it was, it seemed like a battle to get anybody seen, whereas really, there’s no battles anymore.” (GP 16, Female, HSE South)

GPs were very satisfied with the SBD Units and reported positive feedback they had received from their patients on the care they received. GPs commented on the success of the cancer services in general.

“I have never had one come back and complain. They come back and they’re full of praise for the centres. They say the way they’re dealt with is fantastic and the clarity of their results is brilliant.” (GP13, Female, DML)

“I must say, you know, I think the breast service is excellent and I don’t hear complaints about it.” (GP 23, Female, Dublin North-East (DNE)
“Always a good standard of service. I think the cancer service has really, really become very good. It’s really an excellent system.” (GP 27, Male, DNE)

Public vs. private health care
GPs compared public and private services for breast disease. GPs stated that, since the designation of the cancer centres, their preference is to refer their patients with suspected breast cancer to the designated cancer centres in the public hospitals, regardless of health insurance status. However, GPs reported that some of their patients opted for private care to get value from their health insurance. The overall preference for public hospital care was replicated for some other cancers but not for other diseases. GPs recommended breast cancer services in designated cancer centres as an example for other health services to adopt.

“I would actually probably tend to put them public, I probably think the public system is better.” (GP 11, Male, DML)

“I’m not the biggest fan of our public services in general, but I have to say that the cancer referral services in general and the treatment the patient gets, I think is one of the very few parts of the health service where the public service far outdoes the private.” (GP 6, Female, HSE West)

“I tell patients that they’re more likely to get a more efficient streamlined service if they go to the breast clinic than if they go privately to see a consultant. It’s more disjointed if they go privately to see a surgeon. The public is better than the private in my view.” (GP 23, Female, DNE)

Where patients were referred to private hospitals, GPs attributed some decisions to patient choice, as they wished to get value from their health insurance. However, GPs sometimes worried that sending people privately was not necessarily better for their patient.

“There’s the old fashioned idea that private equals better, and it’s absolutely not... It was just their decision and that’s fine too. They’re paying a phenomenal amount of health insurance.” (GP 14, Female, DML)

“I then worry slightly about referring them privately because you think, you know, in a way potentially, it’s almost a second class system to do that.” (GP 10, Female, South)
Volume of referrals
Participants were asked to comment on the increasing volume of GP referrals nationally. A combination of factors was cited as influencing factors, including increased information on breast disease for patients, GP fear of litigation and a change in the referral pathway from private to public for some patients.

“I try not to refer patients to the private.” (GP 31, Male, DNE)

“Nowadays, with persistent things of litigation and, you know, you just have to refer.” (GP 15, Female, DML)

“Even private ones that went privately I’d now send publicly.” (GP 31, Male, DNE)

“An increase in the presentation with breast-related symptoms and a corresponding reduction in the threshold for referring, even when there are perhaps no pressing clinical grounds, just because of the level of anxiety.” (GP 24, Male, South)

Geographical factors
Geographical factors played a role in GP referral decisions, e.g., some GPs in remote rural locations reported referring early, whilst others managed their patients’ care as much as possible in primary care, to avoid lengthy travel for the patient to attend a hospital consultation. Whilst referrals of patients for assessment and for surgery were for single hospital visits, follow-up treatment such as chemotherapy and radiation therapy caused problems for some patients in terms of transport. GPs had concerns about undue hardship, with distances to travel and costs of transport.

In relation to referral to a particular cancer centre, the GP’s stability of intentions was influenced by an allegiance to particular cancer centres, not always the closest one. This was occasionally a GP preference and other times a patient request, due to previous clinical experiences with family members or more practical issues such as transport links.
There were less private medical facilities outside the Dublin city area. However, when GPs were genuinely concerned that their patient had a suspected breast cancer, they preferred to refer them to a specialist cancer centre.

“I think referral rates would probably be higher in the more affluent areas maybe.” (GP 23, Female, DNE)

“The issues that I’ve come across that affect referrals would be remoteness, would be mental health as well.” (GP 18, Male, West)

“In terms of where to go, it might be more to do with patient preference.” (GP 19, Female, DML)

Health service factors
There was a high level of satisfaction with the breast service in general. GPs acknowledged that the service was established as a Symptomatic Breast service but pointed out that there is no alternative service for asymptomatic patients, such as family history, or for screening for those age-groups outside the national BreastCheck screening programme age of 50 - 65.

“One of the very few parts of it that’s actually working well in my opinion is the whole cancer service. I have no problems with it at all. It’s one of the very few parts of the service I can say that about.” (GP 6, Female, West)

“It’s our only way of getting into the system really.” (GP 7, Female, South) (in relation to referral to the SBD unit)

“There’s no middle tier to filter them out before they end up in the big system.” (GP 26, Female, DNE)

Access
Participants were very satisfied with access to the SBD units and were happy with the waiting time targets set up by the NCCP whereby urgent referrals are seen within two weeks and non-urgent referrals are seen within 12 weeks.
“It’s an excellent service, particularly the way the health service is going that you can actually get seen. You’re guaranteed to be seen by a specialist in this area in twelve weeks and that’s an excellent service.” (GP 3, Male, West)

“The system I have to say is very good in terms of time, turnover time is excellent.” (GP 10, Female, South)

“It is one of the few things in the health service that does work; the breast clinic, you know, because patients get access to it.” (GP 31, Male, DNE)

**Hospital - GP interface**

The need to strengthen the interface between primary and secondary care was highlighted. GPs wanted to be able to access consultants and radiographers more readily to discuss individual cases. GPs also wanted further information on clinical pathways for treatment of breast cancer so that they could discuss the treatment options with their patients.

“Until their course of chemo’ has finished we don’t hear anything.” (GP 13, Female, DML)

“It would be nice if GPs could have a little more direct contact with the people at the other end of the service. It would be nice to be able to ring up, you know, the radiographer and just get the verbal report even.” (GP 6, Female, West)

“If you have worrying signs, and you pick up the phone, then you’d have to say, people are very good to get people sorted quickly.” (GP 16, Female, South)

**Resources / costs**

In relation to resources, GPs acknowledged that with more patients being referred to breast clinics based on patient demand and expectations, it was possibly not the best use of hospital resources. It was also debated whether these resources could be channelled into other services.

“If it’s a breast complaint, I send them all off and that’s it. I don’t argue. I just send them and I don’t think that’s the best way to use our resource.” (GP 3, Male, West)
“Sometimes you think, you know, are resources put into this too much, because you kind of know that there’s nothing wrong with somebody, but yet they get an appointment in three weeks time and you kind of go, you know, could resources be put somewhere else?” (GP 5, Female, South)

Access to diagnostic imaging
Increased access for GPs to diagnostics was a strong recommendation and additional resources in the area of diagnostic imaging were sought. The lack of GP direct-access mammography was seen to influence the volume of referrals to the SBD unit.

“It’s very difficult to deal with people, their anxieties you know, without getting a mammogram, that’s the big problem I think.” (GP 25, Female, West)

“I sometimes wonder, the fact that I can’t get a mammogram now, I think clogs up the clinic.” (GP 10, Female, South)

“We don’t have access to mammogram or ultrasound.” (GP 23, Female, DNE)

9.7.2 Social influences

Definition: Those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours.

Themes mapping onto this domain included:
- Patient anxiety
- Media and publicity
- Patient awareness and education
- Patient expectations
- The worried well

Patient anxiety
Patient anxiety was a major theme and GPs reported a high level of anxiety in the patients presenting to them. GPs attributed this anxiety to a high level of knowledge and information of breast cancer among the population generally and also as a result of media and publicity in this area, resulting in
patient fear of having a cancer. GPs perceived that the media were reinforcing patient anxiety and recommended that publicity should be reassuring rather than alarmist in nature. GPs commented that patients were “hyped up” when they presented to them, many were “up to high doh” and were “not going to rest until seen” in the breast clinics.

“If the patient is very concerned, you’ve got to refer.” (GP 11, Male, DML)

“It’s a big anxiety that they have, so any complaint at all about the breast is breast cancer in their eyes until proven otherwise.” (GP 23, Female, DNE)

“I would still say I have a low threshold for referral, especially where there’s a high level of anxiety.” (GP 24, Male, South)

A patient’s personal knowledge of friends or family experience with a cancer diagnosis also heightened their anxieties. Historical past events and incidents that were widely reported in the media were a constant reinforcement of their anxiety and there were concerns that this was leading to inflated norms. The motivation to seek an appointment frequently came from family members, friends or advice from cancer help-lines. TV soaps, radio stations and lobby groups also tended to fuel patient anxieties.

“I’ve had one case recently where she didn’t really need to go anywhere, but a friend of a similar age has breast cancer and she was so freaked out about it that I referred her.” (GP 12, Male, DNE)

“They’ve had friends or family or they’ve seen something on the TV or if they’ve watched soaps. I mean it’s all very current, or if it’s been on Joe Duffy [afternoon radio chat-show host] – he’s probably our biggest nightmare.” (GP 14, Female, DML)

“The health service in general are still in the process of trying to heighten people’s awareness of cancer and while that has a beneficial aspect to it, it has the negative downside of causing many people to be anxious where they have no real cause for anxiety.” (GP 24, Male, South)
Even in asymptomatic patients, such as patients with a family history of breast cancer without any symptoms, the fear of developing a breast cancer was driving the demand for regular check-ups and screening mammography to rule out cancer. Patients were anxious to be referred on to a specialist breast unit and they were familiar with the referral process.

“If someone has a concern about the breast even though I feel there’s nothing going on, and I’m not sure, I feel that there’s nothing, but they’re still concerned and would like a mammogram, I’ll refer them.” (GP 23, Female, DNE)

“Maybe it is to relieve anxiety but I don’t expect anything to be wrong with her.” (GP 3, Male, West)

“We have an algorithm here that was sent out and I try to follow it, but again you see I’m domineered by patient anxiety.” (GP 10, Female, South)

Media and publicity
Participants discussed the power of the media and the influence the media and publicity had on individuals. GPs commented on the impact of the media on breast referrals, particularly in relation to fuelling people’s anxieties about breast disease.

“I suppose if they hear something in the news they might also be more anxious.” (GP 19, Female, DML)

“There’s so much media coverage of it. They’re so worried about it, they’re so hyped up, they want things seen quickly.” (GP 21, Male, DML)

“Media would be a big thing really, media advertising would make people come in.” (GP 5, Female, South)

“There was so much hype in the media, people probably started thinking about their breasts more.” (GP 25, Female, West)

GPs perceived that media messages and national campaigns were not currently in proportion to the incidence of the disease and should be more measured and targeted towards groups most at risk of cancer.
“I think a little bit more publicity, but not too much in the negative end, you know. If you have a breast lump, if you’re worried see your doctor, everything else, I think it should be more of a reassuring publicity.” (GP 15, Female, DML)

“I think the fear is not in proportion to the incidence of the disease.” (GP 18, Male, West)

“I know the Cancer Society brings out leaflets about, you know, bowel cancer and if you have rectal bleeding go to your doctor immediately and all the rest but I think that sometimes they cause more anxiety than they solve, you know.” (GP 9, Male, South)

Celebrities appeared to play a role in referral patterns. Similar to the hospital interviews, GPs reported an increase in patient requests for breast referrals following ‘Kylie’ concerts in Ireland and cervical screening referrals following Jade Goody coverage, two celebrities with a cancer diagnosis. GPs also reported that cancer had become ‘politicised’, sometimes to the detriment of other disease groups.

“Kylie Minogue at the time, because she was so young, I suppose certainly around that time there might have been a small increase in the amount of young women, that, you know, may have come in.” (GP 6, Female, West)

“If somebody on Fair City [Irish soap opera] died of breast cancer, that always affects.” (referrals) (GP 5, Female, South)

Some GPs found an increase in requests for referrals following breast cancer campaigns, in particular during October, which is Breast Cancer Awareness Month in Ireland and internationally, but others did not notice any seasonal variation.

“I've often seen a big campaign over a week or listened to the radio somewhere and say “that will get me busy” and no I haven’t, it hasn’t brought too many people in at all, no.” (GP18, Male, West)
“The government go into these big campaigns and they advertise them and like everything else, if you’re going to do that, people are going to start looking at themselves.” (GP 11, Male, DML)

Patient awareness and education
While patient knowledge and awareness of breast disease was high, GPs recommended additional and targeted patient education in the area of family history of breast cancer. Negotiation and shared decision-making with the patient was sometimes seen as ‘internet driven’. Better-educated patients served as a cue or prompt for GPs, increasing the probability of an onward referral. Patients were keen to attend a ‘one-stop-shop’ to be assessed and specifically requested a referral for this service.

“Well I mean, it probably is a lot to do with patient awareness. We wouldn’t be referring people if they didn’t present.” (GP 19, Female, DML)

“Because people know the clinic is out there, I think we’re referring more.” (GP 3, Male, West)

“I think there’s a society-wide awareness of the prevalence of cancers and a sort of growing neurosis that we’re about to be decimated in a way that, while appropriate to some extent, is having an adverse impact on peoples’ psychological wellbeing out of proportion to the reality of the situation.” (GP 24, Male, South)

Patient expectations
GPs perceived patient expectations as high and GPs discussed the dilemma between their role as the GP, use of scarce hospital resources and anxiety about refusing a request for referral in these patients. Patients were, in general, familiar with the referral process and made specific requests for an urgent appointment, to be seen within 10 days. GPs reported that patients had great trust in the service, based on previous experience of others.

GPs reported that in some cases they felt under pressure from their patients to refer. Patient psychological factors also influenced the urgency of referral and many presented with a fear of having a cancer, seeking investigations to put their minds at rest. GPs indicated that demand for clinic appointments
was growing. GPs attributed this increase in demand to media-induced anxiety, lack of GP autonomy and pressure for referral.

“Any complaint at all about the breast is breast cancer in their eyes until proven otherwise.” (GP 12, Male, DNE)

“At the end of the day I suppose, the patient is the one that needs to be kept happy.” (GP 6, Female, West)

“You will get some pressure from patients from time-to-time, you know, they’re very concerned.” (GP 30, Male, DNE)

The worried well
GPs commented on the growing number of ‘worried well’ with ‘perceived need’, seeking onward referral to specialist breast clinics which did not result in additional cancers being detected.

“I think that they have a low probability of anything serious but if they’re not happy to wait and see type of thing, I refer them if that’s what they want, you know.” (GP 9, Male, South)

“All you’re doing is increasing the worried well and it’s not having any impact on the number of new cases that are being diagnosed.” (GP 3, Male, West)

“To be honest, a lot of the time they would be what I would consider the worried well..... A lot of what I would consider the worried well are very much reassured by negative tests.” (GP 6, Female, West)

9.7.3 Knowledge

Definition: An awareness of the existence of something.

Themes which were mapped to this domain included:

- GP knowledge / education
- Electronic referral
GP knowledge and education

A number of the patient factors which influenced the GP decision to refer to the SBD units were linked to clinical disease factors such as family history of breast cancer. GPs requested standardised information on screening for family risk for breast cancer. Education to assist GPs in reassurance and management of patients in primary care was also suggested.

“What the genetic inheritance significance of it all is, and who needs to be screened and who doesn’t need to be screened.” (GP 11, Male, DML)

“Education around GPs about being confident about reassuring patients with breast complaints.” (GP 23, female, DNE)

“Hone people up on who to hold on to and who to wait, rather than refer.” (GP 19, Female, DML)

Electronic referral

A system to send GP referrals to the cancer centres through a secure electronic facility was introduced by the NCCP in 2010. Knowledge amongst GPs of this electronic referral facility was mixed. Some GPs, whilst aware of the system, were resistant to changing habits and actively disregarded the system. For GPs already using the system, they identified the benefits of electronic referral as quick, innovative and easy to use. The automatic electronic acknowledgement provided confirmation and reassurance for the GP and the patient that the referral had been received, and GPs were very satisfied that rapid appointments were allocated for urgent patients. The early adopters of electronic referral were predominantly young urban GPs in computerised group practices. GPs who were not using the electronic referral system were not aware of the facility, did not have the required technology in their practices, were not using ICGP-accredited GP practice management software, or did not wish to change their existing practice of letters or faxes.

“I’ve only been using it very recently and it’s excellent.” (GP 3, Male, West)
“I fax them in because I’m not electronic. Some of us are very stubborn and we won’t go electronic at all.” (GP 15, Female, DML)

“There’s a few older GPs definitely didn’t get computerized because they know they’re retiring.” (GP 26, Female, DNE)

9.7.4 Behavioural regulation

<table>
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<th>Definition: Anything aimed at managing or changing objectively observed or measured actions.</th>
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Themes mapped to this domain included:

- GP referral practices
- Referral form and guideline
- Protocols and compliance

**GP referral practices**

Some GPs, especially those involved in GP training provision or Continuing Medical Education (CME) regarded themselves as ‘rule followers’ with implementation intention, whilst others preferred to be guided by their own professional judgement. Many GPs had incorporated the GP guidelines into their GP practice protocols, particularly in group practices and found them useful moderators of the intention-behaviour gap. Length of experience of the GP had some influence on referral decisions. Some GPs felt they had developed a more conservative decision-making style as they got older whilst others felt more confident in managing their patient in primary care as they gained more experience. Decision-making in relation to referral was described as ‘not black and white’.

“I’d have a very low threshold for sending people to the breast clinic, more so than I would have had five years ago for sure.” (GP 16, Female, South)

“We each individually do our own thing.” (GP 12, Male, DNE)
Referral form and guidelines
There was a high level of awareness amongst GPs of the national NCCP GP referral guidelines for suspected cancers. GPs regarded following the guidelines as important and trusted the guidelines as evidence-based and helpful for clinical decision-making. However, some GPs followed their clinical judgment instead of the guidelines and felt there may be too many guidelines for them to follow. The majority of GPs were using the NCCP referral forms either in paper format or electronic format, though some preferred the traditional GP letter.

“The referral for the breast is excellent. I’ve had nothing but the highest of praise for them.” (GP 14, Female, DML)

“I probably use my head more than the guidelines.” (GP 26, Female, DNE)

“I just think also there might be a danger of too many guidelines and too much information.” (GP 21, Male, DML)

Protocols and compliance
Protocols and compliance played a role in the referral process. The NCCP GP referral guidelines and referral forms served as a reminder of the GP’s gatekeeping role. Other GPs, while familiar with the guidelines, believed in their capability to follow their own clinical judgement based on their experience and maintained their stability of intentions or engaged in joint decision-making with the patient. GPs were confident they had the requisite procedural knowledge and competence to refer appropriately.

Although there are neither sanctions nor rewards for adherence to the national GP referral guidelines, GPs felt they acted to reinforce the clinical pathway. Increased awareness amongst patients and in the media also reinforced the streamlining of the breast cancer referral process. These environmental triggers assisted conscious decision-making as part of routine practice.
“They’re not going to rest until they get seen and if that’s the case there’s absolutely no point trying to follow, you know, protocols because it just doesn’t work, you know.” (GP 10, Female, South)

“Do I follow them to the strict letter of the law, I probably don’t. We each individually do our own thing.” (GP 12, Male, DNE)

“I think the guidelines are very good and that’s why if you’ve got good guidelines, guidelines are there for a reason.” (GP 14, Female, DML)

9.7.5 Beliefs about consequences

Definition: Acceptance of the truth, reality or validity about outcomes of a behaviour in a given situation.

Themes mapped on to this domain included:

- Risk
- Reliance on diagnostic imaging
- GP reassurance

Risk

GP discussion on risk focused on cautious management of breast referrals in primary care, risk aversion and medico-legal implications.

Cautious management

GPs described a cautious management approach to management of breast disease. GPs expressed a low threshold for referrals, tending to err on the side of caution and were cognisant of outcome expectancies.

“We probably do err on the side of caution and maybe that’s just because people present more often.” (GP 19, Female, DML)

“I’d be very cautious when it comes to the breast, for fear of missing a cancer.” (GP 23, Female, DNE)

“It seems as I get older, I get less cavalier in my approach and I suppose over the years would have had a couple of surprises.” (GP 10, Female, South)
Risk aversion
Risk aversion was a consistent theme raised by GPs and was accepted as a growing trend based on fear of missing a cancer, fear of litigation and the resultant legal consequences. GPs in training practices stated that their registrars (trainee GPs) were more likely to refer the patient on rather than manage the risk themselves.

“Very brave man to sit here and say no.” (GP 11, Male, DML)

“There’s nobody worth their salt that will probably take the chance of not doing it.” (referring) (GP 12, Male, DNE)

“We have GP registrars and I find that they will find relief in referral, rather than manage the risk themselves. It’s a great way of moving the problem on.” (GP 18, Male, West)

Medico-legal implications
The anticipated regret of missing a cancer coupled with the cognisance of medico-legal issues meant that GPs would take a cautious or guarded approach to patient management.

“I really think that is just the whole public perception of breast cancer and that, if you were the one that didn’t send somebody in for six weeks and they had some weird thing and they had a breast cancer, it would be such a huge deal.” (GP 12, Male, DNE)

“Now because of all the possibility of litigations and everything else, everybody is just trying to cover their backs and I think more people are referring now again.” (GP 15, Female, DML)

“We live in an age of litigation.” (GP 3, Male, West)

Reliance on diagnostic imaging
Confirmation of GP diagnosis through diagnostic imaging was a strong recurring theme among GPs in order to provide reassurance to the GP. GPs sought diagnostic imaging to confirm their diagnosis/assessment and to rule out cancer. There were some concerns about lack of GP direct access to
imaging and in some cases this resulted in a referral to a breast clinic, as there was no other route available for them to access this imaging.

“I wouldn’t feel confident in reassuring without a mammogram or an ultrasound.” (GP 23, Female, DNE)

“You examine them and there’s no breast lumps. For me personally I think it’s very hard to say you don’t need a mammogram.” (GP 5, Female, South)

“I think because of the times we live in, doctors are less confident I think to diagnose a benign breast disease without a technical aid.” (GP 3, Male, West)

Breast screening was seen to provide reassurance to patients. GPs reported concerns that there was not a process for screening of asymptomatic women outside the National Breast Screening Programme (BreastCheck). When women outside this age-group requested screening, GPs frequently referred patients even if they believed this was not warranted. GPs reported referring for diagnostic imaging in response to patient anxiety and expectations.

“If somebody is keen for a test and if I’m not sure, it’s very hard to say, you know, not to do the test.” (GP 19, Female, DML)

“A lot of women that would be entirely asymptomatic, the problem with patients nowadays is they’re all on Google and they’re all on these different things and they put huge I suppose belief in tests, you know, they’re so obsessed now...... Once you go in under a machine, people seem to give it great scope.” (GP 6, Female, West)

“Some people put a great faith in the test.” (GP 9, Male, South)

**GP Reassurance**

GPs reported a requirement for reassurance that their diagnosis was correct and that breast cancer could be ruled out. GPs sought reassurance and confirmation of their diagnosis through consultant review or diagnostic imaging.
“I reassure them and they feel reassured but at the same time I’d like to be reassured by the breast clinic.” (GP 12, Male, DNE)

“If you’re not totally reassured you have to send them.” (GP 26, Female, DNE)

“In the past one might have been more ready to simply reassure and dismiss perhaps; now it’s my policy if anybody has a symptom referring to the breast at all I will usually reassure while simultaneously saying to them ‘look we’ll get somebody to have a little look at it’. ” (GP 24, Male, South)

“We had gone through a phase when, you know, everything was fine, you were able to reassure patients and keep them going, but nowadays with persistent things of litigation and, you know, you just have to refer.” (GP 15, Female, DML)

9.7.6 Memory, attention and decision processes

Definition: The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.

Themes mapped to this domain included:

- Family history of breast cancer
- Mastalgia

**Family history of breast cancer**

GPs concluded that patients are very anxious about family history of breast cancer but were not always aware of how to determine their own risk. These patients were generally referred by GPs to the SBD Unit for assessment, particularly if they were outside the age-group for the National BreastCheck Screening Programme (50-64 years). GPs also recommended a dedicated service for family history of breast cancer.

“If there was family history, you’d be more inclined to be cautious, the patient is more anxious to be seen. If there’s a strong family history, I might refer them a bit sooner. Not all would have a genuine family history, some would be quite distant relatives.” (GP 8, Male, West)
“A lot of it is perceived family history. I think it’s difficult for the patient to quantify how high the risk is.” (GP 11, Male, DML)

“I think again because that it’s media driven they’re worried, say if they’ve had any family member who’s had cancer, I think that’s the problem.” (GP 14, Female, DML)

**Mastalgia (breast pain)**

GPs commented on an increase in patients presenting to them with mastalgia. Mastalgia on its own, in the absence of clinical symptoms, is not an indicator for referral. However, GPs found it difficult to reassure patients that breast pain on its own was not an indicator of cancer.

GPs discussed the materials that had recently been developed in Ireland by the NCCP for mastalgia, following the outcomes and recommendations of the hospital interviews. These materials included a referral algorithm for GPs, a patient booklet and a smart phone app’ for patients. GPs reported finding these materials useful. Their patients found the patient diary useful as it helped them to chart their breast pain over three months and then return for assessment if required. GPs reported that some patients were satisfied to be managed in primary care, especially as part of this monitoring process.

“People are scared of lumps, they can put up with pain.” (GP 21, Male, DML)

“I think cancer has become politicised, so a lot of breast symptoms like breast pain, particularly in young women, they’re very anxious to be referred to the breast clinic. I think the public needs to be told that mastalgia is not cancer.” (GP 9, Male, South)

“The only pressure I get from patients goes with the benign breast pain and you try to reassure them and they keep at you, you know.” (GP 15, Female, DML)

“It’s very hard to reassure and I think if there was more public awareness of breast pain as opposed to breast cancer.” (GP 12, Male, DNE)
9.7.7 Skills (Cognitive and interpersonal skills, physical skills)

**Definition:** An ability or proficiency acquired through practice.

Themes mapped to this domain included:
- GP skills
- Patient reassurance
- Follow-up after breast cancer

**GP skills and training**
GPs were asked about requirements for skills training and education. GPs felt their skills in some areas were sufficient, such as triage, but needed updating in other areas such as clinical breast examination. A reliance on diagnostic imaging to back up their clinical examination findings was a recurring theme. Interestingly, some GPs stated that although they had the requisite skills for decision-making, they felt compelled to refer the patient to the breast clinic due to patient pressure.

GPs valued the opportunities to liaise with other GPs on clinical matters. However they found it difficult to attend structured sessions and tended to seek on-line options for convenience and accessibility.

> “Anything that will help improve our skills.” (GP 10, Female, South)

> “Teaching clinics for GPs to learn that sort of thing, you know, breast examination and the difference between a benign and a malignant lump.” (GP 5, Female, South)

**Patient reassurance**
GPs felt they needed to spend a lot of time reassuring the patient. This required time, interpersonal skills and confidence in their ability to provide this reassurance as part of their role as family physician. In certain cases, GPs felt compelled to refer the patient on, just for patient reassurance, even though they were confident of their diagnosis.
“I know we’re sending people to the symptomatic breast clinic and I know in my heart of hearts that it’s really for reassurance.” (GP 25, Female, West)

“It’s the ones who we cannot reassure that everything is fine, we have to send them to the hospital, and invariably it is fine and they’re happy after that.” (GP 15, Female, DML)

“Sometimes you just have to refer for reassurance if they’re not going to take your word for it.” (GP 8, Male, West)

Certainly, when GPs perceived that patients were not adequately reassured during the GP consultation, GPs tended to refer these patients on to the breast clinics for additional reassurance.

“Reassurance is a hollow thing for a lot of people now.” (GP 9, Male, South)

“You’re sitting there thinking, well okay, well ‘I’ll just send you to the breast clinic’ because they’ll get a mammogram or they’ll get an ultrasound and they will be reassured.” (GP 25, Female, West)

“You err on the side of caution and try to; you know, get them checked and make sure they’re reassured.” (GP 30, Male, DNE)

Patient reassurance through diagnostic imaging was a common theme:

“I think if somebody is determined to have a scan, I probably wouldn’t, I wouldn’t go against them, because it may be hard for me to reassure them a hundred percent clinically.” (GP 19, Female, DML)

“If they just aren’t settling and are petrified, there is nothing short of the normal scan that’s going to reassure them that they don’t have a chronic problem.” (GP 26, Female, DNE)

“Some people put a great faith in the test.” (GP 9, Male, South)

“I could stay examining a woman’s breast all day long and tell her I’m feeling nothing but if she can actually get a report where it writes down in black and white, negative mammography, you know, that carries an awful lot more weight... They put huge belief in tests.” (GP 6, Female, West)
Follow-up after breast cancer

There were a number of patient factors which influenced the GP decision to refer to the SBD units. Some of these were linked to clinical disease factors such as follow-up after breast cancer. Current policy in Ireland is to discharge patients from the hospital to their GP five years after initial diagnosis and treatment of breast cancer, provided they have completed their treatment and do not have any symptoms of recurrence. Some GPs were confident to follow up patients with annual check-ups, as long as patients could be referred back to the breast units quickly if they became symptomatic. Other GPs felt that they did not have the requisite skills and would prefer if the patient remained under the care of the hospital consultant.

“Oh no, I mean anyone who’s had breast cancer I’d hope that they’d stay going back to the hospitals, yeah.” (GP 21, Male, DML)

“I suppose as long as we have clear guidelines about what we’re to do, I think we’d all be happy about that.” (GP 10, Female, South)

“Actually I notice that I got a couple of letters asking that we continue surveillance for breast cancer and organise annual mammogram and you know maybe six-monthly breast examination and I felt somewhat uncomfortable about that.” (GP 23, Female, DNE)

9.7.8 Beliefs about capabilities

Definition: Acceptance of the truth, reality or validity about an ability, talent, or facility that a person can put to constructive use.

Themes mapped on to this domain included:

- Empowerment of GPs
- GP confidence

Empowerment of GPs

Participants spoke about empowerment of GPs and some GPs felt disempowered in the management of this group of patients since the establishment of GP referral guidelines for cancer, and expressed a low threshold for referral. Some GPs reported that the triage had been taken out
of primary care and that breast complaints were now the exclusive responsibility of the hospital.

“I wouldn’t be worried about that, losing autonomy, it doesn’t get on top of me.” (GP 30, Male, DNE)

“I think that they’ve taken the triage out of general practice.” (GP 9, Male, South)

“We’re kind of disregarded and also in our local area we cannot access results.” (GP 18, Male, West)

**GP confidence**

A number of GPs did not feel confident in their practical skills of some procedures such as doing clinical breast examinations and felt they needed some training, up-skilling or clinical information updates in this area. Many GPs had confidence in their clinical practice and competence but would welcome more access to diagnostic tests to assist their diagnosis. A second opinion from the breast clinic was frequently cited as a reason for patient referral. Some GPs were confident with their clinical decisions; others felt they had developed greater confidence with longer experience.

“I could stand over my clinical decisions in anything that I would do.” (GP 10, Female, South)

“The longer you’re qualified obviously the more you know, and then the more confident you are.” (GP 6, Female, West)

“I suppose I’m in it ten years now. You feel you have a good feel for what should be done.” (GP 16, Female, South)

“We can’t be a hundred percent sure ever that there’s nothing wrong.” (GP 25, Female, West)
9.7.9 Social/professional role and identity

**Definition:** A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.

Themes mapped to this domain included:

- GP responsibility and ownership
- Gatekeeping

**GP responsibility and ownership**

GPs reported some uncertainty in relation to responsibility and ownership of breast disease in primary care. Whilst GPs felt responsibility for and obligation to their patients, the majority of GPs felt reluctant to manage benign breast disease in primary care. A number of factors, both barriers and facilitators, contributed to this approach, including:

- a perceived lack of autonomy
- pressure from patients to be referred
- ease of access to the breast clinics in the designated cancer centres

Professional role and identity was important to GPs. They “know the patient” and their commitment to the patient and social identity has earned them the respect and trust of their patients. Allegiance to their patients was discussed, with a commitment to deliver the service the patient expected.

“I now think to myself, why do I burden myself with the responsibility of worrying about people when, you know, they can go to the clinic.” (GP 10, Female, South)

“I’ve probably referred a hundred percent of breast complaints.” (GP 12, Male, DNE)

“That’s the nice thing about them being our patients. We know them, so you know the character you’re dealing with.” (GP 7, Female, South)
Professional boundaries were challenged in the area of breast care and GPs felt that, due to patient expectations, they are now referring people into the hospital clinics that they would have previously managed in primary care. Some GPs reported being reliant on technical aids, such as diagnostic imaging. Many GPs took on a leadership role as GP tutors to train other GPs. Group identity, either in terms of organisational commitment to a group practice or as part of a professional community of GPs, was high.

Responsibility for management of breast disease was seen to be migrating exclusively to the hospital setting.

“I mean there’s no point trying to sit on somebody and keep them, you know here with me examining them if they’re just worried out of their mind.” (GP 10, Female, South)

“I think it’s moving towards the situation where, basically breast complaints are regarded as the exclusive territory of the breast team.” (GP 24, Male, South)

Gatekeeping
There was some debate regarding the gatekeeping role of the GP. Whilst GPs felt they possessed sufficient gatekeeping skills, there was divided opinion on whether this was their role. Some GPs saw this as part of their role and others considered that it was outside the professional boundaries of the GP. This differed quite considerably between GPs who had trained or practiced in Ireland and those who had trained or practiced in the UK. GPs who had worked in the UK expressed that gatekeeping was a key part of their GP role while this was not expressed by others.

“I trained in England where we were taught to be the gatekeepers of the hospitals.” (GP 10, Female, South)

“I was trained in the UK so I certainly kind of feel that GPs should be in a better position to say ‘no I’m not going to refer you’.” (GP 7, Female, South)

“If it’s in the breast, I just refer in.” (GP 3, Male, West)
“You want to do the best for the patients.” (GP 19, Female, DML)

9.7.10 Emotion

Definition: A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.

Themes mapped on to this domain included:

- Provider anxiety (GP anxiety)

GP Anxiety
Anxiety was a consistent theme throughout the GP interviews, focusing both on GP anxiety and patient anxiety. GP anxiety was predominantly based on fear of missing a cancer and anticipated future outcomes. Repeated media coverage of critical incidents in the past, sensitisation and salient events reinforced this anxiety.

“A lot of medicine nowadays is anxiety driven.” (GP 25, Female, West)

“If you miss one case of cancer then people will come down on your back and say ‘oh you should have referred me to the clinic’ and I think that’s what worries doctors.” (GP 3, Male, West)

“If you were the one that didn’t send somebody in for six weeks and they had some weird thing and they had a breast cancer, it would be such a huge deal.” (GP 12, Male, DNE)

9.7.11 Reinforcement

Definition: Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.

Themes mapped under this domain included:

- HIQA

NCCP was also a related theme under this domain.
The Health Information and Quality Authority (HIQA) and the National Cancer Control Programme (NCCP) were viewed by GPs as enforcement bodies to which hospitals were accountable for maintaining the standards of the breast service.

“It’s certainly a big improvement on what things were before the formal National Cancer Programme was in place.” (GP 29, Male, West)

9.7.12 Optimism

Definition: The confidence that things will happen for the best or that desired goals will be attained.

There were no themes which mapped directly on to this domain as their primary focus. Related themes included NCCP and the cancer centralisation process.

GPs reported great optimism and belief in the breast service and identified the role of HIQA and the NCCP in the establishment of the cancer centres. GPs identified cancer services as a quality service in which they had confidence and commented on the role of the NCCP and the success of the cancer services in general. The quality of the service in the Symptomatic Breast Units was praised and recommended as a structure for other areas in the health service to adopt.

“One of the very few parts of it that’s actually working well in my opinion is the whole cancer service.” (GP 6, Female, West)

“It will all be done in a one-stop-shop. People want to walk away at the end of the day with an answer.” (GP 7, Female, South)

“I think it’s the best thing about the health service.” (GP 12, Male, DNE)
9.7.13 Intentions

Definition: A conscious decision to perform a behaviour or a resolve to act in a certain way.

There were no themes which mapped directly on to this domain as their primary focus. Related themes included protocols and compliance. The GP referral guidelines prompted GPs to reflect on the management plan for their patients and to take the guidelines into consideration in their professional judgement.

“I think in the main we try and keep to that regime, that what we mean urgent is urgent.” (GP 16, Female, South)

9.7.14 Goals

Definition: Mental representations of outcomes or end states that an individual wants to achieve.

There were no themes which mapped directly on to this domain as their primary focus. While GPs intended to implement the GP referral guidelines in their practice, these goals were not always followed. The priority for GP was to do the best for their patients.

The targets set by the NCCP were seen to be ambitious but in the most part were being achieved. The target to see urgent patients within 10 working days was seen as a model of good practice and GPs were satisfied with this service. GPs recommended that similar targets be set for other diseases, particularly for diagnostics.

“You want to do the best for the patients.” (GP 19, Female, DML)
9.8 Summary of findings

Findings are summarised below, with the main theoretical domains identified in parentheses. Similar to the hospital interviews, results have been summarised into health service, patient and provider factors affecting referrals. Whilst GPs were satisfied with the breast service, this was not reflected in their comments on other cancers. There were conflicting views on the gatekeeping role of the GP.

Health service factors

The rapid-access breast clinics were seen by the GPs as a high-quality service and a model for other parts of the health service to emulate (environmental context and resources). Ease of access to the breast clinics was seen as a contributing factor to increased referrals (environmental context and resources). However, GPs indicated that demand for clinic appointments was growing. GPs attributed this increase in demand to media-induced anxiety (social influences), lack of GP autonomy (beliefs about capabilities) and pressure for referral (social influences). The emergence of a new group of patients seeking breast screening following their completion with the BreastCheck screening programme was unexpected and needs to be considered in future service planning.

GP (provider) factors

GPs attributed the increase in GP referrals to their fear of missing a cancer (emotion). GPs were cognisant of medico-legal issues and opted to take a cautious approach to the management of breast referrals (beliefs about consequences). GPs articulated a need for reassurance through specialist opinion and diagnostic imaging (beliefs about capabilities, beliefs about consequences). GPs saw their role as an advocate of the patient rather than a gatekeeping role for the hospital (professional role and identity).

Patient and social factors influencing GP referral decisions

There were a number of patient factors which influenced the GP decision to refer to the specialist breast units. Some of these were linked to decisions based on clinical disease factors, such as family history of breast cancer,
mastalgia or follow-up after breast cancer (memory, attention & decision processes, skills), whilst others were based on more psychosocial factors, including patient anxiety and perceived expectations (social influences). Patient anxiety was perceived to be fuelled by media reports, publicity and breast awareness initiatives (social influences).

The following is a summary of the recommendations made by the participating GPs. A number of these recommendations have already been initiated or implemented. These initiatives have been included in parentheses and are presented in more detail in the discussion chapter (Chapter 11).

- Information in relation to health and well-being should be realistic and proportionate (joint planning commenced between NCCP and advocacy groups for awareness campaigns).
- Clear referral pathways are required for patients with a family history of breast cancer, with information for GPs and for patients on referral criteria (GP referral guideline updated with advice on family risk).
- Clear advice is required for patients and GPs on the management of breast pain (Information developed for GPs and patients on mastalgia).
- The provision of GP direct access mammography should be considered (BreastCheck age-range extended in 2015).
- Training/up-skilling for GPs in breast examination should be provided (GP education programme commenced).
- The hospital–GP interface should be strengthened, with greater access to consultants to discuss individual cases (Healthlink integrated into accredited GP software systems, breast cancer guidelines for diagnosis and staging developed).
- Education for practice nurses on breast disease should be provided (national training programme commenced for nurses caring for cancer patients).
Overall, GPs have confidence in public hospital care for their breast cancer patients since the establishment of designated cancer centres. However, GPs’ confidence in their own referral decisions was varied. A second opinion from the breast clinic was frequently cited as a reason for patient referral. Whilst some cases were straightforward, the likelihood of referral increased when the cognitive task of diagnosis was more complex.

In conclusion, GP referral practices are influenced by patient, provider and health service factors, which can be both social and contextual in nature and do not follow strictly Bayesian reasoning (282). Social influences coupled with beliefs about consequences are challenging barriers to address and will require multifaceted interventions to overcome.

9.9 Comparison of GP and Hospital interviews

The qualitative datasets from hospital and GPs interviews were triangulated to address completeness, convergence and dissonance of key themes (415). Triangulation is a methodological approach that contributes to the validity of research results when multiple methods, sources, theories and/or investigators are employed (415).

Using the domains from the Theoretical Domains Framework used in the analysis of GP and hospital interviews, a convergence coding matrix was created to summarise the similarities and differences between the two sets of data, as seen in Table 9.5. This table shows a comparison of the ranking of domains from GP and consultant interviews. Whilst environmental context and resources featured most frequently for both groups, the order differs slightly for subsequent domains.
Table 9.5: Convergence coding matrix

<table>
<thead>
<tr>
<th>Primary TDF domain</th>
<th>GPs (n=24) Frequency of responses</th>
<th>Rank</th>
<th>Hospitals (n=9) Frequency of responses</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental context &amp; resources</td>
<td>481</td>
<td>1</td>
<td>219</td>
<td>1</td>
</tr>
<tr>
<td>Social influences</td>
<td>204</td>
<td>2</td>
<td>73</td>
<td>3</td>
</tr>
<tr>
<td>Knowledge</td>
<td>119</td>
<td>3</td>
<td>80</td>
<td>2</td>
</tr>
<tr>
<td>Behavioural regulation</td>
<td>114</td>
<td>4</td>
<td>44</td>
<td>6</td>
</tr>
<tr>
<td>Beliefs about consequences</td>
<td>91</td>
<td>5</td>
<td>28</td>
<td>7</td>
</tr>
<tr>
<td>Memory, attention and decision processes</td>
<td>88</td>
<td>6</td>
<td>61</td>
<td>4</td>
</tr>
<tr>
<td>Skills</td>
<td>86</td>
<td>7</td>
<td>59</td>
<td>5</td>
</tr>
<tr>
<td>Beliefs about capabilities</td>
<td>33</td>
<td>8</td>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>Social/Professional role and identity</td>
<td>18</td>
<td>9</td>
<td>21</td>
<td>8</td>
</tr>
<tr>
<td>Emotion</td>
<td>11</td>
<td>10</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Reinforcement</td>
<td>0</td>
<td>11</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Optimism</td>
<td>0</td>
<td>12</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Intentions</td>
<td>0</td>
<td>13</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Goals</td>
<td>0</td>
<td>14</td>
<td>0</td>
<td>14</td>
</tr>
</tbody>
</table>

9.9.1 Convergence coding

Examination of convergence, complementarity and dissonance increases the likelihood that findings will be found credible, thereby enhancing the validity of the research (455). Convergence coding was used in this analysis to assess the extent to which the different findings in the GP and consultant/hospital interviews showed convergence, complementarity, dissonance or silence. (adapted from Farmer) (415).

9.9.1.1 Convergence

Convergence is when findings from each data source agree and can be described as full or partial agreement. The two sets of data were assessed for agreement on the meaning and prominence of themes presented and also on the similarity of examples provided.

There was full agreement across both GP and consultant/hospital interviews in relation to:

- The high quality of the centralised service for breast cancer
- Increase in patient expectations/demand for the service
- Negative impact of the media on patient anxiety
There was agreement across both GP and consultant/hospital interviews in relation to the following themes, but the level of prominence differed. In each of these cases, the theme was more prominent in the GP interviews:

- Requirement for GP direct access to imaging
- Requirement for patient reassurance
- Risk aversion of GPs
- Health provider anxiety
- Patient anxiety
- Geographical factors

There were no common themes identified where the level of prominence was higher in the consultant/hospital group than the GP group.

9.9.1.2 Complementarity
Findings from different studies can be assessed for complementary information on the same issue. Through ascertaining the complementarity of different data sources, it is possible to increase understanding of the phenomenon being studied (415).

Through exploration of factors influencing referral patterns from the perspectives of both the referring GPs and the hospital SBD units, multiple dimensions of the phenomenon could be examined, providing a more complete picture of the issue. This assessment highlighted the impact of a successful service on subsequent demand in both GP and hospital services. Clinician’s beliefs about consequences and tolerance of risk in both settings influenced the management of these patients which may have accentuated the demand on the service.
9.9.1.3 Dissonance

Dissonance refers to disagreement, unexplainable divergence in meaning or prominence (415), or findings which appear to contradict each other (416). The GP and hospital interviews were assessed for possible areas of dissonance. Four areas of dissonance were identified, as follows:

Access to service: Consultants stated that access to the breast service was now too easy, while GPs were very satisfied with this arrangement. Hospitals declared that they could not continue to provide an equivalent service if the demand kept increasing.

Ownership and responsibility: Consultants wanted GPs to manage the non-urgent referrals in primary care and take on more of a gatekeeping role, while GPs felt the ownership of this condition now lay exclusively with the specialist breast units, with no consensus on the gatekeeping role.

Follow-up after breast cancer: Neither the consultants, nor the majority of GPs, felt that the responsibility of patient follow-up after their hospital discharge (five years after treatment) belonged with them.

Seasonal variation: Although hospitals felt that there was an increase in referrals during breast cancer awareness month in October, GPs did not feel their referrals increased during this time.

9.9.1.4 Silence

The two sets of data were assessed for silence, i.e., where one set of findings is silent on a theme or an example. Themes which featured in consultant interviews but not in GP interviews included:

- Pride in the professional service they provide
- Accuracy of GP referrals
- Impact of the HIQA review
There were no themes which featured in GP interviews but not in hospital interviews.

Multiple-level societal issues were raised at the hospital and GP interviews. However, the findings illuminate issues at various different levels. Consultants refer to macro-level issues as impacting more on referral patterns while micro-level concerns such as patient anxiety influenced GP’s decisions.

Richards (p.146) (469) describes five signs of sufficiency for qualitative analysis:

- Simplicity – a small polished gem of a theory rather than ‘a mere pebble of truism’
- Elegance and balance – it is coherent
- Completeness – it explains all
- Robustness – it doesn’t fall over with new data
- It makes sense to relevant audiences

These two qualitative studies (hospital and GP) have sought to fulfil these five signs of sufficiency though a clear and comprehensive account of factors which GPs and consultants/hospitals identified as influencing referrals to SBD units. The findings are intended to be relevant to and useful for hospitals, GPs, GP training bodies and policy-makers.

Using the COM-B behaviour change model outlined in Chapter 5, an intervention plan has been developed for adherence to GP referral guidelines for suspected cancer. By identifying the barriers and facilitators to use of evidence-based practice in the qualitative studies, an intervention plan was developed applying the principles of behaviour change. This plan was developed by the author (NO’R) at the Centre for Behaviour Change Summer School in University College London in 2014 and can be found in Appendix D.
Findings that are consistent across different data sources enhance the credibility and transferability of results (415). The two qualitative studies explored the perceptions, beliefs and expectations of hospitals and GPs in relation to the symptomatic breast service, the referral process and the impact of the centralisation policy. Participants were satisfied that patients were being seen more quickly in the new centralised service in designated cancer centres and recommended that this structure be replicated in other health services. However, the impact of the centralisation policy had not yet been measured. A quantitative study using the National Cancer Registry of Ireland (NCRI) database was designed as the fourth and final study of this thesis to examine the impact of centralisation on cancer referral patterns in Ireland.
Chapter 10: Study 4: Impact of Centralisation on Breast Cancer Referral Patterns

10.1 Introduction

The organisation of cancer services and the literature examining the impact of service reorganisation on cancer outcomes have been described in earlier chapters. There is strong evidence that centralisation of cancer services results in higher-quality cancer care, improved evidence-based care delivery (19) and better clinical outcomes (7-9, 82, 83). Diagnosing patients at an earlier stage of disease, combined with timely access to diagnostics and treatment, improves patients’ prognosis (6, 11, 48, 157, 159, 166). In order to improve cancer survival, the focus of cancer programmes should be on identification of cancer at the earliest possible stage (280, 470, 471).

The patterns of care and survival of patients with breast cancer can be influenced by both patient and hospital characteristics. Older age, those of African-American race, poor insurance status and later stage at diagnosis have all been associated with poorer survival in the USA (151). Hospital characteristics such as centralisation of breast cancer surgery in high-volume specialist centres have been shown to improve patient outcomes (7-9, 152).

Study 1 highlighted the change in referral patterns in terms of quantity of referrals to the breast clinics. Studies 2 and 3 explored referral patterns from both the hospital and GP perspectives. This final study (Study 4) examines the implications of breast cancer service centralisation on breast cancers diagnosed before and after the centralisation process (2008 vs. 2010), to ascertain if there were changes in the method of presentation, type of hospital where the patient was treated, tumour characteristics and time-to-treatment between the two cohorts.
In the qualitative studies described in Chapter 8 and Chapter 9, consultants and GPs endorsed the policy of centralisation of cancer services in Ireland, and acknowledged the process as a successful health service development in the Irish healthcare system. However, the impact of this health policy on cancer referral patterns and patient outcomes has not previously been investigated in Ireland.

Both consultants/hospitals and community-based GPs highlighted the importance and the success of the cancer centralisation process in terms of access to cancer services through GP referral guidelines, standardised GP referral forms and referral to rapid-access clinics in designated cancer centres with multidisciplinary teams. This study investigated if, indeed, patients are being referred at an earlier stage of disease, whether they are being referred to designated cancer centres and whether they are receiving their cancer treatment sooner.

Patient survival is one of the best indicators of the efficiency of diagnostic and treatment methods in a geographic area and is widely used as a broad indicator of the effectiveness of health services in the treatment of cancer (165, 472). Whilst the referral and access to initial cancer diagnosis and treatment was the primary focus of this study, it is recognised that additional factors such as radiation therapy, hormonal therapy, recurrences and metastases will also impact on survival outcomes. Whilst it is too early to examine the effect of the centralisation policy on survival rates (5-year survival rates for patients referred from 2010 onwards will be available after 2015), early indicators of effects have been investigated in this study, including changes in stage at diagnosis and access to services. Eurocare studies (473) have shown that tumour stage at diagnosis explains much of the survival differences in breast cancer.
Centralisation of cancer services:
The second National Cancer Strategy (11) in Ireland in 2006 recommended the establishment of a National Cancer Control Programme and outlined key recommendations in relation to centralisation and standardisation of cancer services (Appendix C).

These included:

- The establishment of four cancer control networks
- Review of the number of centres required for the management of symptomatic breast disease
- Comprehensive information available for General Practitioners to enable informed referral and other management decisions
- The development of cancer care pathways to link primary care services, hospital services and other relevant services
- Diagnosis and treatment by site-specific multidisciplinary teams (e.g., breast cancer).

These recommendations form the key policy changes implemented for breast cancer as part of the centralisation programme completed in 2009, outlined in Table 10.1.
### Table 10.1: Cancer centralisation policy in Ireland

<table>
<thead>
<tr>
<th>Policy change (inputs)</th>
<th>Intended effects</th>
<th>Expected outcomes</th>
</tr>
</thead>
</table>
| GP referral guidelines, standardised referral forms and electronic referral. | • Increased GP awareness of indications and processes for referral.  
• Streamlined GP referral process.  
• Reduced delays in processing GP referrals. More efficient and safer referral process. | **Proximal (i.e., within 1-5 years)**  
• Decreased time to referral, diagnosis and treatment.  
• Earlier tumour stage at diagnosis.  
• Less invasive treatment required.  
**Distal (i.e., 5+ years)**  
• Increased survival  
• Decreased morbidity (e.g., lymphoedema) |
| Centralisation of cancer care services into designated centres.  
Standardised care pathways. | • Standardised care by a multidisciplinary team in a designated cancer centre.  
• High-volume multidisciplinary cancer centres with full range of diagnostic and treatment specialties.  
• Higher caseloads – experienced specialist clinicians.  
• Enhanced system of coordination and redefined work practices. | **Proximal (i.e., within 1-5 years)**  
• Treatment and planning by MDT meeting.  
• Patients treated in designated cancer centres.  
• Method of presentation via standardised pathways.  
**Distal (i.e., 5+ years)**  
• “Ireland will have a system of cancer control which will reduce our cancer incidence, morbidity and mortality rates relative to other EU15 countries by 2015.”  
| Quality assurance, research and audit | • Audit and other quality-assurance programmes.  
• Key Performance Indicators and standard operating procedures: Targets for time to diagnosis and treatment.  
• Access to clinical trials and cancer research. | **Proximal (i.e., within 1-5 years)**  
• Adherence to quality indicators.  
• Governance framework – clinical leads.  
• Decrease in waiting times to access service.  
**Distal (i.e., 5+ years)**  
• “Internationally-recognised location for education and research into all aspects of cancer”  
10.2 Aim and objectives
The aim of this study (Study 4) is to determine the impact of the policy of centralisation of cancer services on breast cancer referral patterns in Ireland and to ascertain if this policy has achieved early indicators of success. These aims reflect the intended proximal outcomes of the cancer centralisation policy, outlined in Table 10.1 above.

Specifically, the study objectives are as follows:

1. To identify referral route (method of presentation) of patients with breast cancer in Ireland (e.g., screening programme, GP referral).
2. To determine proportion of patients with breast cancer being diagnosed and treated at designated cancer centres vs. non-cancer centres, since service centralisation.
3. To compare breast cancers referred before and after centralisation, in terms of patient, tumour and hospital characteristics.
4. To determine if patients with breast cancer are being referred and diagnosed at an earlier stage of disease since service centralisation.
5. To determine if waiting times from GP referral to diagnosis and treatment (biopsy, surgery, chemotherapy) have changed since the centralisation policy.

10.3 Methods
10.3.1 Study design
This study involved secondary data analysis of an anonymised national dataset from the National Cancer Registry Ireland (NCRI). Specifically, this study compared breast cancers diagnosed in 2008 (pre-centralisation) with those diagnosed in 2010 (immediately post-centralisation). Whilst a longer timeframe may be preferred to show evidence of change, national cancer registry data later than 2010 were not available at the time of the study.

This ‘before and after’ study design examines the implications of restructuring cancer services by centralising cancer surgery, effectively creating a ‘natural experiment’ in the Irish healthcare system. Centralisation...
of cancer services encompassed the development of GP referral guidelines and defined referral pathways to multidisciplinary teams in designated cancer centres. These initiatives were implemented throughout 2009.

Interrupted time series designs are recommended for quasi-experimental, longitudinal analysis of interventions and are frequently used to evaluate programme impact in health services research and naturally-occurring situations (435, 437). While comparing several years before and after this initiative would have provided greater insight into the effects of the centralisation policy as distinct from underlying trends, insufficient post-centralisation data were available for an interrupted time series approach, given the case follow-up period and time-lag before NCRI data is made available for analysis. The current study, therefore, compares data from 2008 (pre-centralisation), to 2010 (post-centralisation), using regression analysis and time-to-event (survival) analysis, which is the best available approach at this time, given data constraints.

10.3.2 Research ethics
Research ethics approval was granted by the Research Ethics Committee of each of the 8 cancer centres and the satellite centre between December 2010 and May 2011. This was required by the NCRI in order to provide the data for this study, as provision of data on the activity of a specific hospital requires consent from that hospital. Copies of these approval letters are in Appendix I.

10.3.3 Data
This study used anonymised national data from the National Cancer Registry database. The NCRI is a statutory body that began full registration of all cancers in the Republic of Ireland in 1994. Tumour Registration Officers collect data from patient charts (such as medical records, imaging reports and pathology reports) and death certificates. The reporting of cancer is not mandatory in Ireland. The cancer registry receives data from other sources such as the Hospital Inpatient Enquiry (HIPE) Scheme, which records all discharge data from public hospitals in Ireland, including all cases of cancer.
The General Registry Office in Ireland also provides copies of death certificates to the NCRI, which are then cross-checked with the cancer registry data. Information on treatment is retrieved from patient’s medical charts 6 – 12 months following diagnosis. The cancer registry uses the IARC-CHECK programme (474) to perform validity checks on the dataset. The registry also checks data for duplication. The Health (Provision of Information) Act 1997 permits the use of anonymised data from the NCRI for research purposes.

The registry data is coded and classified under International Classification of Diseases (ICD10) codes, according to international guidelines, so that Irish cancer statistics can be compared to other countries worldwide (475). Independent case ascertainment has been carried out by the NCRI using breast cancer cases diagnosed through BreastCheck (the National Breast Screening Programme). The completeness of breast cancer ascertainment for the screening age-group (50 – 65 years) was found to be over 99% (476).

Individual hospitals were identified in the dataset by hospital name for the 9 cancer hospitals (8 cancer centres and 1 satellite centre) (Figure 8.1). The remaining hospitals were labelled by category of hospital (other acute hospital, private hospital or hospital in the UK). The anonymised NCRI national dataset on cases and treatments for breast cancer were imported into Stata V12.1 and merged by a unique patient identification number.

10.3.4 Study cohort
All incident primary breast cancers (coded as C50 (invasive breast cancer) or D05 (in-situ breast cancer) in ICD10) diagnosed in the population usually resident in Ireland, both males and females, in all acute hospitals, including private hospitals, were included in this study. A total of 6,624 cases of primary breast cancers in 6,380 patients were included in the NCRI dataset. A primary cancer is one that originates in a primary site or tissue and is not a recurrence or metastasis.
Cases were excluded if they were diagnosed at the time of death or autopsy (n = 17), consistent with the NCRI data quality and completeness protocol (475), and standard international practice, e.g., the Eurocare project (477). Second and subsequent primary breast cancers were excluded (n = 251), consistent with the guidelines developed jointly by the International Association of Cancer Registries (478) and International Agency for Research on Cancer (478) (see Figure 10.2).

Breast cancers in male patients (n = 46) were included in this study. Studies have shown that men with cancer are older, have larger tumours, have less Stage 0 or Stage I disease and a lower overall survival. However, when differences in method of presentation, absence of data on disease-specific survival and data deficiencies have been accounted for, breast cancers in men and in women appeared more alike than different (479). While the centralisation process and GP referral pathways are applicable to both men and women, BreastCheck would not have had an impact on male breast cancers, as males are not included in the breast screening programme. Of the 6,356 eligible cases, 3,211 were diagnosed in 2008 and 3,145 in 2010. Figure 10.2 shows the study cohort at each stage of analysis, with inclusion and exclusion criteria.

For the analysis of route of referral (method of presentation), all eligible breast cancers were included (n = 6,356). Breast cancers detected incidentally (n = 121) and through screening programmes (n = 1,751) were excluded when examining the type of hospital where treatment was received, as the centralisation of breast cancer surgery applied only to symptomatic breast disease (SBD) services and not to the breast screening service.

Finally, cases treated in private hospitals (n = 824) and in the United Kingdom (n = 21) were excluded when examining time to diagnosis and treatment, as the centralisation policy only applied to the public hospital service in the Republic of Ireland and not to the private hospitals. The majority of cases presenting in the Republic of Ireland who were treated in the United Kingdom were treated in Northern Ireland. The final cohort
included in the analysis of tumour stage at diagnosis and time-to-event comprised 3,639 patients (Figure 10.2).

10.3.5 Outcomes

This study’s objectives and related outcomes are summarised in Table 10.2.

Table 10.2: Outcomes for study objectives

<table>
<thead>
<tr>
<th>Objective</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Referral route (method of presentation): Definition: Route by which patient presented or was referred to the cancer service, e.g., screening service, GP referral to symptomatic service, or incidental diagnosis.</td>
</tr>
</tbody>
</table>
| 2         | Hospital of diagnosis/treatment: Definition: The type of hospital where the patient received their treatment, e.g., designated cancer centre, other acute hospital, private hospital, hospital in the UK.  
- Hospital type where biopsy carried out  
- Hospital type where surgery carried out |
| 3         | Tumour characteristics |
| 4         | Stage of disease at diagnosis: Definition: Stage of disease at diagnosis using TNM* summary stage partial (Stage 0, I, II, III, IV) based on AJCC* cancer staging rules, 5th edition. |
| 5         | Time from GP referral to diagnosis and treatment: Definition: The time in days:  
- from GP referral to diagnosis (biopsy)  
- from diagnosis to surgery  
- from diagnosis to chemotherapy |

*TNM: Tumour, node, metastases. Summary stage of disease is derived from the individual T (Tumour), N (Node), and M (Metastases) categories  
*AJCC: American Joint Committee on Cancer

10.3.5.1 Objective 1: Referral route

Centralisation of breast cancer services could be expected to affect the route by which patients present to cancer services and whether they enter via screening services, GP referrals to the symptomatic service, or are identified incidentally at the time of an unrelated procedure or surgery. As such, the referral route (method of presentation) was compared before and after the implementation of the centralisation policy.
Hypothesis: More breast cancers are diagnosed through structured programmes such as the BreastCheck screening programme and GP referral and less cancers present incidentally (i.e., while being investigated for a different disease) or through opportunistic screening, since implementation of the centralisation policy with defined referral pathways.

**[Outcome 1: Referral route: 1 Symptomatic, 2 Incidental, 3 BreastCheck, 4 Other screening]**

Outcomes were compared for breast cancer cases diagnosed in 2008 (pre-centralisation) to those diagnosed in 2010 (post-centralisation), as indicated by the year of incidence (0 = 2008, 1 = 2010).

10.3.5.2 Objective 2: Hospital of diagnosis and treatment

The main aim of the cancer service reorganisation was to centralise breast cancer diagnosis and treatment. To determine if the policy was effective in achieving this aim, the proportion of patients with breast cancer diagnosed (biopsied) and treated (surgery) was compared by hospital type before and after the implementation of the centralisation policy. Chemotherapy services continue to be delivered in general acute hospitals, as close to the patient’s home as possible.

Hypothesis: Breast cancers are more likely to be diagnosed and have surgery conducted at a cancer centre vs. non-cancer centre since service centralisation.

**[Outcomes 2 & 3: Hospital type where biopsy/surgery carried out: 1 Cancer Centre, 2 Other acute hospital, 3 Private hospital, 4 UK hospital]**

10.3.5.3 Objective 3: To compare breast cancers referred pre- and post-centralisation

The profile of the cohort of patients with breast cancer diagnosed pre-centralisation (2008) was compared with those diagnosed post-centralisation (2010) to detect any differences in the two cohorts in terms of patient characteristics (age at diagnosis, gender, marital status, smoking status and...
region of residence), HSE geographical region of treatment and tumour characteristics (tumour stage, nodal stage, metastases, TNM summary stage and tumour grade).

Hypothesis: the two cohorts (2008 and 2010) are similar in terms of patient characteristics and demographics but show differences in tumour characteristics.

10.3.5.4 Objective 4: Tumour stage at diagnosis
(To determine if centralisation of cancer services has led to earlier stage of disease at diagnosis)
Tumour stage at diagnosis explains much of the survival differences in breast cancer (34, 473, 480). Marital status (481), socioeconomic deprivation (33, 482-485), race (483) and age (486) have been shown to influence tumour stage at diagnosis. Rural patients have been found to have more advanced disease on presentation than urban patients (174). Earlier diagnosis can be associated with less advanced stage of disease at diagnosis and improved cancer outcomes (487). Patient awareness of symptoms and early detection are key to improving breast cancer survival (471).

The cancer centralisation process in Ireland encompassed GP referral guidelines and streamlined referral pathways to facilitate earlier GP referral, with the aim of detecting cancers earlier. Cancers detected earlier are more likely to have an earlier tumour stage at diagnosis and therefore a better prognosis. This study examined tumour stage at diagnosis in the two cohorts. Breast cancers detected pre-centralisation (2008) were compared with those detected post-centralisation (2010).

Hypothesis: Patients with breast cancer are being referred at an earlier stage of disease since the centralisation policy was implemented, with GP referral guidelines and defined referral pathways to designated cancer centres.
Summary stage of disease at diagnosis using TNM summary stage was compared for breast cancers diagnosed pre- and post-centralisation.

[Outcome 4: Stage of disease at diagnosis 1 Stage 0, 2 Stage I, 3 Stage II, 4 Stage III, 5 Stage IV].

10.3.5.5 Objective 5. Time to diagnosis and treatment
(To determine if waiting times from GP referral to diagnosis and treatment (biopsy, surgery, chemotherapy) have improved since the centralisation policy).

Prior to centralisation, GPs reported lengthy waiting times for cancer services (260). As part of the centralisation process, national targets were established for waiting times from GP referral to hospital appointment and from diagnosis to treatment for breast cancer. For example, a target of 10 working days has been set by the NCCP from time of GP referral to time of hospital appointment for urgent referrals. A summary of the NCCP Key Performance Indicators (KPI) for waiting times in SBD units is in Appendix P.

Hypothesis: Waiting times from GP referral to diagnosis and treatment (biopsy, surgery, chemotherapy) have improved (decreased) since the centralisation policy was implemented:

**Outcome 5:** The time in days from GP referral to diagnosis (biopsy) has decreased

**Outcome 6:** The time in days from diagnosis to surgery has decreased

**Outcome 7:** The time in days from diagnosis to chemotherapy has decreased

Table 10.6 summarises the outcomes of interest for each objective of this study. These outcomes were selected as early indicators of the effects of the centralisation policy.
10.3.6 Study variables

Study variables were categorised into patient demographics, tumour/disease factors, lifestyle/socio-economic factors and health service factors, as shown in Figure 10.1 below:

![Figure 10.1: Categories of study variables.](image)

Table 10.3 describes the coding of variables and covariates in this study. All covariates were categorical variables.
### Table 10.3: Description of study variables

<table>
<thead>
<tr>
<th>Coding</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Gender** | Male = 0  
Female = 1 | While breast cancer is predominantly a female disease, cases do present in males. There were a total of 46 breast cancers diagnosed in males in the two years being investigated. |
| **Age group at diagnosis** | 20-34 = 1  
35-49 = 2  
50-64 = 3  
65-79 = 4  
80+ = 5 | Age was categorised into 15 year age-groups, keeping the BreastCheck age cohort in one group. There were no cases under 20 years of age. |
| **Marital status** | Ever married = 1  
Never married = 2 | Marital status of patients was recorded as ‘never married’ or ‘ever married’ which included divorced, separated and widowed. |
| **Region of residence** | Dublin North East = 1  
Dublin mid-Leinster = 2  
South = 3  
West = 4 | The patient’s region of residence was coded by HSE region; HSE Dublin Northeast (n=1227), HSE Dublin mid-Leinster (n=1758), HSE South (n=1836) and HSE West (n=1528). |
| **Deprivation index** | Deprivation index 1 = 1  
Deprivation index 2 = 2  
Deprivation index 3 = 3  
Deprivation index 4 = 4  
Deprivation index 5 = 5 | Deprivation index was derived from the electoral register of patient residence, at electoral district (ED) level, based on the 2006 census. The NCRI incorporated the SAHRU Index of Deprivation (488) into their dataset, which provides a measure of relative material deprivation. The scores were presented in quintiles, with a score of 1 given to the least deprived and a score of 5 to the most deprived (488). |
| **Smoking status** | Never smoked = 0  
Ex-smoker = 1  
Current smoker = 2 | Smoking is categorised as current smoker, ex-smoker or never smoked. |
| **Year of incidence** | 2008 = 0  
2010 = 1 | Year in which breast cancer was diagnosed.  
2008 (pre-centralisation)  
2010 (post centralisation) |
| **Tumour** | T0,Tis,T1,T2,T3,T4, | Tumour stage at diagnosis. Describes the size or extent of local invasion of the tumour, with T4 indicating a larger tumour. |
| **Node** | N0, N1, N2, N3 | Nodal stage at diagnosis. Describes the presence or absence of spread to the lymph nodes, with N3 indicating more advanced disease. |
| **Metastases** | M0, M1 | Metastases at diagnosis. Describes the presence or absence of distant spread of metastases to other organs or tissues, with M1 indicating the presence of metastases. |
| **TNM summary stage** | Stage 0 = 1  
Stage I = 2  
Stage II = 3  
Stage III = 4  
Stage IV = 5 | Summary stage of disease was derived from the individual T (Tumour), N (Node), M (Metastases) categories and is presented as an overall summary stage 0, I, II, III and IV in Table 10.4 below, with Stage IV indicating more advanced disease. |
The TNM classification of malignant tumours, fifth edition (489) is used by the NCRI to stage all malignant cancers. The system is used to describe the clinical and pathological anatomic extent of malignant tumours. The pathological stage has been used in this study. After TNM categories are assigned to a tumour, they are grouped into stages, I-IV (475). The summary stage of disease is derived from the individual T (Tumour), N (Node), M (Metastases) categories and is presented as an overall summary Stage 0, I, II, III and IV in Table 10.4 below.

Table 10.4: TNM summary stage

<table>
<thead>
<tr>
<th>Stage 0</th>
<th>Tumour stage</th>
<th>Nodal stage</th>
<th>Metastases stage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tis</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage 1</td>
<td>T1</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIA</td>
<td>T0</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T1</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T2</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIB</td>
<td>T2</td>
<td>N1</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T3</td>
<td>N0</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIIA</td>
<td>T0</td>
<td>N2</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T1</td>
<td>N2</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T2</td>
<td>N2</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>T3</td>
<td>N1, N2</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IIIB</td>
<td>T4</td>
<td>Any N</td>
<td>M0</td>
</tr>
<tr>
<td></td>
<td>Any T</td>
<td>Any N</td>
<td>M0</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Any T</td>
<td>Any N</td>
<td>M1</td>
</tr>
</tbody>
</table>

*Source: (NCRI, 2012)(490), adapted from Sobin (491).*
10.3.7 Data cleaning and missing data

Accuracy of data was assessed through inspection of data frequencies and values, minimum, maximum and negative values (492). The quality of NCRI data has been discussed in Section 10.3.3.

The completeness of data in relation to staging varies between cancers and is better in breast cancer than other cancers. In an NCRI assessment of data completeness, breast cancer was missing information on stage for 5% of cases. This compares to 42% missing information on staging in oesophageal cancer and 20% in prostate cancer (475). Information on staging may be incomplete because staging investigations were not carried out, or were not recorded in the patient’s medical notes.

In relation to waiting times for diagnosis (biopsy), if the GP referral letter is not contained in the patient’s chart, the time from referral to diagnosis will not be available from NCRI data. This was the case for a high number of patients in the database (n = 2,701). For this reason, national NCCP data for this parameter is also presented.

The misscheck function in Stata was used to check for missing values, summarise missing values and provide patterns of those values. Cases with missing values on any variable used in the analysis were dropped using the listwise deletion method in Stata. Table 10.5 below provides details of missing data for predictors in the study dataset. The final sample size in the analysis was Objective 1 (n = 5,722), Objective 2 (n = 4,086) for biopsy hospital and (n = 3,716) for surgery hospital, Objective 3 (n = 3,639), objective 4 (n = 3,377) and Objective 5 (n = 1,208) for time to diagnosis, (n = 2,709) for time to surgery and (n = 1,626) for time to chemotherapy.
### Table 10.5: Overview of missing data in study dataset

<table>
<thead>
<tr>
<th>Missing data</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Total number of cases: 4,484)</td>
<td></td>
</tr>
<tr>
<td>Deprivation index</td>
<td>741 (16.5%)</td>
</tr>
<tr>
<td>Smoking status</td>
<td>243 (5.4%)</td>
</tr>
<tr>
<td>Method of patient presentation</td>
<td>225 (5.0%)</td>
</tr>
<tr>
<td>Marital status</td>
<td>194 (4.3%)</td>
</tr>
<tr>
<td>TNM summary stage</td>
<td>10 (0.2%)</td>
</tr>
<tr>
<td>Region of patient residence</td>
<td>7 (0.16%)</td>
</tr>
</tbody>
</table>

#### 10.3.7.2 Descriptive analysis

Descriptive statistics were used to examine the prevalence of the study variables in the two cohorts pre- and post-centralisation. Frequencies and proportions were calculated for categorical and binary variables. Demographics (age-group at diagnosis, gender, deprivation index, smoking status, marital status) and tumour characteristics (ICD10, tumour, node, metastases, tumour grade) were compared across the two cohorts to assess similarity and differences. The geographical region of patient residence was also compared with region of treatment.

The chi-squared $\chi^2$ test was used to examine whether the distribution of categorised cases in one variable was independent of their categorical distribution for another variable (493). In this study, the chi-squared test ($\chi^2$) was used to test for differences between the distributions of patient or tumour characteristics in the two separate cohorts.

#### 10.3.7.3 Statistical analyses

To determine if patients with breast cancer were being referred at an earlier stage of disease, the median summary stage at presentation was calculated for each year, as data were not normally distributed. Differences between the median summary stage at presentation were compared using the Mann-Whitney test, also known as Wilcoxon rank-sum test (494), which is a non-parametric independent samples t-test for data where the underlying distribution is not normally distributed. The Mann-Whitney test adds the ranks, divides by the total number of cases and then compares groups to what would be expected if the two groups were the same.
Univariable and multivariable ordinal logistic regression models were used to explore the effect of the centralisation policy (year of incidence) on stage of disease at presentation. Odds ratios (OR) and 95% confidence intervals (95% CI) were calculated, with an OR of greater than 1 indicating greater odds of the outcome occurring, an OR of less than 1 indicated a decrease in the odds of the outcome occurring and an OR of one indicating no association between the exposure variable and the outcome (493). In this study an odds ratio of less than 1 indicated a decrease in the odds of the outcome (later stage at diagnosis) occurring in 2010 (post-centralisation).

Variables for the model were assessed for multicollinearity and singularity. Multicollinearity occurs when variables are very highly correlated and singularity occurs when a variable is a combination of two or more of the other variables (495). The region of patient residence and region of patient treatment had a high variance inflation factor (VIF) of 8.17, when tested for multicollinearity and therefore region of residence was dropped from the model.

In health services research, application of the usual assessment of significance at 0.05 in bivariate models can fail to identify factors which are known to predict outcomes. For this reason, hypothesised predictors (e.g., age at diagnosis), which were found to be significant at $p<0.10$ at bivariable level in addition to confounders and effect modifiers, were considered for inclusion in the multivariable model (496, 497). A $p$-value of $<0.05$ in the regression model was considered statistically significant. In logistic regression modelling, a sample size of at least 10-15 events per predictor variable is recommended to avoid biased estimates of effect size (498-500).

To test whether each variable added to the predictive value of the model, the full model was compared to a nested model, removing one variable at a time, using the likelihood ratio test (501). The variables which did not significantly improve the model were dropped from the model. Where the chi-square statistic was statistically significant, this meant that the variable that was removed to produce the reduced model resulted in a model that had a
significantly poorer fit, and therefore that variable should be included in the model. The most efficient model was identified using this process.

The goodness of fit of the final regression model was assessed using the Hosmer and Lemeshow goodness-of-fit test (496). The Lfit command in Stata 12.1(502) was used to compare the predicted and the observed frequencies, based on the assumption that a model with good fit would produce predictions that closely matched the observed frequencies.

Time to event (survival) analysis using Cox proportional hazards models was used to assess waiting times (Objective 5) including: time to diagnosis (Outcome 5), time to surgery (Outcome 6), and time to chemotherapy (Outcome 7). Variables relating to time-to-event (biopsy, surgery, chemotherapy) were assessed for normality of distribution using tests for skewness and kurtosis. Skewness relates to the symmetry of the distribution within a variable and kurtosis relates to the heaviness of the tails of a distribution. None of the variables had a score greater than 3.29 and therefore were considered to be normally distributed (503). The time-to-event data were examined on a continuous scale (in days) and were also categorised into time bands, based on current targets within the health service.

The hazard ratio represents the likelihood of the event (diagnosis/treatment) happening at any point after the referral. Hazard Ratios (HR) for factors associated with time-to-diagnosis/time-to-treatment were modelled, and crude and adjusted models are presented. A hazard ratio greater than one represents a greater likelihood of the patient reaching the event earlier.

Factors which were found to be significant at p<0.10 at bivariable level were considered for inclusion in the multivariable model, in addition to potential confounders, such as smoking status, deprivation index and age at diagnosis (496, 497). Gender was not included in the model as males comprised less than one percent of the total cases.
For variables which were not ordinal (e.g., region of residence, region of treatment), the reference (base) level was specified using the largest category for that variable. For example, for region of patient residence and for region of treatment, the HSE region with the greatest number of patients was HSE South. Therefore, this was designated as the reference region in the model.

Cases with zero delay (e.g., biopsy the same day as surgery) were re-coded to 0.5 days as Stata omits values of zero for time-to-event analysis. Negative values are automatically excluded from the analysis by Stata. Kaplan-Meier failure curves are presented to graphically represent the effect of year (centralisation) on the cumulative proportion of patients reaching the event of interest (time-to-diagnosis) over time, in days.

10.3.7.4 Summary of statistical analysis
Table 10.6 shows a summary of the statistical analysis used for this study. Year of incidence was the predictor variable for each of the objectives.
Table 10.6: Summary of statistical analysis

<table>
<thead>
<tr>
<th>Objective</th>
<th>Primary Outcome</th>
<th>Predictor</th>
<th>Covariates</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Socio economic factors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disease factors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Health service factors.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10.4 Results

Of the 6,356 eligible cases, 3,211 were diagnosed in 2008 and 3,145 in 2010. Figure 10.2 shows the study cohort at each stage of analysis, with inclusion and exclusion criteria.

Figure 10.2: Study cohort.

10.4.1 Objective 1: Referral route

Referral route (method of patient presentation) is presented in Figure 10.3. The proportion of breast cancers detected through the BreastCheck screening programme increased from 22.8% in 2008 to 29.8% in 2010 ($\chi^2 = 54.1$, p < 0.001), while the proportion of breast cancers detected incidentally or at unofficial screening decreased (Table 10.7).
The increase in cancers detected through screening, with slight decrease in those detected at SBD clinics corresponds to the availability of BreastCheck, which was being rolled-out nationally during the period of this research. BreastCheck was available in all areas of the country by December 2011.

Table 10.7: Referral route - breast cancers

<table>
<thead>
<tr>
<th>Method of presentation</th>
<th>Year of Incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>$\chi^2$ p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>2,029 (69%)</td>
<td>1,821 (65%)</td>
<td>$\chi^2 = 54.1$ p &lt;0.001</td>
</tr>
<tr>
<td>Incidental</td>
<td>73 (2.5%)</td>
<td>48 (1.7%)</td>
<td></td>
</tr>
<tr>
<td>BreastCheck</td>
<td>670 (22.8%)</td>
<td>831 (29.8%)</td>
<td></td>
</tr>
<tr>
<td>Other screening</td>
<td>164 (5.6%)</td>
<td>86 (3.1%)</td>
<td></td>
</tr>
</tbody>
</table>

10.4.2 Objective 2: Hospital type

The type of hospital where diagnosis (biopsy) and treatment (surgery) was carried out was examined to ascertain if patients were being treated in designated cancer centres.

10.4.2.1 Hospital of diagnosis before and after centralisation policy

Table 10.8 shows that the proportion of breast cancer cases diagnosed (biopsied) in a cancer centre rose significantly from 58.4% in 2008 to 85.7% in 2010 ($\chi^2 = 576.5$, p<0.001), an absolute increase of 27%. There was a
corresponding drop in cases diagnosed in other acute hospitals which are not cancer centres from 26.5% to 1.2%. The confidence intervals of proportions attending cancer centres give a plausible estimate of value and indicate high study precision (see Table 10.8). The proportion of breast cancers being diagnosed in private hospitals dropped from 14.6% to 12.9% during the same period.

Table 10.8: Type of hospital where diagnosis (biopsy) carried out

<table>
<thead>
<tr>
<th></th>
<th>Year of incidence 2008</th>
<th>Year of incidence 2010</th>
<th>χ²</th>
<th>p -value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>n = 2076</td>
<td>n = 2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer centre</td>
<td>1,213 (58.4%)</td>
<td>1,723 (85.7%)</td>
<td>576.5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>CI: 56-61%</td>
<td>CI: 84-87%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other acute hospital</td>
<td>551 (26.5%)</td>
<td>24 (1.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private hospital</td>
<td>302 (14.6%)</td>
<td>259 (12.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>10 (0.48%)</td>
<td>4 (0.20%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 10.4 below shows the observed proportions in the two separate 12-month windows, which is an indicator of the underlying process.

Figure 10.4: Type of hospital where diagnosis (biopsy) carried out.
10.4.2.2 Hospital of surgery

Table 10.9 shows that the proportion of patients having their breast cancer surgery in designated cancer centres rose from 50.8% in 2008 to 80.7% in 2010 ($\chi^2 = 687$, $p<0.001$), an absolute increase of 30%. The confidence intervals indicate a high study precision. There was a corresponding drop in breast cancer surgery carried out in other acute hospitals (non-cancer centres) from 32.1% to 0.3%. The proportion of patients having surgery in private hospitals also increased slightly from 16.8% to 18.9% during the same period.

Table 10.9: Hospital type for breast surgery

<table>
<thead>
<tr>
<th></th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>$\chi^2$ p -value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>n = 1940</td>
<td>n = 1776</td>
<td>$\chi^2= 687.0$ $p &lt;0.001$</td>
</tr>
<tr>
<td>Cancer centre</td>
<td>985 (50.8%) CI: 49 – 53%</td>
<td>1,433 (80.7%) CI: 79 – 82%</td>
<td></td>
</tr>
<tr>
<td>Other acute hospital</td>
<td>623 (32.1%)</td>
<td>5 (0.3%)</td>
<td></td>
</tr>
<tr>
<td>Private hospital</td>
<td>325 (16.8%)</td>
<td>335 (18.9%)</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>7 (0.4%)</td>
<td>3 (0.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 10.5 below shows that the majority of cancers previously treated at acute general hospitals are now, since the centralisation policy, being treated in designated cancer centres.
Table 10.10 shows the demographic characteristics of the 2008 and 2010 samples. Age-group at diagnosis, marital status and deprivation index are similar in the two cohorts. Less than 1% of cases occurred in males in both cohorts. There was an increase in the proportion of those who had never smoked in the 2010 cohort which was statistically significant ($\chi^2 = 6.43$, $p = 0.040$). The age-group at death was older in the 2010 cohort, which was also statistically significant ($\chi^2 = 11.17$, $p = 0.025$).

Figure 10.5: Hospital type for breast surgery.
Table 10.10: Demographic characteristics of 2008 and 2010 samples

<table>
<thead>
<tr>
<th>Age group at diagnosis (n = 3639)</th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>χ² p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-34</td>
<td>35 (1.9%)</td>
<td>44 (2.5%)</td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>537 (28.9%)</td>
<td>520 (29.2%)</td>
<td></td>
</tr>
<tr>
<td>50-64</td>
<td>531 (28.6%)</td>
<td>472 (26.5%)</td>
<td></td>
</tr>
<tr>
<td>65-79</td>
<td>519 (27.9%)</td>
<td>508 (28.5%)</td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>235 (12.7%)</td>
<td>238 (13.4%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender (n = 3639)</th>
<th></th>
<th></th>
<th>p = 0.502</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13 (0.7%)</td>
<td>16 (0.9%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1844 (99.3%)</td>
<td>1766 (99.1%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deprivation index (n = 3042)</th>
<th></th>
<th></th>
<th>p = 0.506</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI 1</td>
<td>259 (15.5%)</td>
<td>216 (15.5%)</td>
<td></td>
</tr>
<tr>
<td>DI 2</td>
<td>231 (13.8%)</td>
<td>180 (13.1%)</td>
<td></td>
</tr>
<tr>
<td>DI 3</td>
<td>272 (16.3%)</td>
<td>201 (14.7%)</td>
<td></td>
</tr>
<tr>
<td>DI 4</td>
<td>331 (19.8%)</td>
<td>261 (19.1%)</td>
<td></td>
</tr>
<tr>
<td>DI 5 (most deprived)</td>
<td>579 (34.6%)</td>
<td>512 (37.4%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smoking status (n = 2484)</th>
<th></th>
<th></th>
<th>p = 0.040</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never smoked</td>
<td>780 (57.4%)</td>
<td>702 (62.3%)</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>206 (15.2%)</td>
<td>158 (14.0%)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>372 (27.4%)</td>
<td>266 (23.6%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marital status (n = 3380)</th>
<th></th>
<th></th>
<th>p = 0.297</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever married</td>
<td>1505 (83.2%)</td>
<td>1284 (81.8%)</td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>305 (16.9%)</td>
<td>286 (18.2%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age-group at death (n = 628)</th>
<th></th>
<th></th>
<th>p = 0.025</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-44</td>
<td>23 (5.5%)</td>
<td>14 (6.7%)</td>
<td></td>
</tr>
<tr>
<td>45-54</td>
<td>47 (11.2%)</td>
<td>17 (8.1%)</td>
<td></td>
</tr>
<tr>
<td>55-64</td>
<td>58 (13.8%)</td>
<td>23 (11.0%)</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>93 (22.2%)</td>
<td>30 (14.4%)</td>
<td></td>
</tr>
<tr>
<td>75+</td>
<td>198 (47.3%)</td>
<td>125 (59.8%)</td>
<td></td>
</tr>
</tbody>
</table>

Exclusions: Incidental cancers, screen-detected cancers, private hospitals, hospitals in the UK.
Table 10.11 shows a comparison of tumour characteristics across the two cohorts. There was an increase in in-situ breast tumours and T0 tumours in 2010, with a decrease in more advanced T4 tumours ($\chi^2 = 12.25$, $p = 0.032$). There was a slight increase in N0 and N3 tumours in 2010. The overall p-value was statistically significant ($\chi^2 = 9.16$, $p = 0.027$). There were no significant changes in tumour summary stage, tumour grade or metastases detected at diagnosis.

### Table 10.11: Tumour characteristics of 2008 and 2010 cohorts

<table>
<thead>
<tr>
<th></th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>$\chi^2$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICD</strong> (n = 3639)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D05 in-situ</td>
<td>123 (6.6%)</td>
<td>143 (8.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C50 invasive</td>
<td>1734 (93.4%)</td>
<td>1639 (91.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tumour stage</strong> (n = 2820)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pTis</td>
<td>123 (8.8%)</td>
<td>147 (10.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT1</td>
<td>510 (36.4%)</td>
<td>476 (33.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT2</td>
<td>629 (44.9%)</td>
<td>633 (44.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT3</td>
<td>94 (6.7%)</td>
<td>121 (8.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT4</td>
<td>41 (2.9%)</td>
<td>32 (2.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pT0</td>
<td>3 (0.2%)</td>
<td>11 (0.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nodal stage</strong> (n = 2691)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pN0</td>
<td>726 (54.8%)</td>
<td>764 (55.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pN1</td>
<td>482 (36.4%)</td>
<td>467 (34.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pN2</td>
<td>69 (5.2%)</td>
<td>58 (4.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pN3</td>
<td>47 (3.6%)</td>
<td>78 (5.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mets stage</strong> (n = 435)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pM0</td>
<td>277 (93.0%)</td>
<td>174 (91.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pM1</td>
<td>17 (6.9%)</td>
<td>18 (8.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Summary stage</strong> (n = 3378)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>129 (7.3%)</td>
<td>148 (9.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>408 (23.1%)</td>
<td>372 (23.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage II</td>
<td>808 (45.7%)</td>
<td>729 (45.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage III</td>
<td>265 (14.9%)</td>
<td>240 (14.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage IV</td>
<td>160 (9.0%)</td>
<td>119 (7.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tumour grade</strong> (n = 3384)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>7 (0.4%)</td>
<td>6 (0.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>659 (38.2%)</td>
<td>606 (36.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>875 (50.7%)</td>
<td>824 (49.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>184 (10.7%)</td>
<td>223 (13.4%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Exclusions: Incidental cancers, screen-detected cancers, private hospitals, hospitals in the UK.
Table 10.12 shows the region in which the patient lived and the region in which their treatment was received. More patients resided in HSE South than in other regions in both cohorts. The region where most surgery was performed was also HSE South in both cohorts. The region where most chemotherapy was administered changed from HSE West in 2008 to HSE South in 2010.

Table 10.12: Region of residence and region of treatment

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2010</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Region of patient residence</strong> (n = 3632)</td>
<td></td>
<td></td>
<td>0.057</td>
</tr>
<tr>
<td>DNE</td>
<td>344 (18%)</td>
<td>346 (20%)</td>
<td></td>
</tr>
<tr>
<td>DML</td>
<td>425 (23%)</td>
<td>465 (26%)</td>
<td></td>
</tr>
<tr>
<td>South</td>
<td>568 (31%)</td>
<td>497 (28%)</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>520 (28%)</td>
<td>467 (26%)</td>
<td></td>
</tr>
<tr>
<td><strong>Region of surgery</strong> (n = 2935)</td>
<td></td>
<td></td>
<td>0.593</td>
</tr>
<tr>
<td>DNE</td>
<td>336 (22%)</td>
<td>312 (22%)</td>
<td></td>
</tr>
<tr>
<td>DML</td>
<td>288 (19%)</td>
<td>295 (21%)</td>
<td></td>
</tr>
<tr>
<td>South</td>
<td>476 (31%)</td>
<td>423 (30%)</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>421 (28%)</td>
<td>384 (27%)</td>
<td></td>
</tr>
<tr>
<td><strong>Region of chemotherapy</strong> (n = 1627)</td>
<td></td>
<td></td>
<td>0.193</td>
</tr>
<tr>
<td>DNE</td>
<td>187 (21%)</td>
<td>155 (21%)</td>
<td></td>
</tr>
<tr>
<td>DML</td>
<td>178 (20%)</td>
<td>124 (17%)</td>
<td></td>
</tr>
<tr>
<td>South</td>
<td>256 (29%)</td>
<td>241 (33%)</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>274 (31%)</td>
<td>212 (29%)</td>
<td></td>
</tr>
</tbody>
</table>

The proportion of patients having their surgery in the region in which they live is presented in Table 10.13. The majority of patients had their surgery within their own geographical region at both time points. Of those cases resident in HSE Dublin mid-Leinster, 18% travelled to other HSE regions for their breast surgery in both 2008 and 2010, usually to the adjacent region of Dublin-North East.
Table 10.13: Region of residence compared to region of treatment

<table>
<thead>
<tr>
<th>2008</th>
<th>HSE Region of Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSE region of patient residence</td>
<td>DNE</td>
</tr>
<tr>
<td>DNE</td>
<td>95%</td>
</tr>
<tr>
<td>DML</td>
<td>16%</td>
</tr>
<tr>
<td>South</td>
<td>1%</td>
</tr>
<tr>
<td>West</td>
<td>2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2010</th>
<th>HSE Region of Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSE region of surgery</td>
<td>DNE</td>
</tr>
<tr>
<td>DNE</td>
<td>96%</td>
</tr>
<tr>
<td>DML</td>
<td>13%</td>
</tr>
<tr>
<td>South</td>
<td>1%</td>
</tr>
<tr>
<td>West</td>
<td>1%</td>
</tr>
</tbody>
</table>

10.4.4 Objective 4: Tumour stage at diagnosis

The tumour stage at diagnosis was compared for the two cohorts. Data on TNM summary stage were available for 3,377 cases. The median stage remained at Stage II for both years being examined. The mean summary stage is shown for each year. Table 10.14 shows a slight reduction in the mean in 2010.

(1 = Stage 0, 2 = Stage I, 3 = Stage II, 4 = Stage III, 5 = Stage IV)

Table 10.14: TNM summary stage at diagnosis, by year

<table>
<thead>
<tr>
<th>TNM Summary Stage</th>
<th>n</th>
<th>Mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>1,770</td>
<td>Mean = 2.95</td>
<td>Stage II</td>
</tr>
<tr>
<td>2010</td>
<td>1,608</td>
<td>Mean = 2.88</td>
<td>Stage II</td>
</tr>
<tr>
<td>Overall</td>
<td>3,377</td>
<td>Mean = 2.92</td>
<td>Stage II</td>
</tr>
</tbody>
</table>

The rank-sum for both years was calculated using the Mann-Whitney test; the 2010 rank-sum was found to be lower than expected. However, there was no statistically significant difference between the underlying distributions of summary stage between years ($z = 1.8$, $p = 0.0724$).

The ‘P order’ command in Stata 12.1 was used to test the hypothesis that there was a lower stage at diagnosis in 2010. The measure of effect size produced a 51.7% probability of a lower stage in 2010, showing that there was no appreciable effect size ($p$ order = 0.517).
Ordinal logistic regression was used to assess the impact of centralisation (year of diagnosis) on the tumour stage at diagnosis. Table 10.15 shows the univariable model for stage of disease at diagnosis and the multivariable model. Gender was not included in the model as the number of males was too small.

Table 10.15: Impact of centralisation of services on tumour stage (stage of disease) at diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Univariable Crude model OR (95% CI)</th>
<th>p-value</th>
<th>Multivariable adjusted model* OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year of incidence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008 (reference)</td>
<td>0.78 (0.61 - 0.99)</td>
<td><strong>0.043</strong></td>
<td>.94 (.80 - 1.1)</td>
<td>0.438</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age-group at diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(15-year increments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-34 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>0.82 (0.34 - 1.9)</td>
<td>0.642</td>
<td>0.85 (0.47 - 1.5)</td>
<td>0.576</td>
</tr>
<tr>
<td>50-64</td>
<td>0.99 (0.42 - 2.4)</td>
<td>0.985</td>
<td>0.93 (0.52 - 1.7)</td>
<td>0.817</td>
</tr>
<tr>
<td>65-79</td>
<td>1.1 (0.48 - 2.7)</td>
<td>0.771</td>
<td>0.88 (0.49 - 1.6)</td>
<td>0.681</td>
</tr>
<tr>
<td>80+</td>
<td>2.2 (0.84 - 6.0)</td>
<td>0.107</td>
<td>1.9 (0.99 - 3.5)</td>
<td>0.053</td>
</tr>
<tr>
<td><strong>Marital status (reversed)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever married</td>
<td>1.4 (1.1 - 1.9)</td>
<td><strong>0.011</strong></td>
<td>0.92 (0.74 - 1.2)</td>
<td>0.444</td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoked (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>1.7 (0.97 - 2.8)</td>
<td>0.065</td>
<td>1.1 (0.89 - 1.4)</td>
<td>0.337</td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.95 (0.67 - 1.3)</td>
<td>0.762</td>
<td>0.95 (0.78 - 1.1)</td>
<td>0.565</td>
</tr>
<tr>
<td><strong>Deprivation - quintiles</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation index = 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation index = 2</td>
<td>1.1 (0.69 - 1.8)</td>
<td>0.627</td>
<td>1.0 (0.75 - 1.3)</td>
<td>0.983</td>
</tr>
<tr>
<td>Deprivation index = 3</td>
<td>1.1 (0.68 - 1.8)</td>
<td>0.702</td>
<td>1.0 (0.78 - 1.4)</td>
<td>0.860</td>
</tr>
<tr>
<td>Deprivation index = 4</td>
<td>1.1 (0.69 - 1.7)</td>
<td>0.736</td>
<td>1.3 (0.98 - 1.7)</td>
<td>0.068</td>
</tr>
<tr>
<td>Deprivation index = 5</td>
<td>1.3 (0.86 - 1.9)</td>
<td>0.213</td>
<td>1.1 (0.90 - 1.5)</td>
<td>0.266</td>
</tr>
<tr>
<td>(most deprived)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Region of residence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSE South (3) (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSE Dublin North East (1)</td>
<td>1.2 (0.85 - 1.8)</td>
<td>0.284</td>
<td>0.97 (0.75 - 1.3)</td>
<td>0.799</td>
</tr>
<tr>
<td>HSE Dublin mid Leinster (2)</td>
<td>1.2 (0.85 - 1.7)</td>
<td>0.313</td>
<td>1.2 (0.94 - 1.4)</td>
<td>0.162</td>
</tr>
<tr>
<td>HSE West (4)</td>
<td>1.0 (0.74 - 1.4)</td>
<td>0.929</td>
<td>1.1 (0.91 - 1.4)</td>
<td>0.292</td>
</tr>
</tbody>
</table>

*Adjusted for age at diagnosis (20-34, 35-49, 50-64, 65-79, 80+), marital status (never married, ever married) smoking status (never smoked, ex-smoker, current smoker) deprivation index (DI 1, DI2, DI3, DI4, DI5) and HSE region of residence (Dublin North east, Dublin mid Leinster, South, West).
Year of incidence and marital status were significantly associated with stage of disease at the unadjusted level of analysis, indicating that those diagnosed in 2010 and those ever married were at an earlier stage of disease when diagnosed. However, when entered into the multivariable model, controlling for age at diagnosis, smoking status, deprivation index and region of residence, neither retained significance.

Using the likelihood ratio test, none of the independent variables significantly contributed to the explanation of variation in stage of disease at diagnosis.

The goodness-of-fit of the final regression model was not assessed using the Hosmer and Lemeshow goodness-of-fit test (496) as a poor model fit had already been established. This poor model fit suggests either centralisation (year of diagnosis) is the main influencing factor or that additional factors may have influenced staging, such as number of nodes excised and more thorough investigations in specialist centres. However, the data were not available to investigate this hypothesis further – this is one of the limitations of secondary data analysis. It may also be too early to detect a change in tumour stage at diagnosis, given that these data were collected immediately after the centralisation process was introduced. In addition, breast cancer is a slow-growing disease and therefore a more significant shift in timelines would be required to show a difference in staging.

Table 10.16 shows the final model of the impact of year of incidence on tumour stage at diagnosis. Using the likelihood ratio test, none of the independent variables significantly contributed to the explanation of variation in stage of disease at diagnosis. Therefore these variables were dropped from the model and the final model is the unadjusted univariable crude model.
Table 10.16: Impact of year (centralisation) on stage of disease at diagnosis

<table>
<thead>
<tr>
<th>Odds ratio</th>
<th>Confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.78</td>
<td>(0.61-0.99)</td>
<td>0.043</td>
</tr>
</tbody>
</table>

The odds ratio shows that there was a significant reduction in the odds of having a more advanced stage at diagnosis post-centralisation, with a 22% lower chance of more advanced stage of disease at diagnosis in 2010.

10.4.5 Objective 5: Time to diagnosis and treatment

Table 10.17 below compared the waiting time to diagnosis and treatment in the two cohorts. The time from GP referral to diagnosis has decreased significantly, with 73% of cases diagnosed within 2 weeks of GP referral in 2010 compared with 56% in 2008 ($\chi^2 = 46.67$, p < 0.001). Slightly more cases are having surgery in 2010 within 6 weeks of diagnosis, which is the target set by the NCCP for cases whose first line of treatment is surgery. Patients generally have their surgery first, followed by chemotherapy. Patients being treated with neo-adjuvant chemotherapy (NAC) (i.e., chemotherapy before surgery) are excluded from the analysis examining time to surgery. However, time from diagnosis to chemotherapy showed a slight drop in the proportion of cases commencing therapy within 14 weeks of diagnosis; the target set by the NCCP for patients to have undergone diagnosis (biopsy) and surgery, and commenced chemotherapy.
Table 10.17: Comparative analysis of time to diagnosis and treatment

<table>
<thead>
<tr>
<th>Time from GP referral to diagnosis (biopsy) n = 1,208</th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>χ² p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;= 2 weeks</td>
<td>357 (55.9%)</td>
<td>417 (73.3%)</td>
<td>χ² = 46.67 p &lt; 0.001</td>
</tr>
<tr>
<td>2 - 6 weeks</td>
<td>186 (29.1%)</td>
<td>82 (14.4%)</td>
<td></td>
</tr>
<tr>
<td>6 - 12 weeks</td>
<td>57 (8.9%)</td>
<td>36 (6.3%)</td>
<td></td>
</tr>
<tr>
<td>3 - 6 months</td>
<td>27 (4.2%)</td>
<td>26 (4.6%)</td>
<td></td>
</tr>
<tr>
<td>Over 6 months</td>
<td>12 (1.9%)</td>
<td>8 (1.4%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from diagnosis to surgery (excl. NAC) n = 2,709</th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>χ² p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;= 6 weeks</td>
<td>1,233 (87.6%)</td>
<td>1,146 (88%)</td>
<td>χ² = 6.15 p = 0.104</td>
</tr>
<tr>
<td>6 – 12 weeks</td>
<td>131 (9.3%)</td>
<td>98 (7.5%)</td>
<td></td>
</tr>
<tr>
<td>3 – 6 months</td>
<td>25 (1.8%)</td>
<td>35 (2.7%)</td>
<td></td>
</tr>
<tr>
<td>Over 6 months</td>
<td>18 (1.3%)</td>
<td>23 (1.8%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from diagnosis to chemotherapy n = 1,626</th>
<th>Year of incidence 2008 n (%)</th>
<th>Year of incidence 2010 n (%)</th>
<th>χ² p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;= 14 weeks</td>
<td>684 (76.4%)</td>
<td>546 (74.7%)</td>
<td>χ² = 4.12 p = 0.249</td>
</tr>
<tr>
<td>14- 20 weeks</td>
<td>140 (15.6%)</td>
<td>125 (17.1%)</td>
<td></td>
</tr>
<tr>
<td>20-34 weeks</td>
<td>49 (5.5%)</td>
<td>32 (4.4%)</td>
<td></td>
</tr>
<tr>
<td>Over 34 weeks</td>
<td>22 (2.5%)</td>
<td>28 (3.8%)</td>
<td></td>
</tr>
</tbody>
</table>

10.4.5.1  Time to biopsy
The time to event data for time from GP referral to diagnosis (biopsy) are summarised in Table 10.18 below. Negative values were automatically excluded from the analysis by Stata (n = 27).
Table 10.18: Time from GP referral to diagnosis

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of patients (cases)</th>
<th>Mean (days)</th>
<th>Time from GP referral to diagnosis, in days (25% 50% (median) 75%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>639</td>
<td>29.0</td>
<td>7 14 31</td>
</tr>
<tr>
<td>2010</td>
<td>569</td>
<td>22.6</td>
<td>7 11 18</td>
</tr>
<tr>
<td>Total</td>
<td>1,208</td>
<td>25.9</td>
<td>7 12 27</td>
</tr>
</tbody>
</table>

Table 10.18 shows the decrease in median time from GP referral to biopsy from 14 to 11 days (IQR = 7-18) in 2010. In 2010, 75% of patients had their biopsy within 18 days of GP referral, compared to 31 days in 2008. The 95th percentile remained at 92 days in both years.

Figure 10.6 graphically presents the time from GP referral to diagnosis, indicating that the reduction in referral time from 2008 and 2010 takes place most prominently within the first 2-3 weeks of referral. The Cox regression for time to diagnosis was statistically significant overall, with a particular increase in the number of patients receiving a diagnosis within 3 weeks of GP referral.

![Time from GP referral to diagnosis](chart.png)

Figure 10.6: Kaplan Meier failure curve: Time from GP referral to diagnosis (biopsy).
The graph for time to biopsy was truncated at six months (182 days); twenty cases exceeded this value.

In order to analyse the effects of several prognostic variables simultaneously on time from GP referral to diagnosis, a Cox proportional hazards regression analysis was conducted (see Table 10.19). Adjusted analysis was carried out to control for the confounding effects of covariates (age at diagnosis, deprivation index, region of biopsy). The crude and adjusted models are presented.

Table 10.19: The influence of potential prognostic factors on time from GP referral to biopsy (Cox proportional hazards regression)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Crude HR (95% CI)</th>
<th>p-value</th>
<th>Adjusted HR* (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year of incidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>1.2 (1.0 - 1.3)</td>
<td>0.010</td>
<td>1.2 (1.0-1.3)</td>
<td>0.015</td>
</tr>
<tr>
<td>Age at diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(15-year increments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-34 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>1.5 (1.0 - 2.3)</td>
<td>0.042</td>
<td>1.6 (.98 - 2.4)</td>
<td>0.059</td>
</tr>
<tr>
<td>50-64</td>
<td>1.6 (1.1 - 2.4)</td>
<td>0.021</td>
<td>1.7 (1.1 - 2.6)</td>
<td>0.029</td>
</tr>
<tr>
<td>65-79</td>
<td>1.8 (1.2 - 2.7)</td>
<td>0.004</td>
<td>1.8 (1.1 - 2.8)</td>
<td>0.011</td>
</tr>
<tr>
<td>80+</td>
<td>1.9 (1.2 - 2.9)</td>
<td>0.003</td>
<td>2.0 (1.3 - 3.3)</td>
<td>0.004</td>
</tr>
<tr>
<td>Deprivation index</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(quintiles)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 1 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Least deprived</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 2</td>
<td>1.1 (0.90 - 1.4)</td>
<td>0.277</td>
<td>1.2 (0.92 -1.5)</td>
<td>0.205</td>
</tr>
<tr>
<td>DI 3</td>
<td>1.1 (0.89 - 1.4)</td>
<td>0.393</td>
<td>1.1 (0.87 -1.4)</td>
<td>0.447</td>
</tr>
<tr>
<td>DI 4</td>
<td>1.1 (0.89 - 1.3)</td>
<td>0.382</td>
<td>1.1 (0.88 -1.3)</td>
<td>0.430</td>
</tr>
<tr>
<td>DI 5</td>
<td>1.1 (0.88 - 1.3)</td>
<td>0.569</td>
<td>1.1 (0.90 -1.3)</td>
<td>0.364</td>
</tr>
<tr>
<td>Region of biopsy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNE (1)</td>
<td>.87 (0.48 - 1.6)</td>
<td>0.649</td>
<td>1.1 (0.44 - 2.7)</td>
<td>0.872</td>
</tr>
<tr>
<td>DML (2)</td>
<td>.88 (0.75 - 1.0)</td>
<td>0.113</td>
<td>.89 (0.75 -1.1)</td>
<td>0.192</td>
</tr>
<tr>
<td>West (4)</td>
<td>.93 (0.81 - 1.1)</td>
<td>0.301</td>
<td>.91 (0.79 -1.1)</td>
<td>0.232</td>
</tr>
</tbody>
</table>

* Adjusted for age at diagnosis (20-34, 35-49, 50-64, 65-79, 80+), deprivation index (D1, D2, D3, D4, D5) and region of biopsy (Dublin North East, Dublin mid Leinster, South, West).
In crude modelling, year of incidence and age at diagnosis were statistically significantly associated with shorter time to event (diagnosis), both of which retained significance in the multivariate model. A hazard ratio greater than 1 represents a greater likelihood of reaching the event, in this case, shorter waiting time from GP referral to diagnosis. Age over 80 years increased the likelihood of shorter time to event (diagnosis) two-fold, indicating that older age-groups may have been prioritised in the triage and appointments process. This is appropriate, given the epidemiology of the disease.

Generally, in time-to-event (survival) analysis, the event of interest is death or disease. In this study the event is receipt of biopsy (diagnosis). Patients with breast cancer diagnosed in 2010 were 20% more likely to have a shorter time to event (diagnosis) than those diagnosed in 2008, when adjusted for age, deprivation and HSE region where biopsy was carried out.

10.4.5.2 Time to surgery
Patients who received neo-adjuvant chemotherapy (chemotherapy before surgery) were excluded from this analysis, as surgery is postponed for these patients until chemotherapy has been completed, usually to decrease the size of the tumour before surgery (n = 224; 114 in 2008, 110 in 2010). An additional two negative values were automatically excluded from the analysis by Stata. The time-to-event data for surgery is summarised in Table 10.20 below.

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of patients (cases)</th>
<th>Mean (days)</th>
<th>Time from diagnosis to surgery, in days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>25%</td>
</tr>
<tr>
<td>2008</td>
<td>1,407</td>
<td>Mean = 30.4</td>
<td>15</td>
</tr>
<tr>
<td>2010</td>
<td>1,302</td>
<td>Mean = 33.6</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>2,709</td>
<td>Mean = 31.9</td>
<td>15</td>
</tr>
</tbody>
</table>

Table 10.20 shows that the median time to surgery has increased slightly from 22 to 25 days. The 95th percentile increased from 64 days in 2008 to 80 days in 2010. Table 10.21 shows the Cox proportional hazards regression
for analysing several prognostic variables simultaneously for time from diagnosis to surgery. The crude and adjusted models are presented.

Table 10.21: The influence of potential prognostic factors on time from diagnosis to surgery (Cox proportional hazards regression)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Crude HR (95% CI)</th>
<th>p-value</th>
<th>Adjusted* HR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year of incidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>0.88 (0.82-0.95)</td>
<td><strong>0.001</strong></td>
<td>0.89 (0.82-0.97)</td>
<td><strong>0.006</strong></td>
</tr>
<tr>
<td>Age at diagnosis (15-year increments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-34 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>1.2 (0.91 - 1.6)</td>
<td>0.201</td>
<td>1.0 (0.75 - 1.4)</td>
<td>0.876</td>
</tr>
<tr>
<td>50-64</td>
<td>1.2 (0.94 - 1.6)</td>
<td>0.130</td>
<td>1.0 (0.75 - 1.4)</td>
<td>0.917</td>
</tr>
<tr>
<td>65-79</td>
<td>1.0 (0.79 - 1.4)</td>
<td>0.791</td>
<td>.85 (0.63 - 1.2)</td>
<td>0.306</td>
</tr>
<tr>
<td>80+</td>
<td>0.89 (0.66 - 1.2)</td>
<td>0.491</td>
<td>.81 (0.58 - 1.1)</td>
<td>0.243</td>
</tr>
<tr>
<td>Deprivation index (quintiles)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 1 (reference) Least deprived</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 2</td>
<td>0.94 (0.81 - 1.1)</td>
<td>0.394</td>
<td>0.94 (0.80 - 1.1)</td>
<td>0.339</td>
</tr>
<tr>
<td>DI 3</td>
<td>0.96 (0.83 - 1.1)</td>
<td>0.591</td>
<td>0.97 (0.84 - 1.1)</td>
<td>0.719</td>
</tr>
<tr>
<td>DI 4</td>
<td>0.88 (0.76 - 1.0)</td>
<td>0.066</td>
<td>0.88 (0.76 - 1.0)</td>
<td>0.079</td>
</tr>
<tr>
<td>DI 5</td>
<td>0.87 (0.77 -0.98)</td>
<td><strong>0.025</strong></td>
<td>0.89 (0.78 - 1.0)</td>
<td>0.064</td>
</tr>
<tr>
<td>Tumour summary stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>1.2 (1.0 - 1.4)</td>
<td><strong>0.022</strong></td>
<td>1.1 (0.96 - 1.3)</td>
<td>0.129</td>
</tr>
<tr>
<td>Stage II</td>
<td>1.1 (0.97 - 1.3)</td>
<td>0.117</td>
<td>1.1 (0.91 - 1.2)</td>
<td>0.408</td>
</tr>
<tr>
<td>Stage III</td>
<td>0.87 (0.74 - 1.0)</td>
<td>0.112</td>
<td>0.83 (0.69 - 0.99)</td>
<td>0.050</td>
</tr>
<tr>
<td>Stage IV</td>
<td>0.87 (0.67 - 1.1)</td>
<td>0.333</td>
<td>0.88 (0.65 - 1.2)</td>
<td>0.415</td>
</tr>
<tr>
<td>Region of surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South (3)(reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNE (1)</td>
<td>0.99 (0.89 - 1.1)</td>
<td>0.967</td>
<td>0.96 (0.85 - 1.1)</td>
<td>0.444</td>
</tr>
<tr>
<td>DML (2)</td>
<td>0.89 (0.79 -0.99)</td>
<td><strong>0.039</strong></td>
<td>0.90 (0.79 - 1.0)</td>
<td>0.100</td>
</tr>
<tr>
<td>West (4)</td>
<td>1.0 (0.91 - 1.1)</td>
<td>0.863</td>
<td>1.0 (0.92 - 1.1)</td>
<td>0.632</td>
</tr>
</tbody>
</table>

* Adjusted for age at diagnosis (20-34, 35-49, 50-64, 65-79, 80+), deprivation index (DI 1, DI2, DI3, DI4, DI5), TNM summary stage (0, I, II, III, IV), and HSE region of surgery (Dublin North-East, Dublin mid-Leinster, South, West).
In crude modelling, tumour summary stage I was statistically significantly associated with shorter time to surgery, while year of incidence, deprivation index 5 (most deprived) and the HSE region of Dublin mid-Leinster were statistically significantly associated with longer time to surgery. However, only year of incidence retained significance in the multivariable model.

A hazard ratio less than 1 represents a lesser likelihood of reaching the event (shorter time to surgery). Patients with breast cancer diagnosed in 2010 were 11% less likely to have a shorter time to event (surgery) than those diagnosed in 2008 when adjusted for age, deprivation, tumour summary stage and HSE region of treatment.

10.4.5.3 Time to chemotherapy
Time to event data from diagnosis to receipt of chemotherapy is summarised in Table 10.22 below. One negative value was automatically excluded from the analysis by Stata.

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of patients (cases)</th>
<th>Mean (days)</th>
<th>25%</th>
<th>50% (median)</th>
<th>75%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>895</td>
<td>Mean= 86.2</td>
<td>54</td>
<td>76</td>
<td>98</td>
</tr>
<tr>
<td>2010</td>
<td>731</td>
<td>Mean= 89.6</td>
<td>56</td>
<td>76</td>
<td>99</td>
</tr>
<tr>
<td>Total</td>
<td>1,626</td>
<td>Mean= 87.7</td>
<td>55</td>
<td>76</td>
<td>98</td>
</tr>
</tbody>
</table>

Table 10.22 shows that the median time to chemotherapy has remained unchanged. The 95th percentile increased slightly from 179 days in 2008 to 186 days in 2010. Table 10.23 shows the Cox proportional hazards regression, analysing several prognostic variables simultaneously for time from diagnosis to chemotherapy. The crude and adjusted models are presented.
Table 10.23: The influence of potential prognostic factors on time from diagnosis to chemotherapy (Cox proportional hazards regression)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Crude HR (95% CI)</th>
<th>p-value</th>
<th>Adjusted* HR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year of incidence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>0.96 (0.87 - 1.1)</td>
<td>0.385</td>
<td>0.93 (0.83 - 1.0)</td>
<td>0.168</td>
</tr>
<tr>
<td><strong>Age at diagnosis</strong> (15-year increments)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-34 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-49</td>
<td>1.0 (0.77 - 1.4)</td>
<td>0.896</td>
<td>0.91 (0.67 - 1.2)</td>
<td>0.537</td>
</tr>
<tr>
<td>50-64</td>
<td>1.0 (0.78 - 1.4)</td>
<td>0.805</td>
<td>0.94 (0.69 - 1.3)</td>
<td>0.671</td>
</tr>
<tr>
<td>65-79</td>
<td>0.92 (0.69 - 1.2)</td>
<td>0.583</td>
<td>0.85 (0.62 - 1.2)</td>
<td>0.324</td>
</tr>
<tr>
<td>80+</td>
<td>0.67 (0.39 - 1.2)</td>
<td>0.150</td>
<td>0.48 (0.25 - 0.92)</td>
<td>0.026</td>
</tr>
<tr>
<td><strong>Deprivation index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 1 (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI 2</td>
<td>1.1 (0.87 - 1.3)</td>
<td>0.584</td>
<td>1.0 (0.86 - 1.3)</td>
<td>0.669</td>
</tr>
<tr>
<td>DI 3</td>
<td>1.1 (0.88 - 1.3)</td>
<td>0.526</td>
<td>1.1 (0.87 - 1.3)</td>
<td>0.588</td>
</tr>
<tr>
<td>DI 4</td>
<td>1.0 (0.85 - 1.2)</td>
<td>0.926</td>
<td>1.0 (0.87 - 1.2)</td>
<td>0.686</td>
</tr>
<tr>
<td>DI 5</td>
<td>1.1 (0.92 - 1.3)</td>
<td>0.356</td>
<td>1.1 (0.92 - 1.3)</td>
<td>0.317</td>
</tr>
<tr>
<td><strong>Tumour summary stage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>0.23 (0.09 - 0.56)</td>
<td>0.001</td>
<td>0.23 (0.09 - 0.63)</td>
<td>0.004</td>
</tr>
<tr>
<td>Stage II</td>
<td>0.25 (0.10 - 0.59)</td>
<td>0.002</td>
<td>0.25 (0.09 - 0.68)</td>
<td>0.006</td>
</tr>
<tr>
<td>Stage III</td>
<td>0.27 (0.11 - 0.65)</td>
<td>0.004</td>
<td>0.28 (0.10 - 0.76)</td>
<td>0.012</td>
</tr>
<tr>
<td>Stage IV</td>
<td>0.31 (0.13 - 0.76)</td>
<td>0.010</td>
<td>0.35 (0.12 - 0.97)</td>
<td>0.043</td>
</tr>
<tr>
<td><strong>Region of chemotherapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South (3) (reference)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNE (1)</td>
<td>1.1 (0.95 - 1.3)</td>
<td>0.201</td>
<td>0.99 (0.85 - 1.2)</td>
<td>0.969</td>
</tr>
<tr>
<td>DML (2)</td>
<td>1.3 (1.2 - 1.5)</td>
<td>0.000</td>
<td>1.2 (1.0 - 1.4)</td>
<td>0.011</td>
</tr>
<tr>
<td>West (4)</td>
<td>1.2 (1.1 - 1.4)</td>
<td>0.005</td>
<td>1.2 (1.0 - 1.3)</td>
<td>0.033</td>
</tr>
</tbody>
</table>

* Adjusted for age at diagnosis (20-34, 35-49, 50-64, 65-79, 80+), deprivation index (DI1, DI2, DI3, DI4, DI5), TNM summary stage (0, I, II, III, IV) and HSE region of treatment (Dublin North East, Dublin mid Leinster, South, West).

A hazard ratio less than 1 represents a lesser likelihood of reaching the event (shorter time to chemotherapy). Patients with breast cancer diagnosed in 2010 were 7% less likely to have a shorter time to event (chemotherapy).
than those diagnosed in 2008 when adjusted for age, deprivation, tumour summary stage and region of treatment. This was not statistically significant.

In crude modelling, tumour summary stage was associated with longer time to chemotherapy, while the HSE regions of Dublin mid-Leinster and the West were associated with shorter time to chemotherapy, indicating some regional variation. Significance was retained in the multivariate model. Age over 80 years was also associated with longer time to chemotherapy in the multivariate model.

10.5 Conclusion
The National Cancer Control Programme centralised breast cancer surgery into 8 specialist centres in 2009. The final study in this thesis (Study 4) investigated whether this policy of centralisation achieved proximal indicators of success. The proportion of patients having their diagnosis and surgery at designated cancer centres rose significantly, indicating a high level of policy implementation. Waiting time from GP referral to diagnosis was also significantly improved. Waiting time to surgery and chemotherapy has increased. However, these waiting times are still within national targets. These results show some early indicators of success in relation to the implementation of centralisation policy and prompt access for GP referrals. Additional parameters such as stage at diagnosis and access to surgery/chemotherapy will require monitoring over a longer timeframe, along with patient outcome data.

Chapter 11 will discuss the findings of the studies in this thesis in relation to centralisation of cancer services and the implications for our cancer services. Findings will be discussed in the context of current international literature in this area. The strengths and limitations of the studies and directions for future research will be discussed. Finally, the impact of the findings of this research will be discussed in the areas of research-related impact, policy impact, service impact and societal impact.
Chapter 11: Discussion

11.2 Introduction
This health services research thesis examined factors influencing GP referrals to symptomatic breast disease (SBD) units in Ireland. The phenomena of unexplained substantial increases in GP referrals had been identified as an issue by practitioners and policy makers in the Irish healthcare system. This research sought to investigate the factors influencing GP referrals to SBD clinics and to make policy recommendations, so that urgent cases can be seen quickly and non-urgent cases can be seen in the most appropriate setting. Taking an investigative approach which spanned macro, meso and micro levels, this thesis investigated whether health systems and organisational structures were the dominant factors influencing referral patterns to breast clinics or, alternatively, if other non-medical or social factors were the main drivers of change in GP referral patterns.

This discussion chapter will summarise the key findings of each study individually and then outline strengths, limitations and recommendations for further research. A comparison with an Irish study with GPs in 2006 is included to demonstrate the changes which have been implemented since that time. The impact of this research on policy and practice will then be outlined, using the Kuruvilla Research Impact Framework (352).

11.2 Aims of this thesis
The 2006 National Cancer Strategy (11) recommended timely access to cancer services in Ireland for earlier detection and treatment. The National Cancer Control Programme was established in 2007 to implement the recommendations of this strategy. Through these strategy initiatives, breast cancer surgery was centralised into 8 cancer centres and one satellite centre, with GP referral guidelines and specialist multidisciplinary teams in place, by the end of 2009. However, since the reorganisation of cancer services, GP referrals for symptomatic breast disease have risen
substantially nationally, without a corresponding increase in breast cancers detected. This increasing number of benign referrals to specialist clinics has implications for increased healthcare costs, unnecessary exposure to radiation from diagnostic imaging and high levels of patient anxiety whilst waiting for appointments and test results. Moreover, there are concerns that the service for urgent cases could be jeopardised if the clinics are “over-run by the worried well” (p.1251)(315).

Factors influencing GP referrals to SBD clinics were the focus of this study. The phenomenon of increasing referrals was investigated in this research from several perspectives, to ascertain whether structural or organisational level forces, such as centralisation of cancer services and GP referral guidelines, were the predominant factors influencing GP referral behaviour, or if there were other non-medical societal factors influencing referral behaviour.

The overarching research question of this thesis was:
What are the factors influencing GP referrals to symptomatic breast units in Ireland?

The research was conducted through four inter-related studies which sought to address the current knowledge deficits relating to breast cancer referral patterns in Ireland. Specifically, the individual studies explored the following areas:

- What are the referral patterns for GP referrals to SBD units in Ireland? (Study 1)
- What are the factors which influence GP referrals to SBD units in Ireland? (Studies 2 and 3)
- Has centralisation of cancer services in Ireland had an impact on breast cancer referral patterns? (Study 4)
11.3 Summary of thesis findings

11.3.1 Study 1: Mapping study

The HIQA review of SBD services identified variation in breast referrals and recommended a review of referral and triage processes (6). Breast care units also reported trends of increasing GP referrals to their symptomatic units.

Study 1 sought to explore referral patterns to symptomatic breast units to identify variation, if present, and to examine overall trends, using data from the National Cancer Control Programme, the HSE and HIQA. The analysis outlined in Chapter 7 found that the level of variation between hospitals found in the HIQA review (6) (based on 7 months of 2009 data before centralisation was completed) had decreased substantially by 2010. A 60% national increase in GP referrals to Symptomatic Breast Units was identified between 2006 and 2010, without a corresponding increase in cancers detected. An examination of referrals to SBD units found that 9.1% of referrals were received for assessment of breast cancer family history and 15.3% were referred for mastalgia. Studies have shown that family history and mastalgia are not predictive of breast cancer (49, 184, 187).

Management of these women in primary care would significantly reduce the number of GP referrals to SBD units. SBD units reported an ‘October surge’ in referrals, coinciding with breast cancer awareness month each year. While increases in referrals were seen in some years following breast cancer awareness campaigns, this was not consistent across all years.

This was the first study, to the author’s knowledge, examining referral patterns before and after the centralisation of breast cancer services in Ireland and provides useful evidence on the impact and effectiveness of this policy initiative in Ireland.

The findings from Study 1 set the context for Studies 2 and 3, as participants in the qualitative studies were presented with these national data on referral trends for discussion at the qualitative interviews. This is described as the development stage in mixed-methods research (417). While this could have
created a bias in the participants’ responses, this data was already in the public domain through media reports and publications e.g. HIQA (6) and had also been highlighted at national conferences on breast cancer.

11.3.2 Studies 2 and 3: Factors influencing GP referrals to SBD units
The literature reviewed in this thesis (Chapter 2) described GP, patient and health system factors which can influence referrals to specialist care (15, 118, 183, 235). The analysis presented in Studies 2 and 3 sought to explore these and other influencing factors on GP referrals to symptomatic breast units. These qualitative studies explored the perceptions of hospital SBD staff and GPs of the factors influencing referrals to SBD units. Analysis of interviews found that referral patterns can be affected by a combination of medical and non-medical factors which include GP, patient, health service and social factors.

Hospitals attributed the increase in referrals to enhanced patient awareness, media-induced anxiety, ease of access to the breast clinics and transfer of ownership from primary care to hospital teams. These perceptions were consistent across all units. Consultants recommended that patients should receive care in the most appropriate setting and should not be subjected to unnecessary investigations. One consultant also had concerns about effective use of resources in the Irish health-care system, an area which was not raised in the GP interviews. An alternative explanation for the increase in referrals could be the increased awareness of the benefits of screening through the national breast screening programme. While the symptomatic service was not established to provide opportunistic screening for asymptomatic women, those outside the age-group eligible for breast screening may seek this service.

There was a high level of pride evident from SBD unit personnel in the service they provide. Participants also remarked on the level of confidence patients now have in public breast cancer services. However, there was a concern that ‘we have become victims of our own success’, in that patients and GPs are now seeking to use the service more because of its improved
access and efficiency. Consultants felt that this has implications for the establishment of other ‘rapid-access' services for suspected cancers, e.g., prostate cancer, lung cancer and melanoma, and for the wider health service delivery mechanism. In contrast, whilst GPs acknowledged the quality of the breast service, they highlighted the deficits in other health services.

Psychological factors are an integral component of decision-making models – referral decisions are rarely based on clinical factors only, but rather “a complex interaction of clinical and non-clinical factors” (p.309)(218), including the doctor’s anxiety, their level of confidence and their tolerance of uncertainty (218, 253). Bate (293) describes cognitive and affective biases in decision making, including personal problems, stress and fatigue. Anxiety can impact on information processing and decision-making. Mathews, for example, describes how “anxious subjects selectively attend to threatening information, and interpret ambiguous events in a relatively threatening way” (p.455)(504). The impact of anxiety on information processing in the referral process should be considered. Fear of missing a cancer and fear of legal implications can increase a GPs’ tendency to refer (218, 232, 256). It is likely that fear and anxiety affect referral patterns leading to defensive practice and over-cautious management. Interventions to increase management of breast symptoms in appropriate settings need to take into account the influence of anxiety on referral patterns. The Kings Fund (238) described two approaches to clinical decision making – one which uses rule based systems such as referral guidelines and decision support tools and the other which involves negotiation as part of a social process of diagnosis and referral, through communications and shared decision making. GPs in this study tended to use both approaches, based on the presenting features and patient wishes.

The difference in opinion between participating GPs regarding the gatekeeping role of the GP was interesting. Some GPs considered gatekeeping as part of their role and others considered that it was outside their professional boundaries. A notable difference was evident between GPs
who had trained or practiced in Ireland and those who had trained or practiced in the UK; with GPs who had worked in the UK expressing that gatekeeping was a key part of their GP role. There was evidence of role conflict in relation to responsibility and ownership in the management of patients with breast complaints, with many GPs concluding that responsibility for this cohort of patients now lay exclusively with the specialist breast units.

GPs requested standardised information on family risk of breast cancer. Approximately 3,500 patients were referred to SBD Clinics in Ireland in 2011 for assessment of breast cancer family risk. Clear referral pathways are required for patients with a family history of breast cancer, with information for GPs and for patients on referral criteria. Based on this recommendation, the NCCP has developed referral criteria for GPs on family risk, which will be disseminated in 2015.

An additional 5,807 patients were referred to SBD units in 2011 for assessment of mastalgia. GPs recommended the development of information materials for mastalgia, differentiating bilateral cyclical mastalgia from unilateral non-cyclical mastalgia. Based on these recommendations, the National Cancer Control Programme has developed information materials for GPs and for patients which were disseminated in 2014, including an algorithm for GPs on the management of mastalgia in primary care, an information leaflet for women and a mobile phone app. A nursing role for the management of benign breast conditions was recommended and this is being considered by the NCCP in future service development plans.

Analysis of the GP interviews highlighted an apparent cycle of reinforcement that strongly increased GP referral behaviour. Commencing with patient anxiety, the referral behaviour of the GP may reinforce the referral-seeking behaviour of the patient. GP referral behaviour may also be negatively reinforcing the patient’s anxiety, i.e., it takes away anxiety (negative reinforcement) and confirms the belief that the patient was right to seek referral (positive reinforcement). Referral to the specialist units generates positive reinforcement for the GP by generating a good feeling, i.e., they are
doing the best for their patient. However, this can also serve as a negative reinforcement by doing something to remove an unpleasant stimulus, e.g., patient anxiety, perceived social pressure and the GP’s own self-doubt or fear of consequences of missing a cancer. In combination, these two influencing factors of positive and negative reinforcement are powerful drivers of GP referral behaviour.

Risk aversion of GPs was identified by participating GPs as a significant factor influencing referral decisions. Tolerances of uncertainty and tendency to take risks have been identified as important factors influencing GP referrals (205, 206, 218, 232, 252, 254, 256). It appears from this study that GPs’ inflated perception of misdiagnosis or malpractice may have reduced their diagnostic threshold. GPs reported a reliance on diagnostic imaging as a source of reassurance.

Concerns were expressed about exaggeration of risk in breast cancer educational messages and campaigns. GPs and consultants felt that current media messages and campaigns were not in proportion to the incidence of the disease and should be more measured and age-appropriate, i.e., targeted towards the older age-groups most at risk. There is an onus on the media to deliver an accurate message. To maximise the reach of the message, it may also need to be supplemented by diffusion (505). For an innovation to be integrated at a system level, it must be seen to be superior to what was there before (the concept of relative advantage), compatible (compatible with the beliefs and perceived needs of the intended audience) and observable (visibility of potential benefits) (505). Therefore, awareness campaigns on breast cancer and the services available need to be tailored to the target audience, with information relevant to specific groups, e.g., women under 30 with breast pain or women over 65 when they have moved beyond screening age.
GP perceptions of patient anxiety or patient expectations combined with prompt access to the breast clinics may influence GP referral. In the absence of clinical symptoms, the perceptions of the GP may drive their referral behaviour.

GP referral practices are influenced by GP, patient and health service factors, which can be both social and contextual in nature (15, 118, 183, 282). Interventions aiming to influence referral decisions should include an implementation plan specifying behavioural endpoints of the intervention, using a framework such as the Behaviour Change Wheel (251) and the Behaviour Change Taxonomy (379). These behavioural endpoints need to be included as implementation outcome variables (506, 507), to assist measurement of effectiveness (508). This approach has previously been used in guideline implementation (248, 345) and provides a transparent structure for evaluation and audit. Use of the Behaviour Change Taxonomy also assists future replication of successful initiatives, as the components of the intervention are clearly defined (379).

As described in Chapter 9, an action plan for an intervention using the Behaviour Change Wheel has been developed based on the findings of this research and is presented in Appendix D. Examples of recommended interventions and policies include:

Interventions with GPs:
- Education (about cancer risk)
- Persuasion (to refer appropriately)
- Training (dealing with patient expectations, interpersonal skills)
- Environmental restructuring (clinic types, access to imaging)
- Enablement (risk management, confidence in referral decision)
Policy:
- Communication/marketing (role of breast clinics, appropriate health messages)
- Guidelines (ensure guidelines are evidence-based)
- Regulation (via professional bodies)
- Environmental/social planning (social norms and reporting)
- Service provision (alternative clinic for benign/non-urgent conditions, GP access to imaging)

Both consultants and GPs in this study praised the success of the centralisation process in terms of access to services and standardisation of care. However, the impact of this centralisation process had not yet been evaluated. Study 4 was conducted to determine if the centralisation policy in Ireland has achieved early indicators of success.

11.3.3 Study 4: Impact of centralisation on cancer referral patterns
The literature review presented in Chapter 2 outlined the evidence supporting centralisation of breast cancer surgery into specialist centres to improve patient outcomes. However, the impact of centralisation of breast cancer services had not yet been examined in Ireland. The analysis presented in Study 4 sought to address this research gap by comparing breast cancers diagnosed immediately before and after the centralisation process (2008 vs. 2010).

Findings indicated a significant drop in cases diagnosed in acute hospitals which are not cancer centres from 26.5% in 2008 to 1.2% in 2010, signifying the success of implementation of the national centralisation policy in Ireland. There was a smaller change in the proportion of patients being diagnosed in private hospitals, from 14.6% to 12.9%. Clinicians attributed the continued referral of some patients to private hospitals to patients wishing ‘to get value’ from their health insurance. Whilst none of the private hospitals in Ireland are designated cancer centres, many of consultants in the public service also have sessions in the private hospitals. The centralisation policy was only
applicable to the public health system and therefore only the data from the public centres was used to measure outcomes of this study (stage at diagnosis, time to event).

A majority (80.7%) of breast cancer cases are now having their breast cancer surgery in designated cancer centres. The proportion having breast surgery in private hospitals increased slightly from 17% to 19%. The results show that a cohort of patients is presenting to the SBD clinic for assessment and diagnosis with the multidisciplinary team and subsequently transferring to private hospitals for their surgery. This was higher in co-located hospitals, i.e., hospitals with both a public and private hospital in the same geographical location, with consultant appointments across both sites.

The results suggest that there was not a statistically significant difference between the underlying distributions of TNM summary stage of disease between years, although a positive trend in that direction was detected. This finding is not surprising, as the study was carried out immediately after the centralisation process and probably too early to detect a change in stage at presentation. The change in time to diagnosis pre- to post-policy implementation is probably not large enough to materially impact stage, except perhaps in the most aggressive cases. Stage at presentation is also affected by other factors such as patient delay, in addition to GP or hospital delay.

The stage of disease at diagnosis may also be influenced by stage migration – patients diagnosed more recently or in a specialist hospital may be more likely to be assigned a higher category of tumour stage because more thorough staging investigations are performed. The accuracy of staging classification has improved as more sensitive imaging technologies become available (37). Cancer centralisation, approach to axillary surgery and regional differences in diagnostic activities have been shown to result in more extensive investigations, causing stage migration (509).
The results showed an increased detection of metastases at diagnosis. This may be due to stage migration, more intensive testing and more advanced technology in cancer centres. This is consistent with international studies examining specialisation of breast cancer services (7, 26, 509). Gillis found that less information on staging data was recorded and was more likely to be missing in patients cared for by non-specialists. New technology has resulted in stage migration, by detecting metastases that had previously been silent and unidentified, thereby migrating these cases to higher TNM stages than would have been recorded previously (p.1604)(26). Stage is also “highly sensitive to the diagnostic procedures used to define it” (p.416)(473) and is influenced by the thoroughness of the investigations carried out.

The time from GP referral to diagnosis has improved, reduced from a median of 14 days to 11 days since the reconfiguration of services. The results show that the changes which have occurred are within the first 2-3 weeks of referral. This is in line with the NCCP target of 10 working days from receipt of GP referral to diagnosis for urgent referrals. While there has been notable improvement, a quarter of patients waited longer than 18 days from GP referral to diagnosis. Ensuring that 100% of cases are diagnosed in the appropriate timeframe is an important goal for cancer services.

The median time from diagnosis to surgery has increased slightly from 22 to 25 days. This is still within the NCCP national target of surgery within 4 weeks of diagnosis. This may suggest that when more time is available to treat the patient, this treatment may be delayed. This paradoxical effect has been observed in other scenarios where target times have been established, such as time to thrombolysis for stroke (510, 511). This has implications for the setting of Key Performance Indicators across the health system. However, there are still 12% of cases having surgery outside this timeframe. Data from the NCCP (personal communication) on reasons for delay in surgery in 2010 showed that 30% of surgical delays were due to patient’s personal choice, 29% due to medical reasons and 24% due to capacity issues in hospitals.
The median time from diagnosis to chemotherapy has remained unchanged at 76 days. This is within the NCCP national target of commencing chemotherapy within 8 weeks of surgery, which equates to 98 days from initial GP referral. However, there are still 25% of breast cancer cases receiving chemotherapy outside of this timeframe, indicating a need for improvement. Data from the NCCP (personal communication) on reasons for delay in chemotherapy in 2010 showed that 22% of delays were due to patient’s personal choice, 43% due to medical reasons and 2% were due to capacity issues in hospitals.

11.3.4 Comparison of GP needs assessment pre- and post-centralisation of breast cancer services

A comparison with a previous Irish study (260) is presented here, to illustrate how this research has contributed to and created new knowledge. The ICGP carried out a needs assessment with General Practitioners in Ireland in 2006 in relation to the early detection of cancer in primary care (260). The aim of their study was to identify the barriers experienced by GPs to early diagnosis of cancer in order to improve early detection, increase the number of patients diagnosed at an early stage of disease and maximise potential for cure. The needs assessment included five focus groups (n = 47 participants in total) and a postal survey, to which 950 GPs (47% of the ICGP membership) responded.

The findings of the ICGP qualitative study showed that barriers to early detection of cancer identified by GPs in 2006 were mainly delay in patient presentation; lack of GP direct access to radiological and endoscopic investigation; difficulties referring patients to hospital services for investigations and/or assessment; lack of clear recommendations for cancer screening; poor communication between GPs and hospital staff; and inequitable access with long waiting lists for investigations and referral.

This current study has demonstrated that significant changes have been made in the area of cancer services, particularly for breast cancer services, since the ICGP study was carried out in 2006. In relation to the barriers
previously listed by GPs above, this study found that GPs are not currently experiencing difficulties referring patients to breast services and have clear criteria for breast screening. Gaps identified in this study on patient information have now been addressed. Only one of the original barriers was raised in this study as a remaining issue, which was communications with hospital staff. GPs in the current study expressed a preference to be able to contact a hospital consultant directly for advice on particular patients, when required. In relation to access to imaging, whilst this is now readily accessible through the SBD clinics, GPs who were interviewed also expressed a need for access to diagnostics for asymptomatic patients, e.g., for screening (outside the BreastCheck programme) or for reassurance. However, the 2006 National Cancer Strategy (11) specifically states that opportunistic testing of asymptomatic individuals for cancer is not recommended. The recent announcement by Government to extend the BreastCheck screening programme to the age-group 65-69 will provide access to mammography for an extended cohort of the population, commencing at the end of 2015.

In the ICGP quantitative postal survey, the factors identified by GPs which would assist them in the early detection of cancer were listed in order of importance as: agreed criteria for screening high-risk individuals; agreed referral criteria for suspected cancers; a ring-fenced budget for community diagnostic services; increased public awareness of early cancer symptoms; earlier patient presentation/increased patient awareness; further GP education on identification of early-stage cancer and clinical practice guidelines; appropriate investigative pathways; a hospital-based GP liaison nurse; and meaningful GP representation at senior level of local hospitals.

This study found that the majority of these factors have since been addressed for the breast service. GPs who participated in the interviews acknowledged the progress and developments in breast disease, including criteria for screening, public awareness campaigns, electronic referral, rapid-access clinics in designated cancer centres and the recruitment of cancer nurse specialists. Whilst a budget for community diagnostics is not ‘ring-
fenced’, GPs found that access to mammography and ultrasound for symptomatic breast patients is generally available within 10 days for urgent referrals. Additional recommendations were made by participants in this study in the areas of GP e-learning, GP referral guidelines and development of national clinical guidelines, which have resulted in developments in these areas.

Areas of cancer in which GPs wished to receive further education and clinical practice guidelines in the 2006 study included identification of early-stage cancer, appropriate investigative pathways for suspected cancer, referral criteria for suspected cancer, familial cancers, identification of high-risk individuals, and targeted cancer screening for high-risk individuals. This study found that education on each of these topics has now been addressed through a GP e-learning programme, GP study days, GP CME sessions, GP referral guidelines, clinical practice guidelines, the national cancer screening programme and a newly-established national hereditary cancer programme. The need for additional education in breast examination was highlighted in this study as a gap, which has now been incorporated into an e-learning programme. Based on recommendations from this study, information on familial cancers has been added to the national GP referral guideline and hospital cancer treatment care pathways have also been developed.

Significant progress has been made in health services to assist GPs in the early detection of cancer since the initial needs assessment was carried out by the ICGP in 2006. Remaining areas identified in this thesis where GPs would like to see further development include communications between hospitals and GPs, and increased access to diagnostics (mammography).

Whilst GPs in the current study acknowledged current initiatives to improve GP-hospital communication, such as the use of HealthLink for electronic messaging in the areas of referral, laboratory results and discharge letters, they felt there was still room for improvement, in particular in the area of specialist opinion, when required by the GP. GPs reported that direct access to imaging varies in different centres and is not standardised. However, the
extension of the BreastCheck age range to 69 later in 2015 will help to alleviate this issue in that particular age-group.

11.3.5 Overall thesis findings
Convergence coding (415) was used in Chapter 9 to assess convergence, complementarity, dissonance and silence in the GP and hospital interviews. Convergence assessment and completeness assessment is used here to assess the global findings of all 4 studies combined. This convergence approach can facilitate the identification of overriding meta-themes. Farmer et al. (415) describe how this approach generates higher-level interpretations of the data which enhances both the credibility and the transferability of the findings: “Findings that are consistent across diverse data sources and confirmed by multiple data sets provide greater confidence in the credibility of interpretations and the potential to transfer key learnings to other similar contexts” (p.390)(415).

Completeness assessment was conducted by comparing the nature and scope for each data source, to enhance the completeness of the combined findings (415). The findings from the 4 studies demonstrated a complex interaction of patient, provider and health system factors influencing referral patterns. Using a mixed-methods approach facilitated an iterative research design to build on each study sequentially and explore emerging hypotheses throughout the research. An area which was found to be similar across studies was the increased demand following restructuring of the service, which has been reported in other international studies (5, 46, 210, 227). Factors which were missing or undocumented in official reports or audits, such as the contextual social factors, were supplemented by the results of the qualitative studies. These broadened the perspective, providing a richer more complete view, “a higher level of analysis, and a broader understanding of the research question” (p.388)(415). A unique contribution was related to costs, as this was only raised by one hospital in the qualitative studies. Areas missing from the analysis were consensus on ‘ownership’ or responsibility for care of the patient with benign breast symptoms or defined pathways for integrated care.
11.4 Strengths of this thesis
This study was the first to quantify rates of referral to SBD units in Ireland pre- and post-centralisation of cancer services. It was also the first study to quantify referrals to SBD units for breast cancer family history and for mastalgia on a national basis in Ireland. This study was also, to the author’s knowledge, the first to explore seasonal variation in breast cancer referrals in Ireland.

All SBD units agreed to participate in the hospital interviews. This ensures that the views of all units are included and makes the results transferable to our public health service as a whole. The response rate for the GP study was 49%, which, although low, is similar to the response rate of 47% in the ICGP study on needs assessment of GPs in early detection of cancer in Ireland (260). Data saturation was reached, with no new themes emerging. Participants included GPs from each of the four geographical regions with equal numbers of male and female GPs. Single-handed and group-practice GPs, and GPs caring for both public and private patients were included in this study to enhance representativeness.

This research portrays a dual perspective, i.e., the hospital perspective and the GP perspective, of factors influencing referrals to breast units. Convergence coding was used to compare the two qualitative studies and to enhance their validity (415, 455). The qualitative studies illuminated the richness and diversity of factors influencing referral which could not be explored in the quantitative analyses in Studies 1 and 4.

Sample size was a considerable strength in the dataset used for Study 4, which allowed for greater power for investigating relationships between variables and detecting small differences in outcome with some statistical validity. These data contain all breast cancers diagnosed in the Republic of Ireland in 2008 and 2010 (n = 6,624). Cancer is the only disease to have an established registry in all hospitals in Ireland and the quality of the data for cancer is therefore more comprehensive than other diseases. Using a
national tumour registry database minimizes the chances of institutional bias and selection bias.

The use of mixed-methods as the methodology for this thesis helped to counteract weaknesses in individual studies. Morgan (512) has described mixed methods as ‘the third effort’ of integrating quantitative and qualitative results. Lingard et al. (513) emphasised that central to the effectiveness of a mixed-methods study is a clear and strategic relationship among the methods, to ensure that the data converge to produce greater insight than a single method could. Using a mixed-method approach in this thesis facilitated a more comprehensive analysis than a single approach in isolation (399, 400), offering strengths to offset any weaknesses of individual studies (398).

The qualitative studies illuminated the richness and diversity of factors influencing referral which could not be explored through the other studies. The quantitative data in Study 1 provided a development function for the design of the qualitative studies (Studies 2 and 3) and the quantitative analysis in Study 4 tested the hypotheses generated in the earlier studies.

11.5 Limitations of this thesis
National data is available for GP breast referrals since 2009 from the NCCP. However, comparative data for all variables was not available for the period pre-centralisation, as these referrals were recorded under general surgery at that time. In addition, data on patients who presented to their GP but were not referred to the SBD units are not routinely collected or collated. Data on 2006 referrals was collected through a national audit. Whilst data collection mechanisms were not as developed in 2006 and were collected from a greater number of hospitals, the audit data were consistent with HIPE data for that period.
The national roll-out of the BreastCheck screening programme was not fully completed in all areas at the time of the study. Therefore, some areas did not have access to structured screening services, which may have influenced referrals to symptomatic breast clinics for that particular age-group.

It is possible that there was a social desirability bias in relation to some of the respondents’ answers to questions during the interviews, respondents providing what they believed to be the ‘correct’ answers. However, participants spoke openly and spontaneously about their experiences and referral practices, and their responses in relation to mode of referral and trends in referrals are consistent with national reports (3). GPs openly criticised their own actions and acknowledged that they would not consider all of their referrals to be appropriate. The interview method allowed an open and honest conversation, enabling the collection of rich data to answer the research question. In addition, the hypotheses created from the qualitative studies in relation to the impact of centralisation were tested in Study 4 using a national dataset.

Presenting data from the mapping study (Study 1) may have influenced participant’s responses in the qualitative interviews. However, this data was already in the public domain through media coverage, a HIQA report (6) and through discussions and presentations at GP study days and national breast cancer conferences (1) (2).

The majority of the GPs chose to conduct their interview by telephone. Irvine (444) found that the duration of telephone interviews was generally shorter than face-to-face. However, when interview duration of telephone vs. face-to-face interviews was compared for this thesis, there was little difference in duration. For GP interviews the average duration of face-to-face interviews was 19.3 minutes (range 15-26), while the average duration of telephone interviews was 18.8 minutes (range 10-30). Similarly for hospital interviews, the average duration of face-to-face interviews was 42.8 minutes, while the average duration of telephone interviews was 41.5 minutes.
GP and hospital interviews may have been influenced by recall bias. This is particularly pertinent in the GP interviews as it may be several weeks since a breast referral was made.

In terms of respondent bias, GPs who did not respond were more likely to be male and from urban areas. This is a potential bias, however, participating GPs were stratified to provide an equal number of male and female GPs and also an equal number of GPs from each of the four HSE geographical regions.

The use of the TDF as an interview topic guide has been criticised as being too focussed and constraining (380). However, for this study the TDF framework was not used in the formulation of the topic guide, but rather, introduced at the coding and analysis stage. Inter-coder agreement has also been reported as low in interview studies using the TDF (393) but coding in this study was carried out by the same researcher (NO'R).

Given that the centralisation policy had just been implemented, it was probably too early to examine stage of disease at diagnosis. The change in time to diagnosis pre- to post-policy implementation is probably not large enough to materially impact stage, except perhaps in the most aggressive cases. However, this will provide useful baseline data for further studies.

A major limitation of an uncontrolled before-and-after study is that it is not possible to discern the effect of the centralisation policy as distinct from other changes that may have been happening simultaneously. A degree of centralisation had been ongoing in the Irish health system over a number of years in the smaller regional hospitals. For this reason, the years for this before-and-after study were chosen directly before and after the year when the major interventions took place in 2009 (centralisation of cancer surgery into designated centres with multi-disciplinary teams and GP referral guidelines). However, additional health service developments may have contributed to the changes observed. Whilst the focus of the NCCP was on centralisation of surgery and GP referral processes, additional elements of
the 2006 Cancer Strategy were also in progress such as health promotion and breast screening. The additional studies in this thesis mediated this limitation by providing insights into the effect of the centralisation policy from those working directly in the service.

A limitation encountered in quantitative analysis in Study 4 was that the national cancer dataset was missing data in some areas under investigation in this thesis, in particular in relation to date of GP referral, as a copy of the GP letter was not always available in the patient’s file. This reduced the size of the cohort for this area of investigation.

A number of additional phenomena may also have impacted on the findings of the quantitative analysis, including the following:

**Lead-time bias:** Patients diagnosed earlier can appear to survive longer even if no true survival benefit occurs. This has also been described as ‘zero time shift’ (26). Lead-time bias can therefore exaggerate the differences seen. Length bias where slower-growing tumours are more likely to be detected earlier is common in breast screening programmes.

**Stage migration:** The ‘Will Rogers effect’ is described as stage migration resulting from new diagnostic techniques – new technology identifies metastases that were previously silent or unidentified. Will Rogers was a humorist–philosopher in the USA who commented on geographical migration during the US economic depression in the 1930s (26). The statistical consequences of stage migration are now termed ‘the Will Rogers Phenomenon’ and have been described as a source of misleading statistics for survival in cancer.

**Stage shift:** The introduction of the national breast screening programme (BreastCheck) is already showing a stage shift towards less advanced more treatable breast cancers (514).
11.6 Directions for future research
Statistical analysis using time-series analysis (Poisson segmented regression) is recommended to examine seasonal variation in more detail. Interrupted time series analysis is the strongest quasi-experimental study design to analyse longitudinal effects of interventions (435-437), including natural experiments or ‘real world events’. Autoregressive integrated moving averages (ARIMA) models could also be used to smooth out curves and test for trend. The impact of campaigns such as breast cancer awareness month could be assessed using these methods, to explore if the type of referrals received during these campaigns is different, e.g., is there a higher cancer detection rate in these referrals or are they predominantly benign? This would assess the effectiveness of such campaigns and help inform the future direction of awareness and education initiatives.

Ongoing monitoring of referral trends is recommended; particularly in the area of benign referrals, with a focus in particular on age groups and presenting symptoms.

The ‘ownership’ and responsibility for the patient with breast disease was discussed in both the hospital and GP interviews. Joint research between primary and secondary care into effective care pathways is recommended to ensure an integrated service, with care provided in the most appropriate setting.

While this study focussed on GP referral, it is only one component of the patient journey. Interviews with patients in Ireland on their reasons for presentation to their GP and also with those who had concerns but did not present to their GP would be useful to explore reasons for any delays in presentation to GP. Prompt presentation to the GP in addition to prompt referral onwards to specialist centres facilitates earlier diagnosis and improved prognosis.
Both the consultant and GP studies commented on patients’ expectations of specialist review and diagnostic imaging and also on patients’ own heightened assessment of their risk. Research into patient expectations is recommended, particularly in relation to referrals to specialist clinics, the perceived need for diagnostic imaging and the perception of risk in relation to breast disease. The Health Research Board (HRB) Centre for Primary Care Research has commenced a study at the Royal College of Surgeons in Ireland (RCSI) in 2014 on patient preferences for breast cancer screening and referral which investigates these research questions. The aim of this study is to find out participants’ preferences about referral to a breast cancer clinic compared to watchful waiting, using decision analysis.

The methods used for disseminating information have changed in recent years. The role of social media as a conduit for information and education about breast cancer in Ireland should be explored.

It is recommended that further research is carried out on the impact of centralisation of breast cancer services 5 years post-centralisation. Interrupted time series designs are recommended for quasi-experimental, longitudinal analysis of interventions. In addition, 5-year survival rates for cases diagnosed post-centralisation (2010) will be available after 2015. Regional variation in access to treatment should also be monitored.

The influence of non-medical factors on medical decision-making has implications for the scope and structure of our health services. With increasing levels of specialisation and centralisation, it is recommended that research on the development of referral pathways, clinical prediction rules and decision models is conducted in advance of reconfiguration of clinical services. The role of the Nurse Specialist (CNS/ANP), breast physicians and GPs in breast cancer clinics should be explored for planning of future service provision.
11.7 Impact of the findings arising from this thesis

11.7.1 Research translation: research to policy and practice

While maintaining the integrity of the research, the researcher was located in the health services in an area where the findings were important and relevant, facilitating the potential for immediate impact in terms of translation into policy and practice.

The Kuruvilla Research Impact Framework (352) is described in Chapter 4, outlining areas where this research can have an impact, specifically in the areas of research, policy, societal impact and service impact. Each of these areas of impact will be examined separately in the context of the findings of the current study.

11.7.2 Research-related impacts

The findings from this study have several research-related impacts. The proportion of referrals for conditions such as family history of breast cancer and mastalgia has now been quantified in Ireland and has provided the evidence and justification for interventions in this area. A report on the findings of the hospital study (Study 2) was circulated to those involved and key professional stakeholders in the NCCP and HSE, entitled Review of Referral Practices and Triage Processes in Symptomatic Breast Units – a hospital perspective’ (3) and is now available on the NCCP website www.cancercontrol.hse.ie

Findings from this study have identified changes for current GP referral guidelines in relation to inclusion of referral advice for family risk. The use of theory in the development of health service interventions using the Behaviour Change Wheel has been adopted for use in the development of national clinical guidelines for breast cancer. These guidelines were completed in December 2014 and were widely disseminated in Ireland, and are available on the NCCP website www.cancercontrol.hse.ie
This study provides the first evaluation of outcomes of centralisation of cancer services in Ireland. The findings in Study 4 provide a baseline for future longer-term studies on the impact of centralisation in the Republic of Ireland.

A list of conference presentations is contained in Appendix Q.

11.7.3 Policy impacts
Table 4.1 in Chapter 4 outlines the expected research impact from this thesis. Policy impact can be described under 4 headings developed by Weiss (515) and Kuruvilla et al. (352):

1) Instrumental use, where research findings directly drive or define policy.
2) Mobilisation of support, where research findings provide persuasive evidence to back ongoing and proposed policy activities or raise awareness and support for new policy making.
3) Conceptual use, where research leads to new ideas and language that influence the nature and substance of policy discourse.
4) Redefining/wider influence – research impact that leads to a wide change or transformation of accepted beliefs and practices.

The policy impact of this research will now be outlined under these headings.

1) **Instrumental use, where research findings directly drive or define policy.**
Reasons for GP referral, such as mastalgia and family history have now been quantified in Ireland and have been used as a basis for development of information materials and services in these areas.

Training needs for GPs have been identified and incorporated into training programmes, e.g., breast examination. Information needs for patients have been identified and information materials have been developed to address these areas, e.g., mastalgia.
A GP algorithm and referral pathway for mastalgia has been developed and distributed to all GPs. National clinical guidelines for diagnosis, staging and treatment of breast cancer have been developed and disseminated.

2) **Mobilisation of support, where research findings provide persuasive evidence to back ongoing and proposed policy activities or raise awareness and support for new policy making.**

The national GP referral guidelines for breast cancer have been updated, with specific guidance on family risk of breast cancer. Recommendations from GPs in this study in relation to standardised care pathways have been incorporated into national guidelines for diagnosis, staging and treatment of breast cancer.

Findings from this research on awareness campaigns and recommendations from GPs and consultants on targeted age-appropriate information have been discussed with charity and advocacy groups to inform future campaigns.

3) **Conceptual use, where research leads to new ideas and language that influence the nature and substance of policy discourse.**

Based on the findings of this research, recommendations have been made regarding the scope and structure of clinics for future delivery of cancer services to ensure that those with urgent symptoms are seen quickly and those with non-urgent presentations are seen in the most appropriate setting.

4) **Redefining/wider influence – research impact that leads to a wide change or transformation of accepted beliefs and practices.**

The findings from this research have been used to input into national reports and planning in relation to scope and structure of SBD clinics and access to diagnostic imaging.
Findings from this research were used for the external evaluation of the implementation of the 2006 Cancer Strategy, carried out in 2014. In particular, findings from the qualitative studies and impact of centralisation study will contribute to the evidence base for the development of a new national cancer strategy for 2016.

11.7.4 Service impacts
The findings from this research have already impacted on the health service. Identification and prioritisation of service needs have been used for resource planning, e.g., GP sessions and Advanced Nurse Practitioners in breast clinics. Identification of GP education and training needs have been used in the development of an e-learning programme for GPs and the national GP referral guideline has been updated with advice on family risk following a need expressed by GPs.

Identification of information needs for GPs and for patients in the area of mastalgia has resulted in the development of a referral pathway, algorithm, patient booklet and mobile phone app’ for mastalgia. Recommendations from consultants and GPs in this study have been incorporated into national clinical guidelines for diagnosis, staging and treatment of breast cancer.

11.7.5 Societal impacts
This thesis is broadly concerned with GP referral. However, findings have some societal impact and relevance, such as the development of education / health promotion materials and patient-centred services. One example of developing patient-centred services in this context relates to identification of the need for patient information in relation to mastalgia. The influence and advice from family and friends triggered many patients to seek referral to specialist units, according to GPs. The social impact of the media was also a strong influencing factor. The role of the media in health information and awareness should be a collaborative approach with the health services, to ensure consistent and evidence-based messages. Where such an approach has been adopted (e.g., the stroke FAST campaign), there is evidence of significant increases in knowledge and awareness of the condition (516).
11.7.6. Contribution of this study

**Methodologically**

Mixed methods have been used in implementation research to explore barriers to implementation (404) and in health services research for comprehensiveness in the complex area of healthcare (401) (402) (396). The model chosen for this study is Teddlie & Tashakkori’s iterative sequential mixed design (349). Pragmatism is used for solving practical problems in the real world, providing an innovative approach to address contemporary issues in the health services (402) (412).

This research methodology sought to take account of the multi-factorial nature of the phenomenon under study. This required a research approach which recognised that reality is “subjective, constructed, multiple and diverse” (p.41) (418), yet is cognisant of seemingly objective forces that influence referral patterns e.g. policy and evidence based medicine.

Lingard et al. (513)(p.460) describe how, in medicine, “mixed methods have arisen in the wake of attention to the psychosocial determinants of health and the human aspects of medical care”. The effectiveness of a mixed-methods study is a clear and strategic relationship among the methods, to ensure that the data converge to produce greater insight than a single method could.

Mixed methods in health research has shown a lack of integration, which limits the overall yield (416). The justification for using this method and the level of integration should be clearly outlined (405) (517). According to Teddlie and Tashakkori, a study is only truly mixed if approaches are integrated across the stages of the study (349). As described by Morse (417), “each component should fit like pieces of a puzzle” (p.122). Leech (403) discusses the difference between partially mixed methods, where the quantitative and qualitative components are only linked at the data interpretation stage, and fully mixed methods where mixing occurs within or across stages.
Mixed methods, using data from primary care, secondary care and the National Cancer Registry database were used to examine a complex health services phenomenon from several perspectives. The individual studies which were integrated across all stages, related in an organic way, combining to add an additional layer of meaning. This is the first mixed methods study to examine factors influencing referrals to breast clinics, combining the qualitative data from primary and secondary care with a national population based cancer registry.

**Conceptually**

Conceptual use refers to where research leads to new ideas and language that influence the nature and substance of policy discourse (515) (352). Based on the findings of this research, recommendations have been made regarding the scope and structure of clinics for future delivery of cancer services, to ensure that those with urgent symptoms are seen quickly and those with non-urgent presentations are seen in the most appropriate setting.

GPs reported pressure from some patients for onward referral. This is perceived by the doctors and as patient interviews were not conducted, pressure from patients cannot be verified. While GPs perceived pressure from patients for onward referral, research suggests that “pressure from patients may be stronger in the doctor’s mind than in the patient’s mind” (p.416)(231). This has implications for communications and shared decision making.

A number of findings were unexpected and were not reflected in previous literature. The first related to the finding that GPs favoured the public hospitals over the private hospitals to refer their patients with breast complaints, as they felt the care was better and more coordinated. This was in contrast to other medical conditions that they tended to refer privately, if their patients had private health insurance, to avoid any delays.
The second are related to seasonal variation. While the hospital units perceived an ‘October surge’ during Breast Cancer Awareness Month each year, this was not apparent in the data. This research has therefore dispelled the myth of the October surge. In addition, clinicians in this study reported that some patients believe that they won’t get breast cancer after the age of 65 (the age when the Breast Screening programme ceases), which has implications for health promotion and disease prevention messages.

While this study focused on GP referrals to Symptomatic Breast units, this has wider implications for health services research. Restructuring of health services has implications for education and training. Referral pathways are a core component of integrated care models, as proposed by the Government in ‘Future Health’ (108) and has implications for the wider health system.

The Department of Health report into the perinatal deaths in Portlaoise in 2014 (518) recommended that national standards be developed for clinical practice guidance to ensure consistency of approach and utilisation of appropriate methodology. This research provides recent evidence on the attitudes of clinicians in Ireland towards evidence based medicine and adherence to clinical practice guidance.

Mixed methods using a theoretical framework to facilitate analysis provided a comprehensive exploration of factors influencing referrals, from several perspectives. Whilst the National Cancer Registry data is a robust population-based registry, it only collects data on diagnosed cancers. To provide a deeper understanding of referral patterns, the benign as well as the malignant referrals were investigated.

This research adds data on family risk, mastalgia and seasonal variation, areas which had not heretofore been investigated on a national basis in Ireland. This is also the first research to examine the effectiveness of the centralisation policy of cancer services in Ireland, which has implications for the centralisation of other cancer services and other parts of the health service.
Findings from this study showed increased waiting times for surgery and chemotherapy, which had lengthened towards the outer limit of the national targets set (e.g. 20 days from diagnosis to surgery). Whilst the paradoxical effect has been described in the literature about thrombolysis for stroke (510, 511), there was evidence lacking in the area of cancer. This has implications for the setting of KPIs and the possible negative effects arising when treatment can be delayed if there is more time available.

This research addressed several areas which were previous unexplored and represented significant gaps in the current literature. Conceptually it sought to examine a major health service restructuring with many components, using a psychological framework.

**Practically / clinically**

Many interventions which are found to be effective in health service research fail to translate research into practice and policy (519) and more importantly “fail to translate into meaningful patient care outcomes” (p.1) (520).

The impact of this thesis in the areas of research, policy, societal and service impact has been described in the previous section using the Kuruvilla Research Impact framework (352).

Based on the findings of this research, education and health promotion materials for GPs and patients have been developed for mastalgia, GP referral advice has been developed for family risk and GP e-learning has been expanded to include areas identified by GPs in this study.

Data from this research on proportion of referrals for mastalgia and for family history have been used to support proposals to develop services in these areas and to reconfigure the overall structure of the breast service. The findings from Study 4 provide a baseline for future longer-term studies on the impact of centralisation and health service restructuring.
The unwanted consequences of unnecessary diagnostic and therapeutic procedures have been documented in the literature on breast screening (521) but this has not been researched as much in relation to the symptomatic service. It is important that patients are aware of the possible risks and side effects of undergoing investigations, weighing up the magnitude of benefits and harm.

Findings from this thesis have been used to inform the review of the implementation of the 2006 cancer strategy (11) (4) and to address a recommendation from HIQA (6) in 2012 to review referral and triage patterns (3). In addition this work has contributed to the development of national clinical guidelines for breast cancer (345) and the development of the next national cancer strategy, due for publication in 2016.
Chapter 12: Conclusion

This research has raised important questions about the role of primary and secondary care in symptomatic breast disease, the role of the media and advocacy groups, the management of GP and patient anxiety, the impact of centralisation on breast cancer services and the challenge of meeting patient expectations while continuing to ensure an effective service for urgent cases. These are issues that can be addressed and have implications for the future structure and scope of services.

This is the first study to examine the policy of centralisation of cancer services in Ireland and provides useful evidence on the impact and effectiveness of this policy initiative.

Risk aversion and the cautious management by GPs of breast conditions, many of which are benign, are having an impact on the numbers referred to SBD clinics and the volume of diagnostic imaging. The volume of benign referrals to symptomatic breast clinics remains a significant challenge to the health service. There are challenges meeting the target waiting times for these non-urgent referrals. However, the rate of increase in referrals has lessened in recent years and the total number of referrals in 2013 was 37,890, the first year a reduction in referrals has been recorded (although this is still very high relative to the number of cancers detected).

It is opportune to examine the scope and structure of the SBD clinics in relation to suspected cancers and benign/non-urgent referrals, to ensure that suspected cancers are seen quickly and non-urgent referrals are seen in the most appropriate setting. Based on the findings of this research, a range of initiatives to optimise care in the community are now being progressed within cancer services to ensure appropriate referrals to specialist centres, e.g., management of mastalgia, family risk and benign breast conditions. There are opportunities to look at a diversity of roles in the SBD Clinics, such as
Advanced Nurse Practitioner led clinics for some non-urgent referrals, which are used in other jurisdictions (522-524). Clear information for GPs on family history of breast cancer should assist the streamlining of the referral process.

The findings from this research contributed to the development of national clinical guidelines for breast cancer in 2015 (345) which will assist in standardisation of practice nationally. The author (NO’R) coordinated the development of these guidelines with a multidisciplinary team of breast cancer specialists and the guidelines are internationally peer reviewed and published on the NCCP website. These guidelines were endorsed by the Minister for Health in June 2015.

The findings of this thesis have been included in the NCCP evaluation of the 2006 cancer strategy, which formed part of the external review carried out in 2014. The evaluation and review will form the basis of the next national cancer strategy, to be published in 2016. Similar to the policy window (64) which enabled the implementation of the 2006 strategy, this research comes at an opportune time to influence national policy in this area.

This thesis has addressed gaps in research, both nationally and internationally, in the areas of GP referral and societal impact on referral patterns. The factors influencing GP referrals were explored to ascertain whether structural or organisational factors were the dominant factors influencing referrals, or if other non-medical factors such as social factors or changes in patient and clinician behaviour were the main drivers of change in referral patterns. A complex interaction of both medical and non-medical factors influencing GP referrals was found. The thesis highlighted that non-medical factors such as anxiety and risk aversion (micro-level factors) have a significant impact on medical decision-making, over and above structural and organisational factors (macro- and meso-level factors), despite guidelines for referral being in place.
The role of evidence based guidelines, alongside patient values and shared decision making will need to be considered in the context of scare resources and iatrogenic consequences of unnecessary investigations.

The combination of factors influencing referrals is complex and requires a multifaceted approach to optimise their appropriateness. GP referral practices are influenced by factors which can be both social and contextual in nature and do not follow strictly Bayesian reasoning. Social influences coupled with beliefs about consequences are challenging barriers to address and will require multifaceted interventions to overcome.

The complexity of these social factors, alongside complex organisational and structural factors highlighted in this thesis, provides a basis for intervention and improvement of referral practices in asymptomatic and symptomatic breast disease.
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Appendix A: GP Referral Guideline

NATIONAL BREAST CANCER GP REFERRAL GUIDELINES

Breast cancer is the leading cause of cancer in women (excluding skin cancer). Nearly 2,500 women are diagnosed with breast cancer in Ireland each year. 75% of patients are over the age of 50. The cumulative risk of a woman developing breast cancer before the age of 40 is 1 in 201, before the age of 50 is 1 in 48, before the age of 65 is 1 in 16 and before the age of 75 is 1 in 11.

**WOMEN WHO CAN BE MANAGED INITIALLY BY THE GENERAL PRACTITIONER**

- Asymptomatic women, whose only family history of breast cancer is one first degree relative who was diagnosed over the age of 40, should be reassured and given advice on lifestyle and routine screening.
- Young women with tender, lumpy breasts and older women with symmetrical nodularity, provided that they have no localised abnormality.
- Women with minor and moderate degrees of breast pain who do not have a palpable lesion.
- Women aged under 50 who have nipple discharge that is bilateral or is intermittent and is not bloodstained.

**GENERAL RECOMMENDATIONS**

A patient who presents with symptoms suggestive of breast cancer should be referred to one of the national symptomatic breast clinics. Primary healthcare professionals should encourage all patients, including women over 50 years of age, to be breast aware in order to minimise delay in the presentation of symptoms. It is the best practice not to aspirate breast cysts or biopsy breast lumps in GP practices.

To make a referral, FAX or POST a SYMPTOMATIC BREAST CLINIC REFERRAL FORM to one of the Symptomatic Breast Clinics. Electronic breast cancer referral will be introduced in 2020.

Additional breast cancer referral forms can be obtained by ringing the National Cancer Control Programme on (01) 828 7100 or by logging onto [http://cancercontrol.hse.ie](http://cancercontrol.hse.ie).

GPs should refer any patient whom they deem to have a suspicion of cancer regardless of age.

**NATIONAL SYMPTOMATIC BREAST CLINICS**

- Beaumont Hospital, PO Box 1297, Dublin 9. Tel: (01) 809 3992 Fax: (01) 809 3999
- Cork University Hospital, Wilton, Cork. Tel: (021) 492 0189 Fax: (021) 492 2391
- Galway University Hospital, Newcastle Road, Galway. Tel: (091) 543 446 Fax: (091) 542 877
- Satelite Centre, Letterkenny General Hospital, Co. Donegal. Tel: (074) 9123 737 Fax: (074) 9188 816
- Limerick Regional Hospital, Dooradoyle, Limerick. Tel: (061) 482 832 Fax: (061) 482 572
- Mater Misericordiae University Hospital, Eccles St., Dublin 7. Tel: (01) 803 4269 Fax: (01) 803 2369
- St. James's Hospital, Dublin 6. Tel: (01) 416 2192 Fax: (01) 410 3415
- St. Vincent’s University Hospital, Dublin 4. Tel: (01) 221 3778 Fax: (01) 221 3778
- Waterford Regional Hospital, Dunmore Road, Waterford. Tel: (051) 842 544 Fax: (051) 848 844

**REFERRALS FOR SUSPECTED BREAST DISEASE**

**URGENT REFERRALS**

- Discrete breast or axillary lump (nipple, distant, separate mass in patients over 35 years)
- Ultrasonography
- Skin distortion
- Nipple eczema
- Discrete nipple retraction or distortion (less than 3 months)
- Blood-stained nipple discharge
- Patients with an acute discharge should be referred immediately to the nearest available breast clinic

**URGENT REFERRALS**

(To be seen within 1 week)

- Inflammation that persists after antibiotics
- Persistent redness or recurrent cyst
- Ultrasound (not bloodstained)
- Irreversible pain that does not respond to reassurance or to measures such as wearing a well-fitting bra, or a 3 month course of evening primrose oil or common anti-inflammatory drugs
- Discrete lump in women under 35 years
- Asymptomatic nodularity that persists after review after menstruation

**EARLY REFERRALS**

While 12 weeks is the standard, we aim to see patients sooner.

- Minor or moderate degrees of persistent breast pain
- Persistent bilateral nipple discharge (not bloodstained)

**ROUTINE REFERRALS**

(to be seen within 12 weeks)

Published April 2009 by full review in April 2012
Appendix B: Literature search strategy

Research question: What are the factors which influence GPs to refer patients to symptomatic breast units?

PICO
Population: General Practitioners (GPs)

Intervention: (Influencing factors)
- Symptoms: lump, pain, breast changes, family history
- Patient factors: anxiety, media influences
- GPs factors: anxiety, skill, knowledge, medical influences
- Health service factors: Centralisation /specialisation / specialist centres

Outcome: Referral of patients to symptomatic breast unit/clinic.

Databases searched: Pubmed, MEDLINE, CINAHL, TRIP Database, Cochrane Library

Limits
10 years
Humans

Search terms
Search strategy using combination of keywords and MeSH heading below:
"general practitioners"[MeSH Terms] OR "general practitioners" [All Fields] OR "general practitioner" OR “Family Doctor” OR “Primary Care”
"breast neoplasms"[MeSH Terms] OR "breast neoplasms"[All Fields] OR "breast cancer"[All Fields] OR “Breast symptoms”
"referral and consultation"[MeSH Terms] OR ("referral"[All Fields] AND "consultation"[All Fields]) OR "referral and consultation"[All Fields] OR "referral"[All Fields])
“Specialist breast unit” OR “specialist breast clinic”
Research question: Has the policy of centralisation of cancer services in Ireland had an impact on breast cancer referral patterns?

PICO
Population: Patients with suspected breast cancer/breast disease
Intervention: Centralisation/ specialisation/ specialist centres
Outcome: Referrals to breast clinics/units, overall survival, disease free survival, local/regional recurrence, diagnostic yield, stage at diagnosis.

Databases searched: Pubmed, MEDLINE, CINAHL, TRIP Database, Cochrane Library.

Limits
10 years
Humans

Search terms
Search strategy using combination of keywords and MeSH heading below:
"breast neoplasms"[MeSH Terms] OR "breast neoplasms"[All Fields] OR "breast cancer"[All Fields])
"referral and consultation"[MeSH Terms] OR ("referral"[All Fields] AND "consultation"[All Fields]) OR "referral and consultation"[All Fields] OR "referral"[All Fields])
Centralisation OR centralization OR centrali*
Specialisation OR specialization OR speciali*
Regionalisation OR regionalization OR regionali*
Designated centre AND breast cancer AND referral
Breast unit AND cancer AND referral
Appendix C: Recommendations from the National Cancer Strategy.

A Strategy for Cancer Control in Ireland, Department of Health and Children, 2006

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<td>13 Population-based screening programmes should only be introduced where their population health benefit can be demonstrated using the National Cancer Forum criteria.</td>
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<td>14 Breast screening should be extended to include all women aged between 50 and 69.</td>
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<td>15 The national roll-out of the Irish Cervical Screening Programme should be completed as a matter of priority.</td>
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<td>16 A colorectal cancer programme should be established to encompass population screening, high risk screening and necessary developments in symptomatic colorectal cancer services. In preparation for this programme, the Department of Health and Children should establish a working group under the aegis of the National Cancer Forum to address a range of implementation issues.</td>
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<td>17 The Department of Health and Children in conjunction with the HSE and BreastCheck should plan the alignment of population-based screening programmes.</td>
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<td>18 Population-based prostate screening should <strong>NOT</strong> be introduced in Ireland at present. The National Cancer Forum should keep emerging international evidence on population screening for prostate cancer under review.</td>
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<td>19 Opportunistic testing of asymptomatic individuals for cancer is not recommended.</td>
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<td>20 The HSE should develop specific programmes that promote early detection of cancer.</td>
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<td>21 All cancer care should be delivered through a national system of four Managed Cancer Control Networks, each serving a population of approximately one million people.</td>
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<td>22 A Network Director should be appointed by the HSE as soon as possible to each Managed Cancer Control Network to support and direct implementation of cancer policy.</td>
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<td>23 A lead clinician for each Cancer Centre should be appointed. In addition, a clinician should be appointed to lead the development of cancer care pathways for each major site specific cancer in partnership with all stakeholders within the network. The Cancer Control Network Director should head this team of lead clinicians.</td>
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<td>24 The HSE should develop care pathways for cancer care to link primary care services, hospital services and other relevant services.</td>
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<td>25 Improved cancer information services should be available to primary care.</td>
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<td>26 The HSE should develop programmes that support primary care professionals in the provision of cancer services.</td>
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# Appendix D: Centre for Behaviour Change Summer School, UCL 2014

## Development of an action plan for behaviour change

**Workshop / Session:** Development of an action plan for behaviour change

*In this session, you will be writing an ‘Action Plan’; a detailed plan of your project/intervention, applying the principles of behaviour change. Think about things which could potentially make it difficult (barriers) as well as things which could make it easier (facilitators) to carry out your project.*

<table>
<thead>
<tr>
<th>ACTION PLAN</th>
<th>Adherence to GP referral guidelines for suspected breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briefly describe your intervention</td>
<td>GP referrals to Breast Cancer Units increased by 60% in Ireland in five years, without a corresponding increase in breast cancers detected.</td>
</tr>
<tr>
<td></td>
<td>Interviews with hospital consultants and GPs suggested that existing GP referral guidelines were not being adhered to, due to:</td>
</tr>
<tr>
<td></td>
<td>• GP fear of missing a cancer</td>
</tr>
<tr>
<td></td>
<td>• GP risk aversion</td>
</tr>
<tr>
<td></td>
<td>• Patient expectations</td>
</tr>
<tr>
<td></td>
<td>• Ease of access to the breast clinics</td>
</tr>
<tr>
<td></td>
<td>This is a retrospective study examining possible reasons why existing GP referral guidelines were not adhered to. Recommendations are made for future intervention design.</td>
</tr>
</tbody>
</table>

**Specify the target behaviour of the intervention**

<table>
<thead>
<tr>
<th>The target behaviour is:</th>
<th>Adherence to GP referral guidelines for suspected breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Appropriate GP referral behaviour, resulting in reduction in the number of referrals to breast clinics)</td>
<td></td>
</tr>
<tr>
<td>Context: GP referral from primary to secondary care for suspected breast cancer</td>
<td></td>
</tr>
<tr>
<td>Who needs to perform the behaviour? i.e. ‘target population’</td>
<td>GPs (General Practitioners / Family Doctors)</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>What do they need to do differently to achieve the desired change?</td>
<td>Adhere to GP referral guidelines</td>
</tr>
<tr>
<td>When do they need to do it?</td>
<td>At time of each patient consultation / assessment, when making referral decision</td>
</tr>
<tr>
<td>How often do they need to do it?</td>
<td>When referring any patient to Symptomatic Breast Clinics</td>
</tr>
<tr>
<td>With whom do they need to do it?</td>
<td>Patients who present to them with breast symptoms / concerns</td>
</tr>
</tbody>
</table>

### Developing an intervention strategy

Use the APEASE criteria to select appropriate intervention functions, policy categories and behaviour change techniques (BCTs)

- Affordability
- Practicability
- Effectiveness
- Acceptability
- Side effects / Safety

The intervention functions I have selected are:

i.e. functions that an effective intervention is likely to serve

**COM-B**

- Capability (psychological) - knowledge & psychological skills.
- Opportunity (physical) – time, competing tasks, cues.
- Opportunity (social) – media, social norms, patient expectations.
- Motivation (reflective) – guidelines, confidence, beliefs.
- Motivation (automatic) – relationship with patient, emotional reactions.

**Interventions**

- Education (about cancer risk)
- Persuasion (to refer appropriately)
- Training (dealing with patient expectations, interpersonal skills)
- Environmental restructuring (clinic types, access to imaging)
- Enablement (risk management, confidence in referral decision)
APEASE criteria

Affordability: guidelines already in place, but alternative service for non-cancer (benign) conditions not available.
Practicability: Paper based, fax and electronic options available.
Effectiveness: evidence based guidelines developed.
Acceptability: acceptable to hospital consultants, not as acceptable to GPs and patients.
Side effects / Safety: medico-legal risks, fear of missing a cancer.
Equity: same service around the country in public hospitals but referral criteria not defined for private hospitals.

Intervention functions removed following review of APEASE criteria: restriction, modelling, incentivisation & coercion.

<table>
<thead>
<tr>
<th>The policy category (or categories) I have selected are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>i.e. how I am planning to implement my intervention</td>
</tr>
</tbody>
</table>

Policy categories

- Communication / marketing: role of breast clinics, appropriate health messages.
- Guidelines: ensure guidelines are evidence-based.
- Regulation: via professional bodies.
- Environmental / social planning: social norms & reporting.
- Service provision: alternative clinic for benign / non urgent conditions / GP access to imaging.

APEASE criteria

Affordability: guidelines already in place, service provision needs to be expanded to include benign conditions.
Practicability: fiscal measures and regulation not implementable.
Effectiveness: guidelines shown to be effective if used.
Acceptability: Fiscal measures & regulation not acceptable.
Side effects / Safety: Regulation through professional bodies.
Equity: does not apply to private hospitals.
Following review of APEASE criteria, the following policy categories were removed: fiscal measures & legislation.

<table>
<thead>
<tr>
<th>The BCTs (based on intervention functions above) I have selected are:</th>
<th><strong>Education</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>i.e. <em>the active ingredients of my intervention</em></td>
<td>• Information about health consequences (BCT 5.1) – provide information about delay in appointments for genuine urgent cases due to volume of inappropriate referrals received.</td>
</tr>
<tr>
<td></td>
<td>• Feedback on behaviour (2.2) – feedback to individual GPs on referral patterns and adherence to GP guidelines.</td>
</tr>
<tr>
<td></td>
<td>• Prompts / cues (7.1) – use of standardised GP referral forms, incorporate cues into electronic referral.</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td>• Instruction on how to perform the behaviour (4.1) – training for GPs and trainee GPs in dealing with patient expectations, interpersonal skills.</td>
</tr>
<tr>
<td></td>
<td>• Feedback on the behaviour (2.2) – feedback to individual GPs on referral patterns and adherence to GP guidelines.</td>
</tr>
<tr>
<td><strong>Environmental restructuring</strong></td>
<td>• Prompts / cues (7.1) – use of standardised GP referral forms, incorporate cues into electronic referral.</td>
</tr>
<tr>
<td></td>
<td>• Restructuring the physical environment (12.1) – availability of referral forms in GP surgery, electronic referral, GP access diagnostics, alternative nurse-led clinic for family risk / mastalgia / benign conditions.</td>
</tr>
<tr>
<td>Persuasion</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>• Credible source (9.1) – provide verbal or visual communication from a</td>
<td></td>
</tr>
<tr>
<td>credible source such as their professional body e.g. ICGP, IMO,</td>
<td></td>
</tr>
<tr>
<td>CME tutor.</td>
<td></td>
</tr>
<tr>
<td>• Social comparison (6.2) – Draw attention to other GP’s performance.</td>
<td></td>
</tr>
<tr>
<td>• Information about health consequences (5.1) – provide information</td>
<td></td>
</tr>
<tr>
<td>about delay in appointments for genuine urgent cases due to volume</td>
<td></td>
</tr>
<tr>
<td>of inappropriate referrals received.</td>
<td></td>
</tr>
<tr>
<td>• Feedback on behaviour (2.2) – feedback to individual GPs on referral</td>
<td></td>
</tr>
<tr>
<td>patterns and adherence to GP guidelines.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enablement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Incompatible beliefs (13.3) – Draw attention to discrepancies between</td>
</tr>
<tr>
<td>behaviour and their self-identification as a proponent of evidence-</td>
</tr>
<tr>
<td>based practice.</td>
</tr>
</tbody>
</table>
Thinking about barriers and facilitators…

<table>
<thead>
<tr>
<th>BARRIERS</th>
<th>HELPFUL THINGS / FACILITATORS</th>
</tr>
</thead>
</table>
| a) **Places and things**  
  Is there anything about the physical surroundings that my target population are in that could make it difficult for them to achieve the target behaviour? What can I do to change this?  
  - Availability of GP direct access diagnostics / imaging.  
  - Lack of alternative service for benign conditions - look at nurse-led clinic.  
  - Competing activities / prioritisation.  
  - Adequate time to spend with patient (physical opportunity).  
  - Ease of access to the breast clinics (are we victims of our own success?). | b) **Places and things**  
  Is there anything about their physical surroundings that makes it easier for them to achieve the behaviour? What can I do to provide these helpful things?  
  - Availability of IT software for electronic referral  
  - GP referral guidelines |
| c) **People**  
  Are there any people around my target population who could make it difficult for them to achieve the target behaviour? What can I do to change this?  
  - Patient expectations / pressure to refer (psychological capability)  
  - Social norms: Portrayed as new ‘centres of excellence’ and now everyone wants to be referred for reassurance/ second opinion.  
  - Media: responsible/ measured | d) **People**  
  Are there any people around my target population who make it easier for them to achieve their target behaviour? How can I ask these specific people/groups to help them?  
  - Role for Practice Nurses  
  - Other GPs in group practice  
  - Hospital consultants |
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
|   | Reporting.  
- Campaigns: non alarmist in nature.  
- Patient information: accurate realistic information.  
- Professional body – medical indemnity / back-up  
- CME group   |
| e) Thoughts and feelings | Is there anything that they are thinking or feeling that makes it easier for them to do this behaviour? How can I encourage these thoughts and feelings?  
- Fear of missing a cancer / anxiety  
- Risk aversion (medico-legal consequents)  
- GP – patient relationship  
- Motivation to continue behaviour  
- Practicing evidence based medicine  
- More appointments available for urgent cases, seen quicker  
- Social norms  
- Media portrayal   |
**Difficult situations and ‘if – then’ plans…**

Are there any situations that you can think of that could make it especially difficult for your target population to perform the behaviour? A time or a place or a feeling that might tempt them to go back to their old behaviour?

Make a list of their difficult situations:

- Patient anxiety
- Patient expectations / pressure for referral

Now make some plans for how to avoid these situations or make them more manageable. For each difficult situation, think of something you could do that would lower the chance of it interfering with your planned behaviour.

<table>
<thead>
<tr>
<th>Difficult situations IF….</th>
<th>How I will avoid or cope with them THEN…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is anxious</td>
<td>Reassurance</td>
</tr>
<tr>
<td>Patient expectations / pressure for referral</td>
<td>Involve Practice nurse</td>
</tr>
<tr>
<td></td>
<td>Active surveillance</td>
</tr>
<tr>
<td></td>
<td>Patient information</td>
</tr>
</tbody>
</table>
Appendix E: Data from mapping study (Study 1) used for interviews.

Figure 1. Referrals for breast disease.

<table>
<thead>
<tr>
<th>Year</th>
<th>Benign referrals</th>
<th>Breast Cancers detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>21,438</td>
<td>2,137</td>
</tr>
<tr>
<td>2009</td>
<td>30,370</td>
<td>1,879</td>
</tr>
<tr>
<td>2010</td>
<td>35,619</td>
<td>2,012</td>
</tr>
</tbody>
</table>
Figure 2. Triage categorisation, by hospital

Figure 3. Diagnostic yields, by hospital

Ratio of the number of patients seen and diagnosed as having benign conditions with the number diagnosed with primary breast cancer. i.e., in 2009 during the HIQA review there was one primary breast cancer diagnosed per 17 referrals (range 13-37), this has changed to one in 18 in 2010 (range 13-23).
Appendix F: Interview topic guide – Hospital Interviews

Referral and Triage Processes – Symptomatic Breast Units

“The HSE, together with the designated centres, should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians”.

(National Quality Review of Symptomatic Breast Disease Services in Ireland, HIQA, 2010. Recommendation # 12)

Review of referral and triage processes

In order to address the HIQA recommendation above, an interview will be scheduled with a nominee from each SBD unit to discuss:

1. Referral patterns.
2. Referral and triage processes in each unit.
3. Level of agreement between GP triage categorisation and breast clinic triage categorisation.
4. Mode of referral.
5. Adequacy/completeness and accuracy of GP referral information received.
6. Possible factors influencing local referral patterns.
7. Possible actions / solutions.
8. Feedback on NCCP referral guidelines / referral form and electronic referral - any recommendations for change?

The participant(s) should be the Lead Clinician for Symptomatic Breast Disease or their nominee.

The interview will be taped and transcribed, with the consent of the participants.
Appendix G: Participant information leaflet – Hospital study

Staff Information Leaflet

Protocol Title:

| Review of Referral and Triage processes in Symptomatic Breast Units |

Principal Investigator’s Name: Niamh O'Rourke

Principal Investigator’s Title: HRB PhD Scholar in Health Services Research

Telephone No. of Principal Investigator: xxx-xxxxxxx

You are being invited to take part in a national research study which is being carried out at each of the Cancer Centres, including xxxxxxxx Hospital. Before you decide whether or not you wish to take part, you should read the information provided below carefully and if you wish, discuss it with colleagues and management at the hospital. Take time to ask questions – do not feel rushed or under any obligation to participate. You should clearly understand the purpose and benefits of participating in this study so that you can give informed consent.

You are not obliged to take part in this study - participation is voluntary. You may change your mind at any time (before the start of the interview or even after you have commenced the interview) for whatever reason without having to justify your decision.

WHY IS THIS STUDY BEING DONE?

The Health Information and Quality Authority (HIQA) conducted a national review of the Symptomatic Breast Disease services in 2009 which made several key recommendations with regard to cancer referral practices:

“The HSE, together with the designated centres should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians”.

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This study will address this requirement for the cancer centres, the National Cancer Control Programme (NCCP) and the HSE.

This study is being done because referrals to symptomatic breast clinics in Ireland have increased rapidly in recent years, without a corresponding increase in breast cancer incidence. There were 23,575 referrals to the symptomatic breast disease (SBD) clinics in 2006, which increased to 32,249 in 2009. The estimated number of referrals for 2010 is 38,000. This study will explore reasons why the numbers of referrals have increased so rapidly.

The interviews with a staff member from each Symptomatic Breast Unit will address the HIQA recommendation to conduct a review of referral and triage practices and also help to formulate the next stage of the research in which interviews will be held with individual GPs to discuss factors influencing their referral decisions.

WHO IS ORGANISING AND FUNDING THIS STUDY?

The Principal Investigator is undertaking this research as part of a PhD research project on cancer referral patterns for the HRB PhD Scholars Programme in Health Services Research (part time). She is also an employee of the National Cancer Control Programme.

The Principal Investigator is funding the PhD costs and there have been no grants or sponsorship received.

HOW WILL IT BE CARRIED OUT?

The interviews will be carried out in each of the 8 cancer centres and the satellite centre, with a key informant nominated by the Symptomatic Breast Unit in each hospital. The interviews will commence in December 2010 once research ethics approval has been granted by the hospital. Each interview is expected to take 40 minutes in total. A pilot interview will take place in one hospital.

Once the interview has been transcribed, a copy will be sent to the interviewee to check for accuracy.

WHAT WILL HAPPEN IF I AGREE TO TAKE PART?

Once the key informant has been nominated by the Symptomatic Breast Unit, an interview date, time and location will be agreed to suit the staff member. It is expected that the venue will be at the hospital site. The list of
questions / themes will be sent to the staff member in advance. The same questions / themes will be discussed in each hospital.

**BENEFITS:**
This research will examine factors influencing referrals to rapid access cancer clinics. Based on study findings, recommendations will be made regarding the future delivery of services, to ensure that patients with urgent symptoms are seen quickly and those with non-urgent presentations are seen in the most appropriate setting. Service needs such as training requirements for GPs may also be identified.

**RISKS:**
There are no known risks to taking part in this study.

**CONFIDENTIALITY ISSUES**
Your identity will remain confidential. The interview will be taped (with your permission) and the interview transcript will be coded with a reference number. The identity of the interviewee and hospital will be kept in a separate secure location in the Royal College of Surgeons, accessible only to named individuals. The computer storing the data will be password protected.

The identity of the staff member and the hospital will remain confidential. Study findings will be reported on a national or regional basis. The data will be kept for seven years, in keeping with the Data Handling guidelines of the Population Health Division of the RCSI. Hard copy data will then be destroyed by shredding and electronic data will be erased from the system, including back-ups.

**IF YOU REQUIRE FURTHER INFORMATION**
If you have any further questions about the study, or if you wish to withdraw from the study, you may do so without justifying your decision.

For additional information now or any future time, please contact:
Name: Niamh O'Rourke
Address: Royal College of Surgeons, (Population Health Division),
123 St Stephens Green, Dublin 2.   Phone No: xxx-xxxxxxxx
INTERVIEW THEMES / QUESTIONS

• Overview of referral patterns and triage processes in that unit e.g. Standard Operating Procedures (SOPs), proportion of patients triaged as urgent and non-urgent, current audit processes, who triages the patients?

• Discuss possible factors influencing local referral patterns (e.g. clinical need, demographics, availability of alternative services/providers, GP referral practices).

• Discuss possible actions/solutions (GP education, patient education, differentiated service).

• Feedback on NCCP referral guidelines / referral form and electronic referral. (e.g., usefulness of guidelines and referral forms, proportion of referrals coming in by letter format and NCCP referral forms, recommended changes, adequacy and accuracy of GP referral information received).
STAFF CONSENT FORM

Protocol Title: Review of Referral and Triage processes

Please tick the appropriate answer.

I confirm that I have read and understood the Information Leaflet dated December 1st 2010 attached, and that I have had ample opportunity to ask questions, all of which have been satisfactorily answered. □ Yes □ No

I understand that my participation in this study is entirely voluntary and that I may withdraw at any time, without giving reason. □ Yes □ No

I understand that the interview transcript may be viewed by individuals with delegated authority from Niamh O’Rourke (Principal Investigator) □ Yes □ No

I understand that my identity will remain confidential at all times. □ Yes □ No

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I have been given a copy of the Information Leaflet and this Consent form for my records.

☐ Yes
☐ No

FUTURE USE OF ANONYMOUS DATA:
I agree that I will not restrict the use to which the results of this study may be put. I give my approval that unidentifiable data from this interview may be stored or electronically processed for the purpose of scientific research and may be used in related or other studies in the future.

☐ Yes
☐ No

Staff member

Name in block capitals:

________________________________

Signature and date
To be completed by the Principal Investigator or nominee.

I the undersigned, have taken the time to fully explain to the above staff member the nature and purpose of this study. I have explained the reason for the study and the possible benefits and have invited him/her to ask questions on any aspect of the study that concerned them.

Signature: Niamh O’Rourke
Name in Block Capitals: RGN, MPH, MSc
Qualification: Date:

Version number: V1.0   Date: December 1st 2010
Appendix I: Research Ethics Approval  
– 9 Hospitals

Mr Malcolm Kell  
Consultant Surgeon  
Breast Health  
Mater Misericordiae University Hospital  
Eccles Street  
Dublin 7  
06th May 2011

RE: Cancer Referral Patterns: Impact of centralisation of cancer services on referral patterns and patient outcomes  
Research Proposal and Protocol, V1.0, December 2010  
Staff Information Leaflet, Version number: 1.0 December 1st 2010  
Staff Consent Form, Version number: V1.0 Date: December 2010

Dear Mr Kell

I acknowledge receipt of Ms Catherine Carew’s correspondence dated 30th March 2011 clarifying that you are the Principal Investigator for the above research study and enclosing details of arrangements in place with the Mater Misericordiae University Hospital (MMUH) Human Resource Department in respect of Ms Niamh O’Rourke’s involvement with the above research study to be carried out at the MMUH.

This correspondence has been noted. Approval to proceed with this research study at the MMUH is granted; this approval is valid until 26th January 2013.

It is your responsibility to adhere to the approved study protocol and ensure that all investigators involved with the research only use the approved documents without deviation (unless they have been approved by the Research Ethics Committee), to submit annual reports setting out the progress of the research and to notify the Research Ethics Committee when the research is concluded.

The Mater Misericordiae University Hospital and Mater Private Hospital Research Ethics Committee would like to remind all investigators involved in research of their legal obligations under the law on Data Protection.

Yours sincerely

Dr Gormlaith Harrigan  
Alternate Vice Chairperson Research Ethics Committee

cc. Ms Niamh O’Rourke, PhD Student, HRB Health Services Research Institute, Royal College of Surgeons in Ireland  
Ms Catherine Carew, Cancer Nurse Coordinator

“159 Years Caring for the Nation”

Directors: Mr. John Morgan (Chairman), Mr Kevin O’Reilly, Mr Eamon Clarke, Mr Den Whitaker, Sr. Margaret Bock, Mr. Martin Cowley, Prof. Conor O’Flanagan, Ms. Mary O’Dwyer, Dr. Brian Corbett, St. Eugene Nolan, Dr. Anthony Gately, Dr. Kevin Murphy, Dr. Nuala Healy, Mr. Caroline Fitzgerald.
7th February, 2011

Dr. A. O’Doherty
Consultant Radiologist
St. Vincent’s University Hospital
Elm Park
Dublin 4

Re: Cancer Referral Patterns: - Impact of centralisation of cancer services on referral patterns and patient outcomes. Checklist V1.0 10/1/11. Detailed Protocol V1.0 dated 10/01/11. Standard Application Form V1.0 10/01/11. Revised Participant (Staff) Consent Form. PIL-Staff V1.1 07/02/11. Insurance Cert RCSI. Insurance Cert UCC. Ethics Approval from other hospitals. PI CV.

Dear Dr. O’Doherty,

Ms Niamh O’Rourke has forwarded the revised Patient Information Leaflet that was requested prior to granting full ethics committee approval, at the Ethics and Medical Research Committee meeting held on Wednesday 2nd February, 2011 at which the above study was reviewed.

Following review of the revised document, vs 1.1 dated 7/2/2011, this study is now granted full ethics committee approval.

Yours sincerely,

Dr. B. Kirby,
Chairman,
Ethics and Medical Research Committee.

c.c. Ms Niamh O’Rourke, General Manager – National Cancer Control Programme.
Ms. Niamh O’Rourke  
Division of Population Health (Beaux Lane House)  
Royal College of Surgeons  
123 St. Stephens Green  
Dublin 2

Please quote this reference in any follow up to this letter: 2011/02/01 Chairman’s Action

Re: Cancer Referral Patients: Impact of centralisation on referral patterns and patient outcomes

Dear Ms. O’Rourke,

Thank you for your recent submission of the above proposal to the SJH/AMNCH Research Ethics Committee. The Vice-Chairman, having reviewed the proposal had given ethical approval on behalf of the Ethics Committee.

Yours sincerely,

Ms. Ursula Ryan  
Secretary  
SJH/AMNCH Research Ethics Committee
Beaumont Hospital
Ethics (Medical Research) Committee

Chairperson: Professor Gerry McElvaney
Convenor: Professor Alice Stanton

REC reference: 10/90

Ms. Niamh O’Rourke
HRB PhD Scholars Programme in Health Services Research
Division of Population Health Sciences
Beaux Lane House
RCSI, 123, St. Stephen’s Green
Dublin 2

Dear Ms. O’Rourke,

RE: 10/90 – Ms. Niamh O’Rourke (RCSPI) – Cancer Referral Patients: - Impact of Centralisation of Cancer Services on Referral Patterns and Patient Outcomes

I acknowledge receipt of the following documents:

1. Application Form,
   - signed N. O’Rourke, 24/11/10
   - signed Academic Supervisor, A. Hickey, 24/11/10
   - signed Co-Investigator, R. Conway, 25/11/10
   - signed Collaborator, J. Browne, 11/11/10; D. Murray, 16/11/10
2. Study Summary & Interview Prompts, 9/8/10
3. Cert of Insurance, RCSPI, 23/11/10
4. CV: N. O’Rourke, 23/11/10

There appear to be three aspects of this study: 1) Audit of Hospital Charts / Systems; 2) Interview with one staff member at Beaumont Hospital; 3) Interviews with GPs.

A separate application applies, to the Irish College of General Practitioners, with regard to interviews with general practitioners

1) I attach a letter in respect to Part 1 of this study.
2) I attach ethical approval with respect to Part 2 of this study.
3) No comment is being made in respect of the third part of this study, as this committee has no remit in respect of interviews with General Practitioners.

Yours sincerely

Gillian Vale
Administrator

Gillian Vale
Administrator

Ethics (Medical Research) Committee  Beaumont Hospital  Dublin 9
Tel: 353-1-809 2680  Email: gillianvale@beaumont.ie  www.beaumontethics.ie

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Beaumont Hospital
Ethics (Medical Research) Committee

Chairperson: Professor Gerry McElvaney
Convenor: Professor Alice Stanton

REC reference: 10/90

Prof. A. Hill
Professor of Surgery
RCSI / Smurfit Building

Dear Professor Hill

RE: 10/90 – Ms. Niamh O’Rourke (RCSI) – Cancer Referral Patients: - Impact of Centralisation of Cancer Services on Referral Patterns and Patient Outcomes

Part 1: Audit of Hospital Charts / Systems

Further to correspondence from Ms. Niamh Margaret O’Rourke (received 30th November 2010)

The Committee confirms that the approval of Beaumont Hospital Ethics (Medical Research) Committee is not required in order for this prospective ‘chart review’ to proceed.

You are advised however to pay particular attention to whom will be accessing patient charts for the purposes of this review. Secondly, ‘anonymous’ data only should be extracted from charts. Thirdly, the charts should not leave Beaumont Hospital. Fourthly, all laptops and usb sticks used during the course of data collection and analysis should be encrypted.

Our current advice from the office of the Data Protection Commissioner is as follows:

"Irrevocable anonymisation of personal data puts it outside data protection requirements as the data can no longer be linked to an individual and therefore cannot be considered to be personal data."

"Equally, it is recognised that the need to link episodes of care and prevent duplication of data in research, in some instances, requires that information may need to be capable of being matched or linked. This can be achieved through appropriate pseudonymisation (e.g., use of initials, coding) methods without the need to retain all identifying characteristics with the data."

"Similarly to the advice above in relation to anonymisation, where pseudonymisation methods are used, it is recommended that extra efforts, beyond use of initials etc., be incorporated where a condition is particularly rare. Where sufficient measures are put in place to ensure that personal data is not accessible or likely to be identifiable by parties external to the data controller, the requirement to capture consent to use the data for research purposes, in such circumstances, will no longer apply."

Ethics (Medical Research) Committee     Beaumont Hospital     Dublin 9
Tel: 353-1-809 2680     Email: gillianvale@beaumont.ie     www.beaumontethics.ie

8th December 2010
If any other person has been chosen to review and extract data from patient charts on your behalf and this person is not an employee of Beaumont Hospital Board, it is advisable to contact the hospital Data Controller: Mr. Martin McCormack (IT Manager, Beaumont Hospital.)

Kind Regards

Prof. Gerry McElvaney
Chairperson
Ethics (Medical Research) Committee

1Data Protection Guidelines on Research in the Health Sector, available on www.dataprotection.ie
# Ethics (Medical Research) Committee - Beaumont Hospital

**Notification of ERC/IRB Approval**

**Chief Investigator:** Ms. Niamh O’Rourke (RCSI)  

**REC reference:** 10/90  

**Protocol Title:** Cancer Referral Patients: - Impact of Centralisation of Cancer Services on Referral Patterns and Patient Outcomes  

Part 2: Interview with Staff Member (Key Informant)

Reviewed via Sub Committee in December 2010  

**Final Approval Date:** 1st December 2010

**From:** Ethics (Medical Research) Committee - Beaumont Hospital, Beaumont, Dublin 9

<table>
<thead>
<tr>
<th>Document and Date</th>
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Ms. Gillian Vale  
ERC/IRB Administrator  
[Sub-Committee Review]  
Approval # 1, dated 1st December 2010
27th January, 2011.

Ms. Niamh O’Rourke,
Royal College of Surgeons in Ireland,
123 St. Stephen’s Green,
Dublin 2.

RE: Protocol Title:
Cancer Referral Patterns:
Impact of centralisation of cancer services on referral patterns and patient outcomes.

Dear Ms. O’Rourke,

The Research Ethics Committee at the Mid-Western Regional Hospital, Limerick has received a submission for ethical approval for the above study.

The following documents were reviewed and approved by the Research Ethics Committee:

- Application to the Research Ethics Committee
- Study Summary & Interview Schedule
- Participant Information Leaflet – Staff
- Participant (Staff) Consent Form
- Curriculum Vitae – Principal Investigator
- Confirmation of Insurance – Royal College of Surgeons in Ireland
- Professional Indemnity Insurance
- Letter of Request Hospital REC Approval dated 6th December, 2010

This approval is valid for one year from the date(s) accepted above unless otherwise noted on this document.

From an insurance perspective, please note that cover does not extend to those parties not employed by the Health Service Executive (HSE), or non-HSE Institutions.

Yours sincerely,

Mary Donnellan O’Brien,
Business Manager, Medical Directorate,
(For and on behalf of the Research Ethics Committee).
Ref: C.A. 514 – Cancer Referral Patterns – Impact of centralisation of cancer services on referral patterns and patient outcomes

Dear Ms. O’Rourke,

I have considered the above project and I wish to grant Chairman’s approval to proceed.

Yours sincerely,

Dr. Shain T. O’Keeffe
Chairman Clinical Research Ethics Committee.

c.c. Mr. Ray McLaughlin, Consultant Surgeon, University College Hospital, Galway.
16th March 2011

Attn. Ms. Niamh O’Rourke RGN, MPH, MSc
National Cancer Control Programme
King’s Inn House
200 Parnell Street
Dublin 1

Research Ethics Application:
Cancer Referral Patterns: Impact on centralisation on referral patterns and patient outcomes

Dear Ms. O’Rourke,

With reference to application listed above, I have considered your request for Ethics approval and am happy on behalf of Letterkenny General Hospital Ethics Committee to grant Chairman’s approval.

Kind Regards,

Yours sincerely

Mr. Seán Murphy
General Manager &
Chairperson of Ethics Committee
10th February 2011

Ms Niamh O’Rourke
Department of Population Health Sciences
Royal College of Surgeons in Ireland
123 St Stephens Green
Dublin 2

Re: Cancer referral patterns: impact of centralisation of cancer services on referral patterns and patient outcomes.

Dear Ms O’Rourke

Expedited approval is granted to carry out the above study in:

- Cork University Hospital
- Mid Western Hospital, Limerick.

The following documents were approved:

- Application Form
- Participant Information Leaflet Version 1.0 dated January 12th 2011
- Consent Form Version 1.0 dated 12th January 2011
- Certificate of Insurance
- Professional Indemnity Insurance
- Summary of Study Protocol Version 1.0 dated 12th January 2011
- Interview Referral and Triage Processes – Interview Guide/Prompts Version 1.0 dated January 12th 2011
- Ethics approvals from Other Hospitals.

The co-investigators involved in this study will be:

- Ms Louise Kelly, and Ms Anne Mentigan.

Yours sincerely

Dr Michael Hyland
Chairman
Clinical Research Ethics Committee of the Cork Teaching Hospitals
NAME: Ms Niamh Margaret O'Rourke
ADDRESS: Health Services Research
Division of Population Health Sciences
Beaux Lane House
Royal College of Surgeons
123 St Stephen's Green
Dublin 2

DATE: 19th January 2011

RESEARCH ETHICS COMMITTEE,
HEALTH SERVICE EXECUTIVE, SOUTH EASTERN AREA

Study Title: “Cancer Referral Patterns: Impact of centralisation of cancer services on referral patterns and patient outcomes”
Specifically:
1. Interview/discussion with one member of staff from the Symptomatic Breast Unit
2. Review of GP Referrals (chart review) – secondary analyses of existing data

Study Status: APPROVED

Dear Ms O'Rourke

The Research Ethics Committee Coordinator and/or the Chairperson, HSE, South East reviewed the above study on the 19th January 2011

Expedited ethical approval has been granted for the two named aspects of this study listed above in advance of the next scheduled REC meeting and constitutes full ethical approval.

The following documents were reviewed and approved:

1. Ethics Submission Form
2. Research Proposal
3. Participant Information Leaflet/staff
4. Participant (staff) Consent Form
5. Letter to Mr. Tadros, Consultant Breast Surgeon, W.R.H.
6. Signed hard copy of Section F; Declaration (Q53)
7. C.V. – Chief Investigator
8. Insurance/Indemnity cover letter

Version 4, Updated 13/10/10 CL
Folder: Ethics/Expedited Approval Letter Final

Waterford Regional Hospital Mission Statement:
“Together we will provide quality patient care delivered by skilled and valued staff through the best use of available resources.”
9. Ethics Approval from Beaumont Hospital

In addition this study will be outlined at the next planned Research Ethics Committee Meeting for the HSE, South Eastern Area by the Research Ethics Committee Coordinator and any comments made at this meeting in relation to your study shall be communicated to you in writing.

It is a requirement of the REC, HSE, South East that you send copy of your study to the Research Ethics Office on completion.

Yours sincerely,

[Signature]

Ms Caroline Lamb  
Research Ethics Committee Coordinator  
Health Service Executive, South Eastern Area

The Research Ethics Committee, HSE, South East is a recognized Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human use) Regulations 2004 and as such is authorized to undertake ethical review of clinical trials of all descriptions and classes for the Republic of Ireland.

The Research Ethics Committee, HSE, South East issues ethical approval on the basis of information provided. It is the responsibility of the researcher to notify the Research Ethics Office of any changes to a study to ensure that the approval is still relevant.
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March 1st 2012

GP name
GP address
GP address

Re: Research with GPs on Cancer Referrals – Barriers and Facilitators

Dear Dr ____________

I would to invite you to participate in a 20-30 minute meeting or telephone call to discuss factors influencing GP referrals to cancer centres, in particular the breast clinics. This research has arisen from a recommendation in the Health Information and Quality Authority (HIQA) review of the Symptomatic Breast Services, carried out in 2009, to carry out a review of referral and triage processes.

Based on study findings, recommendations will be made regarding the future delivery of cancer services, including the specific needs of GPs and their patients. This process will give GPs an opportunity to contribute to these recommendations.

I enclose an information leaflet outlining the purpose of the review, along with the topics for discussion. Your details have been obtained through random selection from the Irish Medical Directory. Your identity will remain confidential. 24 GPs have been invited to participate in this study - 6 GPs from each region. Additional interviews have already been conducted with hospital consultants to explore factors influencing referral patterns, from the hospital perspective.

The Principal Investigator of the study is an employee of the National Cancer Control Programme and also a participant on the HRB PhD Scholars Programme in Health Services Research. This review has obtained full research ethics approval from the ICGP.

I would be very grateful if you could consider participating in this review to identify any barriers or facilitators influencing the referral process for suspected cancers. If you have any queries, you can contact me by phone or e-mail. If you are willing to take part, I would greatly appreciate if you could confirm your interest by fax, e-mail, phone call or by post (details overleaf). An interview can then be arranged at a time and place to suit you, or by telephone.

Yours sincerely

____________________
Niamh O’Rourke. RGN, MPH, MSc
Appendix L: Consent form – GP study

GP CONSENT FORM

Title of Study: Cancer Referral Patterns: Factors influencing GP referrals
PI: Niamh O’Rourke. Fax: 01-xxxxxxx Ph: 01-xxxxxxx

I confirm that I have read and understood the Participant (GP) Information Leaflet dated October 2011, and that I have had ample opportunity to ask questions, all of which have been satisfactorily answered.

I understand that my participation in this study is entirely voluntary and that I may withdraw at any time, without giving reason.

I understand that the research data may be viewed by individuals with delegated authority from the Principal Investigator (Niamh O’Rourke).

I understand that my identity will remain confidential at all times.

I have been given a copy of the Participant Information Leaflet and this Consent form for my records.

FUTURE USE OF ANONYMOUS DATA:

I agree that I will not restrict the use to which the results of this study may be put. I give my approval that unidentifiable data from this study may be stored or electronically processed for the purpose of scientific research and may be used in related or other studies in the future.

GP Name: ______________
GP Practice: ______________
GP Signature: ______________
Date: ____________________

Please return signed consent form to Niamh O’Rourke, Population Health Division (Beaux Lane House), Royal College of Surgeons, St Stephen’s Green, Dublin 2. Fax: 01-xxxxxxx

Study ID____________

Participant Consent Form version number V1.0 Date: October 2011
Appendix M: Participant Information leaflet and topic guide – GPs

Participant (GP) Information Leaflet

Study Title: Cancer Referral Patterns: Factors influencing GP referrals

Principal Investigator’s Name: Niamh O'Rourke, RGN, MPH, MSc
Telephone No. of Principal Investigator: Ph: ______________

You are being invited to take part in a research study carried out by the Royal College of Surgeons in association with the National Cancer Control Programme. Before you decide whether or not you wish to take part, you should read the information provided below and ask any questions you may have.

You are not obliged to take part in this study. You may change your mind at any time (before the start of the study, or even after you have commenced the study) for whatever reason without having to justify your decision.

WHY IS THIS STUDY BEING DONE?

The aim of the study is to examine factors influencing referrals to cancer centres in Ireland, including barriers and facilitators, since centralisation of cancer services and introduction of GP referral guidelines and rapid access cancer clinics.

Referrals to Symptomatic Breast Clinics in Ireland have increased significantly in recent years. The Health Information and Quality Authority (HIQA) conducted a national review of the Symptomatic Breast Services in 2009, and made several key recommendations with regard to cancer referral practices, including:

“The HSE, together with the designated centres should coordinate, as part of its wider development of clinical audit systems, a review of referral and triage processes, aimed at understanding and addressing any unnecessary variations in referral or triaging practices between the designated centres and their referring clinicians”.

To address this HIQA recommendation, a study was designed in 3 parts to review cancer referral patterns and determine the influencing factors.

• The first part of the study was conducted in 2011 in the 8 cancer centres and the satellite centre in Letterkenny to determine factors influencing referral patterns, from the hospital perspective.
• This GP component will look at factors influencing referral patterns from the General Practice perspective.
• The final component will examine national anonymised data on cancer referral patterns from the National Cancer Registry.
WHO IS ORGANISING AND FUNDING THIS STUDY?

This study is organised and funded by the Principal Investigator as part of a PhD research project on cancer referral patterns for the HRB PhD Scholars Programme in Health Services Research. She is also an employee of the National Cancer Control Programme.

HOW WILL IT BE CARRIED OUT?

This study will commence in January 2012 once research ethics approval is received from the ICGP. It will be a national study, interviewing approximately 24 GPs from the four Cancer Network Regions (Dublin mid-Leinster, Dublin North East, HSE South and HSE West).

The interview will be piloted before use. GPs will be selected from each of the 4 geographical regions and will also include both male and female GPs and GPs from urban, rural and mixed practices. It is expected that interviews will take place over 12 months.

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

Your participation is entirely voluntary. If you initially decide to take part, you can subsequently change your mind without difficulty.

If you agree to participate, you will be requested to participate in an interview which will take about 20-30 minutes. An interview date, time and location will be agreed to suit you. It is expected that the venue will be at the GP practice, or if preferred, by telephone. The list of discussion themes is attached. Once the interview has been transcribed, a copy will be sent to you on request, to check for accuracy. The results of the study will be made available to all participants.

BENEFITS:

You will not benefit directly from taking part in this study but the information we will obtain will provide further knowledge of this area.

Based on study findings, recommendations will be made regarding the future delivery of cancer services, including the specific needs of GPs and their patients. This process will give GPs an opportunity to contribute to these recommendations, based on their own experience.
RISKS:
There are no known risks to taking part in this study.

WILL THERE BE ANY ADDITIONAL COSTS INVOLVED?
Will I be paid for taking part in this study? – No
Will my expenses be covered for taking part in this study? – the interview will take place in a location of your choice so that no additional costs will be incurred.

CONFIDENTIALITY ISSUES
Your identity will remain confidential. A study number will identify you, the code of which will be held by the PI. Your name will not be published or disclosed to anyone. Data which could be identifiable from the interview such as practice name, staff names or reference to geographical locations will be coded in any reports. The data will not be leaving the country.

The interview will be taped (with your permission) and the interview will be erased from the recording device once the interview has been transcribed. The interview transcript will kept in a separate secure location, accessible only to named individuals. The computer storing the data will be password protected.

Study findings will be reported on a national, regional or county basis. Anonymised data may be used in additional related studies.

The data will be kept for seven years, in keeping with the Data Handling Guidelines of the Population Health Division of the RCSI. Hard copy data will then be destroyed by shredding and electronic data will be erased from the system, including back-ups.
IF YOU REQUIRE FURTHER INFORMATION

If you have any further questions about the study, or if you wish to withdraw from the study, you may do so without justifying your decision.

For additional information now or any future time please contact:

Name: Niamh O’Rourke
Address: Royal College of Surgeons in Ireland, Population Health Division (Beaux Lane House), 123 St Stephen’s Green, Dublin 2.
Phone No: __________
Fax: _______________
e-mail: niamhorourke@rcsi.ie
Cancer Referral Patterns: Factors influencing GP referrals

Interview topic guide

The following topics will be explored:

1) **Impact of centralisation of cancer surgery & development of GP referral guidelines.**
   - GP use of the national cancer referral guidelines, referral form and electronic referral (Healthlink).
   - Change in GP referring practice (if any) since introduction of the GP referral guidelines.
   - Change in GP referring practice (if any) since centralisation of cancer surgery.
   - Barriers / pressures and facilitators relating to referral of patients with suspected cancer.

2) **Factors influencing GP referral decisions to cancer centres**
   - Patient factors.
   - Provider factors (GP practice / individual GP).
   - Health service factors.

3. **Recommendations from GPs**
   (in relation to management of patients with cancer / suspected cancer)
   - Additional services / training / support required by GPs (if any).
   - Changes recommended to cancer referral guidelines / referral forms / referral process.
   - Recommendations regarding additional information / support / services required by patients with cancer / suspected cancer.
## Appendix N: GP Characteristics

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<td>&gt; 25 years</td>
</tr>
<tr>
<td>GP4</td>
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<td>&lt; 5 miles</td>
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<tr>
<td>GP5</td>
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<td>&lt; 5 miles</td>
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</tr>
<tr>
<td>GP6</td>
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<td>Group</td>
<td>&lt; 5 miles</td>
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</tr>
<tr>
<td>GP7</td>
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<tr>
<td>GP8</td>
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<td>&lt; 5 miles</td>
<td>&gt; 25 years</td>
</tr>
<tr>
<td>GP9</td>
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<td>GMS + Private</td>
<td>Group</td>
<td>5 - 25 miles</td>
<td>&lt; 10 years</td>
</tr>
<tr>
<td>GP10</td>
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<td>Phone</td>
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<td>DNE</td>
<td>Urban + Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>&gt; 25 miles</td>
<td>11 - 25 years</td>
</tr>
<tr>
<td>GP11</td>
<td>21</td>
<td>Phone</td>
<td>Male</td>
<td>DNE</td>
<td>Urban + Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>5 - 25 miles</td>
<td>&lt; 10 years</td>
</tr>
<tr>
<td>GP12</td>
<td>10</td>
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<tr>
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<td>11 - 25 years</td>
</tr>
<tr>
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<td>17</td>
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<td>GMS + Private</td>
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<td>GMS</td>
<td>Group</td>
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<td>11 - 25 years</td>
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<tr>
<td>GP19</td>
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<td>Phone</td>
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<td>South</td>
<td>Urban + Rural</td>
<td>GMS + Private</td>
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<td>&lt; 10 years</td>
</tr>
<tr>
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<td>South</td>
<td>Urban</td>
<td>GMS + Private</td>
<td>Single-handed</td>
<td>5 - 25 miles</td>
<td>11 - 25 years</td>
</tr>
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<td>GP21</td>
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<td>South</td>
<td>Urban</td>
<td>GMS + Private</td>
<td>Group</td>
<td>5 - 25 miles</td>
<td>&gt; 25 years</td>
</tr>
<tr>
<td>GP22</td>
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<td>South</td>
<td>Rural</td>
<td>GMS + Private</td>
<td>Single-handed</td>
<td>&gt; 25 miles</td>
<td>11 - 25 years</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
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<td>GP (P) 46</td>
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<td>Female</td>
<td>West</td>
<td>Urban + Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>&gt; 25 miles</td>
<td>11 - 25 years</td>
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</tr>
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<td>GMS + Private</td>
<td>Group</td>
<td>&lt; 5 miles</td>
<td>&lt; 10 years</td>
<td></td>
</tr>
<tr>
<td>GP (P) 17</td>
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<td>Male</td>
<td>West</td>
<td>Urban + Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>&gt; 25 miles</td>
<td>&gt; 25 years</td>
<td></td>
</tr>
<tr>
<td>Surplus</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GP17 (S) 18</td>
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<td>DML</td>
<td>Urban</td>
<td>Private</td>
<td>Group</td>
<td>&lt; 5 miles</td>
<td>11 - 25 years</td>
<td></td>
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<td>GP90 (S) 23</td>
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<td>DML</td>
<td>Urban</td>
<td>Private</td>
<td>Group</td>
<td>&lt; 5 miles</td>
<td>&lt; 10 years</td>
<td></td>
</tr>
<tr>
<td>GP 22 (S) 18</td>
<td>Phone</td>
<td>Female</td>
<td>DML</td>
<td>Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>&lt; 5 miles</td>
<td>11 - 25 years</td>
<td></td>
</tr>
<tr>
<td>GP 28 (S) 15</td>
<td>Phone</td>
<td>Male</td>
<td>DML</td>
<td>Rural</td>
<td>GMS + Private</td>
<td>Group</td>
<td>&lt; 5 miles</td>
<td>&gt; 25 years</td>
<td></td>
</tr>
</tbody>
</table>
Appendix O. Research Ethics approval
- GP study

27th January 2012

Ms Niamh O’Rourke
National Cancer Control Programme
Kings Inns House
3rd Floor
200 Parnell Street
Dublin 1

Cancer Referral Patterns: factors influencing GP referrals

Dear Ms O’Rourke,

I wish to confirm that on review of your additional information submitted on the 20th December 2012 the approve study has been granted full ethical approval.

Yours sincerely,

[Signature]

Chair Research Ethics Committee

The Irish College of General Practitioners
Galärisme Dhoachtúirí
Teaghlaigh Eimearr

4-5 Lincoln Place, Dublin 2
Tel: (01) 696 379506
Fax: 01 676 5850
e-mail: info@icgp.ie
www.icgp.ie
## Appendix P: Key Performance Indicators (NCCP)

### National Cancer Control Programme

**Key Performance Indicators (KPIs) for Breast Cancer**

### STANDARD 1: ACCESS

<table>
<thead>
<tr>
<th>Access</th>
<th>KPI No 1a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Referrals triaged as urgent by the cancer centre shall be offered an</td>
</tr>
<tr>
<td></td>
<td>appointment within 10 working days of the date of receipt of a letter of</td>
</tr>
<tr>
<td></td>
<td>referral in the cancer office.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access</th>
<th>KPI No 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Referrals triaged as non-urgent by the cancer centre shall be offered an</td>
</tr>
<tr>
<td></td>
<td>appointment for a symptomatic breast clinic within 12 weeks (less than or</td>
</tr>
<tr>
<td></td>
<td>equal to 84 days) of the date of receipt of the referral letter in the</td>
</tr>
<tr>
<td></td>
<td>cancer office.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access</th>
<th>KPI No 1c</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A new patient deemed urgent following consultant surgeon assessment at</td>
</tr>
<tr>
<td></td>
<td>the clinic [S4, S5] shall have imaging (mammography or ultrasound) done</td>
</tr>
<tr>
<td></td>
<td>within a week of the first visit.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Access</th>
<th>KPI No 1d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Breast imaging requests (that is, mammography or ultrasound) for new</td>
</tr>
<tr>
<td></td>
<td>patients shall be carried out within 12 weeks of the consultant surgeon’s</td>
</tr>
<tr>
<td></td>
<td>assessment in the specialist clinic.</td>
</tr>
</tbody>
</table>
### STANDARD 2: IMAGING

<table>
<thead>
<tr>
<th>Imaging KPI No 2a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with primary operable breast cancer shall have pre-op mammography and ultrasound examination.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imaging KPI No 2b</th>
</tr>
</thead>
<tbody>
<tr>
<td>A new patient aged 36 years or older with a clinically palpable focal abnormality (that is classified as S3, S4 or S5) shall have mammography and targeted ultrasound examination.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imaging KPI No 2c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core biopsies shall be image guided, where an imaging abnormality classified as R3, R4 or R5 is identified.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imaging Additional parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant radiologists shall report on at least 1,000 mammograms annually.</td>
</tr>
</tbody>
</table>

### STANDARD 3: DIAGNOSIS

<table>
<thead>
<tr>
<th>Diagnosis KPI No 3a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with primary breast cancer (invasive or in situ) shall be diagnosed without an operative procedure [open biopsy].</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnosis KPI No 3b</th>
</tr>
</thead>
<tbody>
<tr>
<td>For patients urgently triaged by the cancer centre and subsequently diagnosed with a primary breast cancer, the interval between attendance at the first clinic and the discussion at the multidisciplinary meeting (MDM) where a B5 or C5 is first identified shall not exceed 10 working days.</td>
</tr>
</tbody>
</table>
### STANDARD 4: MULTIDISCIPLINARY WORKING

<table>
<thead>
<tr>
<th>Multidisciplinary working KPI No 4a</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients who have breast investigations that generate a histopathology report shall be discussed at MDM.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multidisciplinary working KPI No 4b</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients with a diagnosis of primary breast cancer from the symptomatic service shall be discussed at MDM.</td>
</tr>
</tbody>
</table>

### STANDARD 5: TIME TO TREATMENT

<table>
<thead>
<tr>
<th>Time to treatment KPI No 5a</th>
</tr>
</thead>
<tbody>
<tr>
<td>For primary invasive or in situ tumours, surgical intervention will be carried out within 20 working days of the date of the multidisciplinary meeting (MDM), when a B5 or C5 diagnosis was first identified, provided surgery is the first treatment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to treatment KPI No 5b</th>
</tr>
</thead>
<tbody>
<tr>
<td>For primary invasive or in situ tumours, following surgery, patients who require radiation therapy alone shall commence treatment within 12 weeks (less than or equal to 84 days) of the final surgical procedure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to treatment KPI No 5c</th>
</tr>
</thead>
<tbody>
<tr>
<td>For primary invasive or in situ tumours, following surgery, patients who require adjuvant chemotherapy and radiation therapy, shall commence radiation therapy within 4 weeks (less than or equal to 28 days) of completing chemotherapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to treatment KPI No 5d</th>
</tr>
</thead>
<tbody>
<tr>
<td>For primary invasive or in situ tumours, following surgery, adjuvant chemotherapy shall commence within 8 weeks (less than or equal to 56 days) of the final surgical procedure where required.</td>
</tr>
</tbody>
</table>
**STANDARD 6: SURGERY – AXILLARY STAGING**

<table>
<thead>
<tr>
<th>Surgery – axillary staging  KPI No 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with a diagnosis of primary operable breast invasive cancer shall have an ultrasound of the axillary nodes.</td>
</tr>
</tbody>
</table>

**STANDARD 7: SURGERY – SPECIALISATION**

<table>
<thead>
<tr>
<th>Surgery – specialisation  KPI No 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual consultant surgeons shall assess and operate on a minimum of 50 new patients with breast cancer per year.</td>
</tr>
</tbody>
</table>

**STANDARD 8: SURGERY – ACCURACY OF SURGICAL INTERVENTIONS**

<table>
<thead>
<tr>
<th>Surgery – accuracy of surgical interventions  KPI No 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>For patients having breast conserving surgery, the number of therapeutic interventions shall be recorded.</td>
</tr>
</tbody>
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**STANDARD 9: PATHOLOGY**

<table>
<thead>
<tr>
<th>Pathology  KPI No 9a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology reports include a standard set of prognostic indicators that will be available to the multidisciplinary team in a timely fashion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pathology KPI No 9b</th>
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</thead>
<tbody>
<tr>
<td>Axillary lymph node status where sampled will be recorded.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Pathology KPI No 9c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial margin status shall be documented (superior, inferior, medial, lateral margins) for all patients who have wide local excision of a primary invasive breast cancer.</td>
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</table>

<table>
<thead>
<tr>
<th>Pathology KPI No 9d</th>
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</thead>
<tbody>
<tr>
<td>The histopathology report containing prognostic data will be available within 10 working days.</td>
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</table>
Appendix Q: Conference presentations and publications

Conference Presentations

Cancer referral pathways. Annual GP study day, Mater Misericordiae University Hospital, Dublin, March 2011. Oral presentation.

A Pain in the Breast. Poster presentations:
- Annual RCSI research day, Dublin, April 2012
- NHS Health Services Research Network Conference, Manchester, UK, June 2012

Mastalgia. Annual GP study day, Mater Misericordiae University Hospital, Dublin. February 2012. Oral presentation.

Breast Cancer Family Risk - Referral Patterns in Ireland. Poster presentations:
- International Association of Cancer Registries, Cancer Epidemiology conference, Cork, September 2012
- Faculty of Public Health, Winter Scientific meeting, Dublin, December 2012
- HSE Health Professionals Research Forum, Dublin, February 2013
- RCSI annual research day, Dublin, March 2013

Are Electronic Cancer Referrals better? Poster presentations:
- International Association of Cancer Registries, Cancer Epidemiology conference, Cork, September 2012
- Faculty of Public Health, Winter Scientific meeting, Dublin, December 2012
- HSE Health Professionals Research Forum, Dublin, February 2013
- RCSI annual research day, Dublin, March 2013
- Department of Health, Patient Safety Conference, Dublin, May 2013

GPs endorse quality of breast cancer care. Poster presentations:
- HSE Health Professionals Research Forum, Dublin, February 2014
- RCSI annual research day, Dublin, March 2014
- Department of Health, Patient Safety conference, Dublin, November 2014
- UICC World Cancer Summit, Australia, December 2014
- SPHeRE annual conference, Dublin, January 2015
Efficacy of centralisation of breast cancer services in Ireland. Electronic Poster presentation:
- UICC World Cancer Summit, Australia, December 2014

Implementation of Cancer guidelines using the COM-B model. Poster presentations:
- Cochrane in Ireland conference, Dublin, January 2014
- Department of Health, Patient Safety Conference, Dublin, November 2014
- SPHeRE annual conference, Dublin, January 2015
- The Ireland-Northern Ireland – National Cancer Institute, Cancer Consortium Conference, Belfast, May 2015

Non-medical factors influencing medical decisions: a study of breast cancer referral patterns in Ireland. Poster presentation:
- The Ireland-Northern Ireland – National Cancer Institute, Cancer Consortium Conference, Belfast, May 2015


Reports and policy papers
Review of Referral Patterns and Triage Processes in Symptomatic Breast Units. National Cancer Control Programme, 2012
Available on www.cancercontrol.hse.ie

Diagnosis, staging and treatment of patients with breast cancer. National Cancer Control Programme, 2015
Available on www.cancercontrol.hse.ie

Press coverage
‘More Irish women are winning breast cancer fight as death rate drops by a third’.

Published March 22nd 2014. Irish Independent. Eilish O'Regan, Health correspondent.