Patient Education, Risk Communication and Informed Choice: Women with a Family History of Breast Cancer who Present to Primary Care

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To my family, to my love,

and to the "worried-well" who benefit and suffer from

the genetic and technological revolutions in health care.

Patient Education, Risk Communication and Informed Choice: Women with a Family History of Breast Cancer who Present to Primary Care.

Anne Andermann, Worcester College, D.Phil., Trinity Term 2000.

This thesis describes research carried out to explore the needs, expectations and experiences of the increasing number of women with a family history of breast cancer who present to primary care. This work was intended to inform clinical practice and policy, and to directly address women's needs where possible.

Although a great deal of research has looked at the experiences of women with a family history of breast cancer in a specialist setting, when this work began, no research had yet been published on women's needs in primary care. This is particularly important, as general practitioners (GPs) are the first port of call, and often the main source of information, advice and support.

A qualitative interview study was used for the preliminary work exploring women's subjective experiences of consulting primary care about a family history of breast cancer and understanding their primary care consultation needs (**Chapter 2**). This work was further elaborated upon using a prospective descriptive study to quantify the extent to which women shared the same views or experiences, and therefore, would benefit from certain changes in health care provision (**Chapter 3**). The qualitative and quantitative research showed that women's main primary care consultation needs were to discuss their risks of breast cancer with their GP and to receive verbal as well as take-home information.

When this work was being carried out, no patient information was available suitable for a general population of women with breast cancer in the family who present to primary care. For this reason, a leaflet was developed based on women's information needs and the best available evidence (**Chapter 4**). The leaflet entitled *Breast and/or Ovarian Cancer in the Family: Learning More about Your Risks and Options* was evaluated with almost 200 women to ensure that it met their needs (**Chapter 5**). Over 90% of women were glad to have received the leaflet and felt that it provided the information they wanted to know.

The implications of the work described in this thesis are that GPs could greatly assist their patients by acknowledging family history concerns as a legitimate reason for presenting to primary care, by providing verbal and take-home information and by inviting patients to return for future discussions if needed. Nationally accepted management guidelines for breast cancer family history and accompanying educational materials for use in primary care will also be instrumental in meeting patient needs and promoting informed choice in this new and difficult area of medicine.

First and foremost, I would like to thank my supervisor, Joan Austoker, for her interest in my work, her generosity with her time and her continual support. I have enjoyed my time here in Oxford and I have learned a great deal in the past three years from working in the CRC Primary Care Education Research Group, the Oxford Primary Care Genetics Group, the Division of Public Health and Primary Care and the Institute of Health Sciences.

I am grateful to The Rhodes Trust for offering me a scholarship in 1997 that enabled me to take a three-year leave of absence from McGill Medical School (Montreal, Canada) to undertake doctoral studies in Oxford. I am also thankful to Professor Martin Vessey who was very prompt and encouraging when responding to my enquiry regarding research opportunities in the Division, and who facilitated my first contact with Joan Austoker and Mike Murphy, who were starting research into the implications of genetics in health care.

Over the years, many people have generously offered their time and shared their knowledge and skills, for which I am very grateful. I would like to thank Giok Ong, who was finishing her D.Phil. studies as I was starting mine, for her advice and support. I am grateful to Eila Watson, who has been like a second supervisor to me, for helping me to plan and execute this research and for reading drafts of my work. I would like to thank everyone in the CRC Primary Care Education Research Group for their indispensable friendship and support. Thanks to Clare Bankhead for her generous assistance regarding all things statistical; to Jo Brett for helping me decide to attend the Evidence Based Health Care course; to Alison Clements for debating the grey areas in qualitative research methodology; and to Colleen Bukach for tireless data entry and lots of good advice. I am also thankful to Claire Davey, now back in Australia, who, by sharing an office, allowed me to see how to start and finish a public health project.

In the Institute of Health Sciences, I would like to thank Muir Gray for being my supervisor on the one-year Evidence Based Health Care Certificate

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Finally, I would like to thank my family and friends, the Oxford Ladies, and especially Guillaume for taking such good care of me and making sure that "we" got the thesis finished in time to move back to Montreal.

When engaging in research, and particularly in social research, it is important to reflect on how one's background and preconceptions may influence the work that one chooses to do and the way that one goes about doing it.

My D.Phil. research on the primary care needs of women with a family history of breast cancer has brought together many different interests that I have pursued over the years. As an undergraduate student at McGill University (Montreal, Canada) I worked in a molecular genetics laboratory as part of my Honours project in Biology. At the same time, I became very interested in social studies of medicine and took courses in biomedical ethics and medical anthropology. During a semester abroad at the Hebrew University of Jerusalem, I had the opportunity to participate on a Department of Public Health research project on the development of lymphomas and leukaemias following exposure to pesticides on kibbutzim. I also spent a summer in Ethiopia funded by the Canadian Society for International Health to explore the potential barriers to polio vaccination in rural areas.

At the end of my undergraduate degree, I applied and was accepted into medicine at McGill. I deferred my entrance for one year to pursue an M.Phil. in history of medicine at the University of Cambridge (UK). This year provided me with a greater perspective about medicine and the way in which medical knowledge and practices develop. I returned to Montreal and completed the first two years of the four-year undergraduate medical programme, which I greatly enjoyed. However, when I received a Rhodes Scholarship to study at Oxford, it was an opportunity I could not pass up.

In October 1997, I deferred my medical studies for a further 3 years and set off for England. Originally I had proposed to do a D.Phil. in the history of medicine looking at a comparative study of the health care systems in the UK, US, and Canada. However, at the time, there was no one available to supervise that topic. Someone offered to supervise my work if I would be interested in focussing on the history of public health. With my background in

medicine and interest in health promotion, I preferred to actually work in public health. Taking my mother's good advice, I wrote a letter to Martin Vessey, then Professor of Public Health at the University of Oxford, outlining my situation and my interest in women's health and genetics. Professor Vessey very kindly and promptly replied that Joan Austoker, Director of the CRC Primary Care Education Research Group in the Division of Public Health and Primary Care, was starting work in that area. Moreover, as I arrived in Oxford, there was a surge of interest in primary care genetics as well as a growing number of researchers working in the area of informed patient choice. Therefore Oxford turned out to be an excellent centre to work on first world public health issues which were central to my interests.

This is how I came to work in the CRC Primary Care Education Research Group and focus on the primary care needs of women with a family history of breast cancer. I have thoroughly enjoyed this work as it touches on many areas and brought together my many, diverse interests including applied ethics, women's health, genetics and clinical medicine.

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1. Introduction

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When the work described in this thesis on the primary care needs of women with a family history of breast cancer was conceived in 1997, systematic searches of the literature revealed no publications specifically on this topic. There was a need for exploratory work in this area, as although breast cancer family history did not constitute a large part of the individual general practitioner's workload, it was becoming an increasingly important issue for primary care as a whole.

This research was exploratory and pragmatic in nature. It was based upon certain themes which are as follows: 1) the increasing knowledge and public awareness regarding breast cancer family history has generated a need for health service provision in this area, 2) primary care is the first port of call for women with family history concerns, thus primary care consultation needs must be established, 3) consumers should be involved in defining the outcomes that are important to them, 4) risk communication is a difficult area that must be further explored, and 5) patient education and informed choice should be central to medical consultations, especially in areas of clinical uncertainty.

This chapter presents selected reviews of these topic areas central to this work as well as an outline of the thesis chapters to follow.

1.1. Breast cancer in the family

Advances in molecular biological techniques that were made a quarter of a century ago [Sanger and Coulson, 1975; Southern, 1975] enabled rapid developments in genetic research, including a multi-national effort to sequence the entire human genetic code (i.e. the human genome project) [Watson J, 1990]. This rise in research activity has led to an increasing emphasis on the potential impact of genetic information in clinical practice [Andrews et al, 1994; Bayley, 1999a; Bell J, 1998; Department of Health, 1995a; Harper and Clarke, 1997; Kinmonth et al, 1998; Richards T, 1999; van Ommen et al, 1999; Weatherall, 1982].

Current genetic research and the potential applications of such research findings concern not only the rare, single-gene, Mendelian diseases, but also common, multi-factorial diseases, such as heart disease and cancer [Department of Health, 1995b; Lander and Schork, 1994]. Thus far, much of the progress into the understanding of complex diseases comes from research into the less common, Mendelian forms of these diseases which have a strong inherited component, but only comprise about 5% of cases [Eeles et al, 1996; Foulkes and Hodgson, 1998]. In particular, a great deal of research has focused on the link between

family history and an increased risk of breast cancer [Easton et al, 1993; Houlston et al, 1992b]. Five years ago, two breast cancer predisposing genes were identified, *BRCA1* and *BRCA2* [Miki et al, 1994; Wooster et al, 1995]. These genes are believed to account for approximately 5% of breast cancer cases, and a further 10-15% of cases may be attributed to single dominant genes yet to be identified or to several lower penetrance genes [Rahman and Stratton, 1998].

In recent years, the field of breast cancer genetics research has flourished [Ford et al, 1998; Krainer et al, 1997; Shattuck-Eidens et al, 1997; Struewing et al, 1997; Thorlacius et al, 1998; Verhoog et al, 1998; Watson P et al, 1998]. This research that relates to a disease affecting 1 in 11 women in the UK by the time they reach the age of 85 has attracted considerable media attention. Newspaper headlines likened breast cancer in the family to a "family curse" [*The Express*, 1999] and the press regularly told stories of women whose "body was a walking time bomb" [Horowitz C, 1999] and thus had "both breasts off to beat family cancer" [*The Mirror*, 2000] or who joined research trials to try and save their lives [*The Daily Mail*, 2000]. The general public who read these emotive headlines are believed to have a limited understanding of genetics, their perceptions of inheritance and risk are rooted in personal

experience rather than scientific fact [Davison et al, 1991; Marteau and Senior, 1997; Nettleton, 1995; Parson and Atkinson, 1992; Richards M, 1996 and 1997; Turney, 1995]. Moreover, it is often left unsaid that the findings of breast cancer genetic research are only relevant to a small proportion of women with breast cancer in the family [Langston et al, 1996]. As a result, the media attention has not only led to an increase in public awareness regarding the implications of genetics in health care, but it has often also led to unrealistic expectations of these new technologies and unfounded fears [Rowan and Bowcott, 1998]. Further fuelling these fears are cancer charity advertising campaigns and even radio and television shows that misrepresent the risks of cancer [Kent A, 2000].

In part, this increase in public awareness and concern has resulted in a rapid increase in medical consultation rates regarding breast cancer in the family, far more so than for any other hereditary cancer [Eccles et al, 2000; Fraser, 1996; Lucassen and Sidebottom, 1998]. The number of general practitioner (GP) referrals to secondary care has risen so rapidly in such a relatively short period of time [Houlston et al, 1992a] that specialist services are finding it difficult to meet the demand [Pharoah et al, 1998a]. There are guidelines regarding the assessment and

counselling of women with a family history of breast cancer [Biesecker et al, 1993; Eccles et al, 2000; Hoskins et al, 1995; Mackay, 1998], genetic testing of at risk individuals [American Society of Human Genetics, 1994] and the follow up of women with an inherited predisposition to breast cancer [Burke et al, 1997]. However, familial cancer is a relatively new field and there is limited evidence regarding the benefits and long-term risks of various preventive and screening options [Byrne and Bundred, 1997; Emery et al, 2000a]. Therefore, it is not clear how best to manage women who present to primary care with concerns about a family history of breast cancer, nor whose role it should be [Donnai et al, 2000; Elwyn et al, 2000; Emery et al, 1999; Fetters et al, 1999; Fry et al, 1999; Geller et al, 1993; Gill and Richards, 1998; Gray J et al, 2000; Holtzman and Watson, 1997; Kumar and Gantley, 1999; North West England Faculty of the RCGP, 1998; Rose and Lucassen, 1999; Rosser et al, 2000; Whittaker, 1996]. This is not simply a matter of practically defining the division of labour between primary care and secondary care, there are ethical and even legal implications involved in the management and follow-up of such patients that must be taken into account [Human Genetics Advisory Commission, 1997 and 1999; Lucassen and Houlston, 2000; Nuffield Council on Bioethics, 1993; Sharpe, 1994; Somerville, 1996; Weatherall, 1991]. A

good first step is to ask patients what they might prefer and what are the outcomes that matter most to them.

1.2. What constitutes a good outcome

Much of the previous research regarding women's experiences of breast cancer in the family has focused on issues regarding genetic risk counselling in a specialist setting [Alexander et al, 1996; Evans et al, 1994a; Hallowell et al, 1997b; Julian Reynier et al, 1996a; Michie, 1997; Richards M, 1995; Watson M et al, 1999], adherence to screening and breast self-examination [Bastani et al, 1999; Hailey, 1991; Kaplan et al, 1991; Kash et al, 1992; Lerman and Schwartz, 1993; Richardson et al, 1996; Ryan, 1997], or the uptake and consequences of gene testing [Cappelli et al, 1999; Chaliki et al, 1995; Eeles, 1996; Geller et al, 1999; Gil, 1996; Julian-Reynier et al, 1996b; Lerman and Croyle, 1994; Lerman et al, 1994, 1995b, 1996a, 1997a and 1997b; Lodder et al, 1999; Lynch et al, 1997; Marteau and Croyle, 1998; Richards C et al, 1997; Stalmeier et al, 1999]. Even though such research is extremely useful and necessary, none of these outcomes are wholly relevant to the general population of women with breast cancer in the family who present to primary care.

For instance, although genetic counselling is an important area of research, not all women with a family history, and not even all those referred to secondary care, are able to receive such time and labour-intensive medical attention. Due to the tremendous pressure placed on genetic services and the limited resources available, many women referred to a genetics clinic, but considered at low risk, are sent a letter of reassurance rather than an appointment for genetic counselling [Lucassen, pers. comm.]. As well, there are many women at moderate risk referred to breast surgeons for mammographic screening, and they too will not receive genetic counselling in the formal sense. Therefore, it would be important to take a wider approach and assess the views of the larger population of women (low to high risk) who approach their GP about family history concerns, since many of them may never be referred to or seen in a genetics clinic [Kahn, pers. comm.]. This argument is even stronger when considering genetic testing as a research topic that could be relevant to the majority of women with a family history of breast cancer who present to primary care. Even smaller proportions of women who actually receive genetic counselling are suitable for and are offered a genetic test [Couch et al, 1997; Lucassen, pers. comm.]. Research into the ethical, legal and psycho-social issues related to gene testing is certainly important, but for the

moment, it is not a service directly offered through primary care practice in the UK (unless Rosgen, a subsidiary of Myriad Genetics which holds the patent for *BRCA1*, manages to open that route) [Department of Health, 2000]. Therefore the uptake and consequences of gene testing is also not an ideal focus for research regarding the general population of women with breast cancer in the family who consult their GP.

With regards to assessing women's adherence to mammography and breast self-examination, mammographic screening has not yet been shown to be effective in decreasing mortality in women under 50 [Berrino et al, 1995; Emery et al, 2000; Forrest and Alexander, 1995; Kerlikowske et al, 1995; Neugut and Jacobson, 1995; Wells, 1998], although the tide of evidence may be turning, especially as concerns women with a family history of breast cancer [Brekelmans et al, 1999; Kerkilowske, 1997; Kollias et al, 1998; Lalloo et al, 1998; Sickles and Kopans, 1995; Sussman, 2000]. There is however strong evidence that mammographic screening is associated with negative physical and psychological consequences [Beemsterboer et al, 1998; Cancer Research Campaign, 1997; Lerman et al, 1991a and 1991b; Nielsen et al, 1991; Ong et al, 1997; Petticrew et al, 2000; Scaf-Klomp et al, 1997; Sox, 1998; Wardle and Pope, 1992]. Therefore women's reasons for

wanting screening and their concerns about regular mammography in pre-menopausal women may be more meaningful and appropriate outcomes than how many women actually attend mammographic screening. Likewise, routine, ritualistic breast self-examination is no longer being advocated because it has not been shown to be beneficial in reducing mortality from breast cancer, and the costs of the associated negative psychological consequences are too great [Austoker, 1994b; Frank and Mai, 1985; Love, 1995; Mant, 1992]. Therefore current research should consider women's knowledge of breast awareness and their levels of confidence in identifying the signs and symptoms of breast cancer, rather than dogmatic adherence to regular breast-self examination regimens.

For the above reasons, the research described in this thesis did not attempt to measure a specific behavioural outcome with respect to hereditary breast-ovarian cancer (such as adherence to preventive behaviours or decision to have a gene test). Nor was the research limited to the genetic counselling consultation. But the question remains as to what would constitute a good outcome (or good outcomes) that would be relevant to the majority of women with a family history of breast cancer who consult primary care?

Patient satisfaction with medical consultations is not necessarily a meaningful primary outcome, as it may reflect complex issues that may be only indirectly related to actual events (this point is further elaborated in **Section 1.4**) [Fairhurst and May, 1995]. Likewise regarding women's anxiety levels or knowledge about breast cancer and breast cancer risks, these may not directly relate to the successfulness of medical encounters nor to patient understanding of the issues and ability to make informed choices [Eiser, 1998; Hallowell and Richards, 1997; Watson M et al, 1999].

Although patient satisfaction, cancer worries and risk understanding may be very important outcomes, ultimately it is up to women with breast cancer in the family to define the outcomes that matter most to them. Therefore, the purpose of the research reported in this thesis was to explore what women wanted from the medical system to help them cope with their breast cancer risk perceptions and cancer worries, and what information they needed to make informed choices about their future health. The following sections of this chapter review some of the themes that are central to this work.

1.3. Consumer views

To provide services that meet the newly emerging needs of the increasing number of women consulting their GPs and being referred because of a family history of breast cancer, it is important to obtain the views of these women. By identifying women's primary and secondary care consultation needs and expectations it should be possible either to meet those needs, or else to inform women beforehand regarding what they may reasonably expect and why, with the aim of increasing their consultation satisfaction, and improving their health care experience in general.

Consumer involvement has become an important element in health service research and policy over the past few decades [Entwistle et al, 1999]. The introduction of the Patient's Charter to the NHS in 1991 pushed forward the consumer movement in health care in the UK [Department of Health, 1991]. The term patient no longer connotes the passive party in the doctor-patient relationship, patients are now considered as consumers, clients, and users of health services, they are partners in shared decision-making as well as participants (rather than subjects) in medical research [Bain, 1999; Bury, 1997; Coulter, 1997;

Entwistle et al, 1996; Fairhurst and May, 1995; Herxheimer and Goodare, 1999; Neuberger and Tallis, 1999; van den Borne, 1998].

Reasons for taking into account user views include the need to assess whether health care services are acceptable to patients and to determine the extent of patients' satisfaction with these services [Calnan, 1996]. There are many different ways to involve consumers at all stages in the research and policy development process [Hanley et al, 1999 and 2000; McIver, 1993b; National Health Service Executive Research Development Directorate, 1998; The Standing Advisory Group on Consumer Involvement in the NHS Research and Development Programme, 1998]. Consumer involvement has already been successfully used in identifying patient needs with regards to cancer services throughout the "cancer journey" [Bell S et al, 1996], and continuing consumer involvement will ensure that research and practice reflect what is important to patients [Chalmers I, 1998].

There are those who claim that user involvement does not only have benevolent motives, but is also used as a "social technology of legitimation" in justifying health policy decisions [Harrison and Mort, 1998]. Obtaining user views for prioritising health services may pose

ethical problems when patient priorities differ from those of medical practitioners and other interest groups [Bowling et al, 1993]. There would even be an inherent conflict of interest if findings of surveys were to be used for rationing services, and this could even lead to biased or uninterpretable results of consumer research [Jenkinson, 1999].

Despite these potential pitfalls, used openly, patient surveys are important when it comes to improving services [Cleary, 1999], and reports of patient views do make a difference in patient care [Longo et al, 1997]. Involving consumers is crucial in providing patient-centered information and services that empower patients [McIver, 1993a] and it is considered that the benefits outweigh the costs [Coulter et al, 1998; Hearnshaw et al, 1996].

1.4. Satisfaction, expectations and primary care

Cancer services, including familial cancer management, require a multi-disciplinary approach [Austoker, 1994c; Summerton, 2000]. Therefore, when examining the health care needs of women with a family history of breast cancer, it is important to focus on the doctor-patient encounter in primary care, as well as the transition between primary and secondary or tertiary care.

There is a very large and longstanding literature on patient satisfaction with their care [Hall and Dornan, 1988]. Surveys of patient satisfaction with primary care consultations consistently show a high level of satisfaction overall [Calnan, 1997; Stott et al, 1997]. Satisfaction has been found to be linked to the length of the consultation [Howie et al, 1999], the provision of relevant information and sufficient explanation [Jones et al, 1999a and 1999b; Rayner, 1999], the provision of reassurance [Donovan and Blake, 2000], trust in the physician and the health care system [Rayner, 1999], and involvement in decision-making [Greenhow et al, 1998].

However satisfaction has its limitations as an indicator of quality of care as there tends to be a skew towards the highest response categories [Rosenthal and Shannon, 1997]. Patient satisfaction is culturally defined [Himmel and Kochen, 1997], and offers only a limited understanding of how patients evaluate their care [Avis et al, 1997; Calnan, 1988]. There is a question regarding what quality outcome measures should be used [Stott et al, 1997]. There is reason to look not only at satisfaction, but also at the complex interaction between patient satisfaction, expectations and experiences [Clancy and Eisenberg, 1998; Haas,

1999; Staniszewska, 1999; Wilkin et al, 1992], although there are no valid and reliable instruments currently available for this purpose [Greenhow et al, 1998].

Patient expectations reflect what patients think *will* happen or what they *want* to happen regarding their care. In the research described in this thesis, women's expectations regarding what they want to happen was considered most relevant. However, it is important to keep in mind that expectations are limited to the patient's knowledge of what is in fact possible, thus expectations may change with new information and experiences [Fitzpatrick and Hopkins, 1983].

1.5. Risk perception and risk communication

Risk perception and understanding is central to the experience of women with a family history of breast cancer [Evans et al, 1993; Ryan, 1997; Thirlaway and Fallowfield, 1993; Watson M et al, 1998 and 1999], more so than an understanding of genes and genetics [Bayley, 1999b]. There has been a great deal of research on how people understand and make sense of health risks and much has been written on the difficulties of communicating risks both at the population level and at the individual level [Alaszewski et al, 1998; Bate, 1999; Beck, 1999; Bennett and

Calman, 1999; Bennett et al, 1999; British Medical Association, 1987; Calman, 1998; Eiser, 1998; Gabe, 1995; Heyman, 1998; Kemp and Wilkinson, 1997; Mann, 1989; Rimer, 1997; Sjoberg, 1987 and 1997; Tennant, 1997; The Royal Society, 1983 and 1997; Viscusi, 1992 and 1998].

It has been suggested that the ambiguities of health risks "stem from its translation from epidemiological findings into clinical knowledge and practice and thus to lay experiences of health and illness" [Adelsward and Sachs, 1996; Mant, 1999; Skolbekken, 1998]. Innumeracy breeds fear [Paulos, 1988; *The Independent*, 1999], as do personal experiences and individual perceptions of the severity and likelihood of the potential outcome. Research findings have shown that twenty years ago, most women with a family history of breast cancer did not consider themselves to be at increased risk [Howe, 1981]. Whereas more recently, even women in the general population overestimate their breast cancer risks and the resultant "breast cancer fears torment women" [*BBC News*, 1999; McCaul and O'Donnell, 1998; Spittle and Morgan, 1999; *The International Herald Tribune*, 1999; *The News of the World*, 1998;*The Sunday Mirror*, 1999]. One woman who does not have a family history of the disease says her "terror of cancer is so great" that

she's having her breasts removed [*The Daily Express*, 1999]. Women recently surveyed from the general population wanted to know more about their personal breast cancer risks [Andrykowski et al, 1996], and heightened breast cancer risk perceptions have caused women to underestimate even more likely risks to their health, such as coronary heart disease [Haybittle, 1999]. Some women even devise fictitious family histories of breast cancer to obtain referrals and receive specialist care [Kerr et al, 1998].

Predicting, let alone communicating, risks about breast cancer is complicated, and even ethically sensitive [American Cancer Society Breast Cancer Network, 1998; de Backer and de Bacquer, 1999; Jungermann, 1997; Love, 1995; Phillips et al, 1999]. Creating a standardised language of risk was proposed as a tool to improve the success of risk communication [Calman, 1996; Calman and Royston, 1997]. Communicating the same risk in many different ways is more commonly suggested as good practice [Bogardus et al, 1999; Department of Health, 1997; Edwards et al, 1998a and 1998b]. Life tables have been recommended to put risks of breast cancer in perspective [Bunker et al, 1998]. Presenting both relative risk and actual risk figures can help to overcome framing bias [Edwards et al, 1999;

Hux and Naylor, 1995; Malenka et al, 1993; McMurray, 1999; Naylor et al, 1992]. Finally, it is important to be open about the uncertainties underlying any risk estimates to avoid patient or public misunderstanding [Tennant, 1997].

Ultimately, risks are complex and a matter of personal values and experiences [Licence and Stark, 2000]. A review of the literature regarding risk communication related to familial cancer [Bottorff et al, 1996] concluded that communicating risk information should take into account pre-existing risk perceptions and be tailored to the individual's affective state and information processing preferences. Women are often not able to [Watson M et al, 1998] or do not feel the need to [Hallowell et al, 1997a] recall numerical risk estimates. However, what is most important is that they are able to develop positive coping strategies regarding their actual or perceived risks [Kash, 1995] and that they feel they have sufficient risk information to allow them to make informed choices about their care.

1.6. Information provision and patient choice

Women with a family history of breast cancer are not themselves ill, and many of them might never develop breast cancer during their lifetimes.

For this reason, it is especially important that these women are made aware of the pros and cons of preventive and early detection options, to aid them in making informed choices. The proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services [Akinyanju et al, 1998] advocated "freedom of choice in all matters relevant to genetics." The document also cited that "education about genetics for the public and health care professionals is of paramount importance." These two concepts are closely linked, as informed decision-making is only possible if it occurs within a framework of unbiased information-giving.

Patient-centered, shared decision-making approaches have been promoted in health care for some time [Entwistle et al, 1998a; Meredith, 1993]. However, research in this area is still quite new [Bekker et al, 1999]. At the heart of evidence-based patient choice is the concept that patients should be able to find evidence-based information about the issues that are important to them in making choices about their health [Hope, 1996 and 1999]. Just as different individuals want and seek varying types and amounts of information [Beisecker and Beisecker, 1990; Miller, 1995], not all individuals wish to be involved in decision-making in the same way, if at all [Benbassat et al, 1998; Charles et al,

1997; Taylor, 2000]. There are pros and cons to decision making as increased choice comes with increased uncertainty and responsibility [Coulter, 1997]. Some even worry that patient choice may lead to deferred physician responsibility [MacFayden, 2000].

Even if information is presented in a comprehensive and unbiased manner [Tversky and Kahneman, 1981], and even if it is well-understood and integrated by patients, decision-making may proceed in simplified, intuitive ways rather than complex, reasoned ones [Ubel and Loewenstein, 1997]. There are many decision aids available for making treatment and screening choices [O'Connor et al, 1999]. Two such tools, aimed at a general population of women with a family history of breast cancer, are currently in the process of development [Warner, pers. comm.; Holmes-Rovner, pers. comm.]. Depending on women's circumstances and preferences, they may or may not consider these decision aids to be useful. Nonetheless, even if they do not want to make the final decision about their management, or they make "intuitive" choices, women may still want information and want to discuss and weigh the pros and cons of their options with health care professionals who are knowledgeable regarding their condition [Harrison A, 2000]. Moreover, the provision of information in itself has been shown to

increase positive perceptions of health and improve health outcomes [Maly et al, 1999].

1.7. Thesis overview

While breast cancer family history has been rapidly increasing as a reason for consulting primary care and being referred to secondary care, there has been a lack of evidence regarding optimal management in this area, and it has not been possible to arrive at a national consensus regarding the delivery of care. Whatever system of care does come into place, it should reflect what the users of the health care system consider to be important, and this requires research into consumer needs. Moreover, such research should focus on the entire "health care journey," beginning with primary care.

In 1997, when the research reported in this thesis was conceived, a great deal had been written about women's needs and expectations regarding breast cancer in the family within a specialist setting. There was evidence that women needed more information prior to being seen in secondary care [Hallowell et al, 1997b]. However, no work had yet been published on the needs, expectations or experiences of women with a family history of breast cancer who present to primary care. Nor

did there exist any patient information suitable for the general population of women with breast cancer in the family who consulted their GP about their family history concerns. These constituted large gaps in the academic and consumer health information literatures. Moreover, the issue of breast cancer family history in primary care is especially relevant in the UK where there is very little self-referral to secondary care, and therefore almost all cases are seen, at least initially, in primary care. In addition, many of these women are never referred, and therefore the only care they ever receive related to this matter is in primary care. Thus primary care genetics is a very important area that until recently has not been explored, especially from the patient's point of view.

The purpose of the research reported in this thesis was to understand better women's needs from the time when they first raised their family history concerns with their GP. The intention of this work was to meet women's needs where possible (i.e. through the development of research-based information materials), and to make suggestions to improve the overall system of care according to what women considered to be important. As this work was exploratory in nature, a combination of qualitative and quantitative descriptive methods was used.

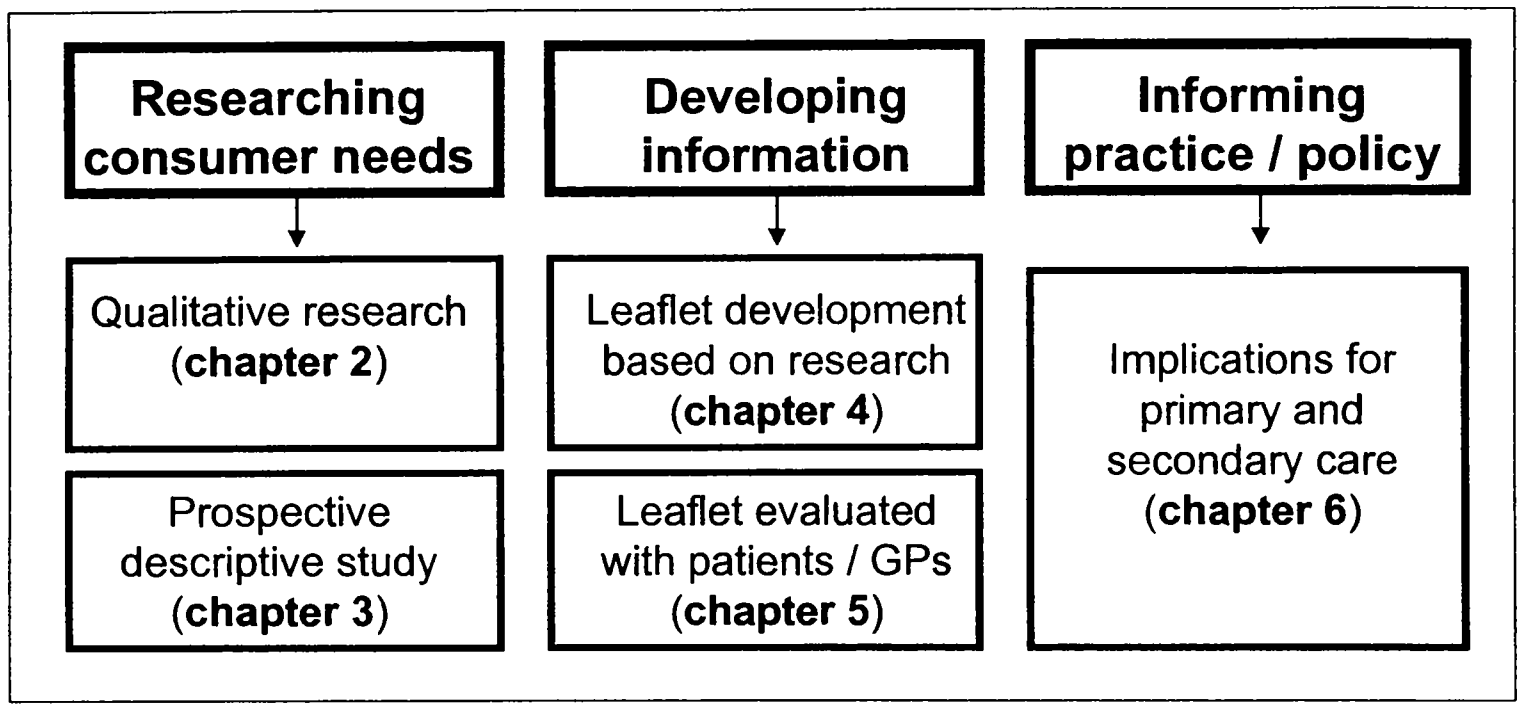
Thus far, this introductory chapter has provided a selected review of the literature regarding women with a family history of breast cancer, as well as a selected overview of the main themes upon which the research described in this thesis is based. These themes include the following:

1) That consumers should be involved in defining the outcomes of care that are important to them,
2) That the primary care consultation should be included in research regarding the management of women with familial cancer,
3) That risk perception and understanding is central to the experience of women with breast cancer in the family, and
4) That information provision is important in and of itself, and is also a prerequisite to informed patient choice.

The following chapters of this thesis describe how women with a family history of breast cancer were invited to give their views regarding their information and consultation needs, as well as their expectations and experiences of both the primary care and secondary care consultations. These aspects in turn informed clinical practice and policy, as well as informing the development of a research-based information leaflet that was then evaluated with the intended audience (see **Figure 1.1**). The

ultimate goal of this work has been to determine women's needs, and in attempting to address their needs, promote patient understanding and choice.

Figure 1.1: Researching consumer needs, developing research-based information and informing clinical practice and policy



Chapter 2 describes a qualitative study that aimed to explore women's primary care consultation needs regarding their family history of breast cancer. Qualitative research aims to understand how people see their world and why they see it in the way that they do. It is a very useful research tool used for exploring new and complex areas. Quantitative methods are able to complement qualitative research.

Chapter 3 describes a prospective descriptive study that aimed to delineate women's breast cancer risk perceptions, cancer worries, information needs and primary and secondary care consultation expectations and experiences. This study was able to quantify which needs and experiences were shared by the majority of women referred on the basis of a family history of breast cancer, with a view to informing patient information materials and consultation practice.

Chapter 4 describes the development of a patient information leaflet that is informed by patients, evidence based and clearly communicated in accordance with the Centre for Health Information Quality guidelines for producing good quality patient information materials. Chapter 5 contains the findings of the evaluation study that assessed the usefulness and acceptability of the leaflet with almost 200 women with a family history of breast cancer.

Chapter 6 contains the general discussion of the qualitative and quantitative research projects as well as the leaflet development and evaluation in the context of current knowledge and practice in this area. Implications for changes to clinical practice and policy are discussed and possible areas for future research are suggested.

2. Qualitative study of primary care consultation needs of women referred regarding a family history of breast cancer

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2.1. Introduction

As outlined in the previous chapter, the highly publicised discovery five years ago of two breast cancer predisposing genes has led to an increasing number of women consulting their general practitioner (GP) about breast cancer in the family, with a corresponding increase in related referrals from primary to secondary care [Lucassen and Sidebottom, 1998]. There are currently no nationally agreed upon management and referral guidelines for GPs regarding women with a family history of breast cancer [Pharoah et al, 1998a]. In addition, many GPs feel they do not have adequate knowledge or skills to address the novel and complex issues raised by family history concerns [Emery et al, 1999; Watson E et al, 1999].

It is considered that by improving their understanding of patient expectations and experiences, health professionals would be better equipped to address patient needs and thus increase patient satisfaction with their care [Greenhalgh and Hurwitz, 1999; Wensing et al, 1994; Williams S et al, 1998]. Qualitative methods are considered most appropriate for exploratory studies of complex issues such as these [Fitzpatrick and Boulton, 1994; Green and Britten, 1998; Pope and Mays, 1995]. A limited number of studies have looked at the information

and support needs of women with a family history of breast cancer using qualitative methods [Chalmers K et al, 1996; Green J et al, 1997; Hallowell et al, 1997b; Richards M et al, 1995]. However, at the time when this work was started (1997), no studies had been published that focussed specifically on women's needs in the primary care setting. Understanding women's needs during the GP consultation could lead to improved patient satisfaction with primary care, as well as with subsequent interactions with the health care system. The use of open and semi-structured interviews to explore the needs, expectations and experiences of women with breast cancer in the family who consult primary care is reported in this chapter.

2.2. Aims

The aim of this study was to explore from the patient's perspective the primary care needs, expectations and experiences of women who consult their GP about a family history of breast cancer and are referred to secondary care.

2.3. Methods

2.3.1. Study design

Of the numerous qualitative methods available [Britten et al, 1995], it was felt that in-depth interviews would be most appropriate for this study. This approach was preferred for several reasons. Interviews are interactive and flexible, they elicit people's experiences and views in their own words, and they permit in-depth exploration of why people hold certain beliefs and what issues they consider to be important [Bernard, 1988]. Moreover, interviews can be used to uncover new areas or ideas that were not anticipated at the outset of the study. These benefits of interviewing also hold true for many other qualitative approaches. However, none of the other approaches was acceptable for the purpose of this study.

Observational methods, which make use of the natural setting, and were used in one of the studies mentioned previously [Hallowell et al, 1997b], would not have been feasible here since individual GPs have so few consultations regarding breast cancer in the family that it would be virtually impossible to recruit enough patients to the study. Focus groups can encourage participation and exploration of issues through interpersonal interaction [Kitzinger, 1995]. However, focus groups can

also be influenced by "dominant" personalities and their views may take on greater weight than more reticent individuals who may be reluctant to express their views. To be sure to obtain a full spectrum of views, it is better to interview participants separately so that each individual is free to express their own views. Therefore, one-to-one interviewing, possibly the most widely used qualitative method in medical research [Britten, 1995], was used in this study.

Due to the novelty of this research area, it was planned to carry out open interviews initially, from which a semi-structured interview guide could be developed for use in subsequent interviews. Prior to the commencement of the study, approval of the local research ethics committee was obtained.

2.3.2. Participants

Purposive sampling was used to recruit women who had consulted their GP about a family history of breast cancer and had been referred for a specialist consultation. These women could be considered as “experts” on what it is like to have a family history of breast cancer, to present to primary care and to be referred for a specialist opinion. As aluded to above, it would not have been feasible to recruit patients directly from

primary care due to the relatively small number of breast cancer family history consultations per GP per year [de Bock et al, 1997; Johnson N et al, 1995]. Thus patients were identified from primary care referrals regarding a family history of breast cancer made within two years prior to the commencement of the study either to a breast surgeon or to a clinical geneticist in Oxford. Recruitment was in proportion to the number of referrals received by the breast surgeon and the clinical geneticist (i.e. a ratio of 1:4), and continued until data saturation was reached (i.e. no new themes were emerging from the analysis).

Women were invited to participate via a letter from the specialist that explained the nature and purpose of the study (**Appendix 2.A**). The personal and demographic characteristics of the 21 women interviewed are found in **Table 2.1**.

Table 2.1: Characteristics of twenty-one (21) study participants

Characteristic	Category	Number of women
Age (years)	20-29	4
	30-39	11
	40-49	6
Stage in referral process	Not yet been to appointment	6
	Already attended appointment	15
Education	No post-secondary education	12
	Post-secondary education	9
Marital status	Married	18
	Single	3
Children	Yes	17
	No	4
Ethnic group	White	19
	Mixed/Other	2
Affected first degree relative	Mother	18
	Sister	1
	Neither	2
Strength of family history*	Low risk	6
	Moderate risk	12
	High risk	3

*Strength of family history was determined according to guidelines established by the Department of Clinical Genetics, Churchill Hospital, Oxford Radcliffe NHS Trust, Oxford.

2.3.3. Interviews

Participants chose to be interviewed either at their home (n=8) or workplace (n=1), or at the interviewer's place of work (n=12). The interviewer (A.A.) clarified at the outset of each interview that she was an independent researcher unaffiliated with either the GP practice or the referral centre, and that the contents of the interview would be reported in such a way that participants could not be identified. Participants were given the opportunity to ask questions about the study, and a standard

consent form was completed. The interviewing style followed accepted practice for unstructured and semi-structured interviews [Bernard, 1988]. Interviews lasted from 60-90 minutes and were audio-taped and transcribed.

The first six interviews were unstructured to allow the participants themselves to set the agenda regarding which issues were most important to them. The interviewer began these interviews by simply asking participants to "tell me about your experiences of seeing your GP about having someone with breast cancer in your family and being referred to a specialist." Findings from these first 6 interviews and a review of the relevant literature shaped the content and structure of the semi-structured interview guide. Semi-structured interviews were carried out over a 5-month period to allow for continual review of the transcripts and refinement of topics covered during subsequent interviews. A list of topics covered during the interviews is found in **Table 2.2**.

Table 2.2: Topics covered in semi-structured interview guide

- Past experiences of breast cancer in the family and personal risk perceptions
- Worries or concerns about breast cancer prior to GP visit
- Triggers to mentioning breast cancer in the family with GP
- Expectations of the primary care consultation
- Experiences during the primary care consultation
- Interim time between the GP referral and the clinic appointment
- Experiences during and following the referral visit (if applicable)
- Overall impression of having raised the issue of breast cancer family history with the GP
- Experiences of relatives consulting GP regarding breast cancer in the family
- Views on mammography
- Cancer prevention behaviours
- Relationship with partner/confidant with regards to having breast cancer in the family

2.3.4. Analysis

A template approach to text analysis as described by Crabtree and Miller (1992) was carried out. Transcripts were read and re-read to identify key concepts and categories. NUD*IST was used for preliminary organisation of the data and open coding of the text sentence by sentence [QSR Nudist, 1997]. Text units relating to each of the major themes were saved separately in different text files. The data relating to each individual theme was then further explored for secondary themes

within and across transcripts. For each of the secondary themes identified, the data in the corresponding main theme text file was re-read to identify which participants shared the expression of the secondary theme and to identify divergent cases (see **Figure 2.1**). A list of the main themes and secondary themes is found in **Figure 2.2**.

Figure 2.1: Analysis of text data

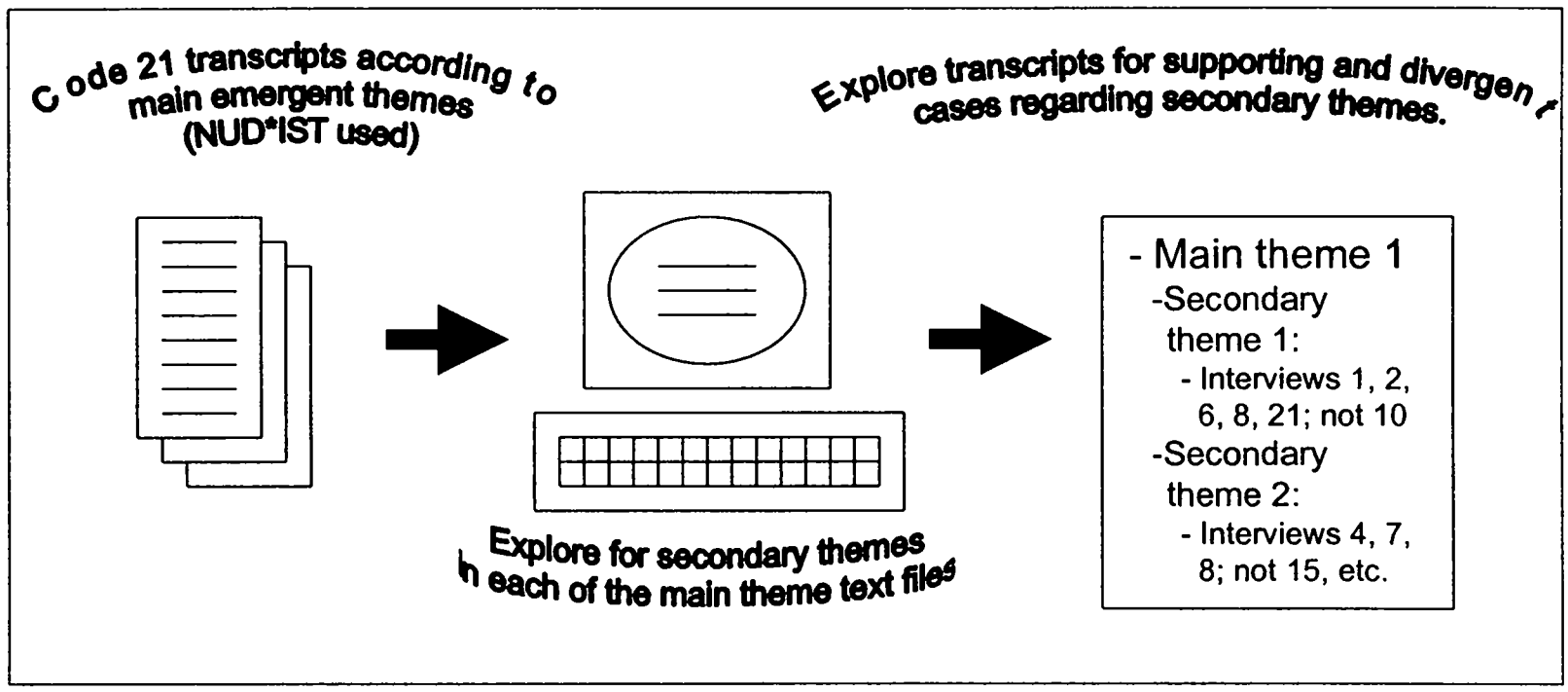


Figure 2.2: Main themes and secondary themes

Information

- Specific information topics women wanted to know more about
- Preferred modes of delivery of information (e.g. verbal, leaflets, etc.)
- From whom women would prefer to receive the information
- Uses of information

Reassurance

- What women found reassuring about their experiences
- What women found distressing about their experiences
- What women found both reassuring and distressing

Access to specialists

- Access to risk assessment
- Access to genetic counselling
- Access to mammographic screening
- Access to genetic testing

Overall, the numbers in this study are small and it was not the original intention to sample according to age, socio-economic status, family history, education level, etc. However, it was considered important to explore any possible similarities or differences among women who were still waiting to be seen by the specialist or had already been seen (see **Table 2.1**), as later experiences may have altered perceptions of the GP

visit. Unless otherwise specified, findings reported in the following section represent the views of the majority of participants.

2.4. Results

The women interviewed fell into four broad categories: those who consulted their GP for information, those who wanted their GP to reassure them, those who wanted to be referred to secondary care and those who wanted any combination of the above. No apparent differences were found in terms of recalled primary care needs of women who had only just been referred by their GP and those who had already been seen in secondary care. Therefore, the 3 key themes most likely to have direct practical implications for meeting the needs of women during primary care consultations are the importance of information, reassurance and access to preventive care. How and why a family history of breast cancer is raised in primary care is also described to provide some context for these consultation needs.

2.4.1. Why women present to primary care

A recent breast cancer diagnosis or death in the family was a common trigger for presentation. However, women said they had their family history of breast cancer "on their minds," and had been generating ideas

about their own risks for some time prior to presenting to primary care. Almost all of the women interviewed said that their mother had been diagnosed with cancer, often when they themselves were only children or young adults. Women who were already older when their mother was diagnosed concentrated primarily on the illness of their loved one before considering the implications for themselves.

The maternal element appeared to be a very significant factor in ultimately presenting to primary care. Women believed that their mother's experience of breast cancer placed them at increased risk. One woman commented "it was probably not until my mum got it that I really talked about the possibility of it being hereditary with the GP" (Participant 12). Women described their risks using words (e.g. average, high, more) with qualifiers (e.g. very, very high). Numbers and percentages were rarely mentioned, and when they were, upon further probing, it turned out that risk figures were often interpreted in different ways by different women or simply misunderstood. Women's perception of their risks "in the back of their minds" was something they found difficult to change.

Although a relative's oncologist, a practice nurse or a friend sometimes recommended that the woman raise the issue of her family history with her GP, more often it was the affected relative who suggested that the woman seek medical advice. One woman (Participant 19) noted that her "mum [previously diagnosed with breast cancer] is so paranoid about it... it's probably made me slightly paranoid." Women also knew of unaffected relatives who had already sought medical advice regarding their family history, and they felt compelled by worry or duty to do the same. They were concerned for their family and for their children in particular. They worried not only that their daughters might develop breast cancer someday, but that if they themselves developed cancer, they would be unable to look after their children. One woman (Participant 19) remarked that "when you have children you're worried more, more worried about your own state of health because you worry if anything happens to you, who would look after the kids?" Women were also concerned about reaching "the age that my mum got the disease" (Participant 10), or simply worried about getting older. Some women had a history of breast problems themselves that concerned them. Others had lost faith in the health care system due to past misdiagnoses or medical errors in the management of their affected relative or in their own care and were worried about such things recurring.

A major reason for presenting to the GP regarding breast cancer in the family was to dispel uncertainties, to get information and advice, to make the GP aware of the family history and to be prepared for the future. A few women sought information because they had had difficulty finding out information from their family. Other women felt they were being "bombarded with all this information, and I just feel like I want to go and hear it from people who really know" (Participant 12). One woman wanted to go to her GP for information because "where else would I go? I don't really know where you would go or who you would talk to really" (Participant 7). All women cited multiple reasons for consulting their GP about their family history of breast cancer.

2.4.2. How women present to primary care

Sometimes the health care professional raised the issue of a family history of breast cancer. However, when that was not the case, women often found it difficult to bring up the subject with their GP. Women were concerned about wasting the GP's time. Some women made a specific appointment to discuss the subject. Whereas most said they had seized the opportunity to raise the subject when they consulted their GP about unrelated medical issues (e.g. routine smear tests, renewing

prescriptions for the contraceptive pill, and consultations regarding a variety of other conditions from chest infections to becoming pregnant). One woman said: "I was in for something else and I said 'while I'm here, would you just look at my breasts because, um, you know, I'm worried,' and I told her the family history" (Participant 19).

2.4.3. Information needs

The acquisition of information was one of women's foremost primary care consultation needs. However, women reported having had limited discussions during the primary care visit. Some felt it was appropriate to defer in depth discussions until they could talk to a specialist. Nonetheless, women would have welcomed more verbal information, as well as leaflets, helpline numbers, and/or website addresses to take-home.

Women's specific information requirements varied. In general, they reported knowing very little about the implications of having breast cancer in the family. One woman felt she knew so little that: "I wasn't really sure what questions to ask" (Participant 16). Another woman complained that: "No one is explaining. You need someone to say 'right, this is what we think you want to know'" (Participant 2). It is often difficult

to gauge "how much is enough information" (Participant 1) because "too many details sometimes it makes it worse" (Participant 2). On the other hand, some women "like to know all the positive sides, the negative sides, and then it's easier to make your mind up" (Participant 17). Women needed "enough information to act on." Therefore the content, amount and level of information must be tailored according to the needs of each patient. Topics that women wanted to know about are listed in **Table 2.3**.

Table 2.3: Topics women wanted to know more about from their GP

Breast cancer – general information, hereditary aspects, diagnosis and treatment
Breast awareness - how to detect a lump in the breast, what to do if a lump is found
Risks of getting breast cancer – personal risks, risks to other family members (girls)
Breast cancer genes and gene tests – gene transmission, implications to carriers
Prevention and early detection programmes – mammography, drug trials
What comes next - what to realistically expect from the referral clinic, waiting lists
Where can further information be obtained – leaflets, helplines, websites

Participants often disseminated the information they received amongst their relatives: "we've collated all our information that we've all received

and it's been like a sort of little net, support network" (Participant 12). It was therefore difficult for women when the information and care they received was not consistent with that received by relatives living in different regions.

2.4.4. Reassurance needs

Participants wanted someone to listen to them and to take them seriously. Some liked hearing words of reassurance from their GP. Others felt reassured when talking to GPs they considered knowledgeable on the subject. However, women were sceptical when their GP's attempts at reassuring them were inconsistent with their previous experiences or were not supported by explanations and "evidence":

> "It's nice to have someone say 'you're worrying for no reason'. The GP did say 'you're not at increased risk, don't worry about it'. But then, how can he say that to me if he doesn't know exactly; without looking at his notes or having information in front of him" (Participant 2).

Another common example of this was women being told that breast cancer does not occur in young women of their age, when they knew from first-hand experience that it does.

Women wanted to know that they were "in the system" and did not have to shoulder the burden of their increased risk alone. They were comforted knowing that they had access to further sources of information. However, it was especially important to know that their GP would welcome them back to discuss any further questions should the need arise and that they could take things one step at a time. One woman said: " At the end of the consultation, I think now I wish [my GP had] said come back and talk about it again... after I'd thought about things that she'd told me" (Participant 12).

Lists of what women found reassuring and distressing during the primary care consultation are listed in **Tables 2.4** and **2.5**.

Table 2.4: What women found reassuring during the GP consultation

- Hearing words of reassurance and understanding
- Being able to talk to someone knowledgeable
- Seeing the GP take action (e.g. recording family history, referring)
- Gaining access to further information
- Being invited to return to talk to the GP at a later date
- Taking things 'step by step'

Table 2.5: What women found distressing at the GP consultation

• GP unaware of family history or insensitive about the issue
• Feeling of wasting GP's time or being "fobbed off"
• Feeling family history issues not acknowledged or dealt with
• GP's statements conflict with patient's prior experiences or beliefs
• Relatives in different regions received different information/care

Interestingly, there were certain aspects of the primary care consultation that women found both reassuring and distressing. Learning the general population lifetime risk of developing breast cancer was one:

> "[My GP] talked a lot about the general risk of breast cancer and that was reassuring in a strange sort of way, that you have a pretty high chance of getting breast cancer whether your mother has it or not. Because she explained the risk was 1 in 10" (Participant 10).

The paradox of not wanting to be at risk of developing breast cancer versus wanting surveillance was, as one woman put it, "a strange situation, hoping you're a high risk case so that you can be seen. It might even cause people to embellish their situation to be [referred]" (Participant 1).

Even when women did feel reassured, they anticipated that feelings of reassurance ultimately fade and require perpetual reinforcement: "I feel

reassured, but I'm sure that reassurance will have worn off by another couple of years and I'll be thinking, 'oh, maybe it's time I had another mammogram'" (Participant 21). Several participants had unanswered questions and felt they were left on their own during the waiting period before a referral visit (which in some areas could be up to 18 months). Women also required assistance during the follow-up period after the specialist consultation. Having ongoing access to further information and preventive care were considered important in providing and maintaining reassurance.

2.4.5. Access to preventive care

Some women were satisfied with the prospect of self-monitoring and had not expected a referral or had mixed feelings about being referred, whereas other women "would look into anything really, other than being left on my own to check myself" (Participant 16). However, participants often felt they had "to push" to receive access to the care they wanted:

> "And after about, like I said, the fourth time, I decided I was going in [to see my GP], but it was over something else, and then I sort of said, 'I really, you know, my mother is getting really angry. She can't understand why I've not been referred on.' And that's when I was referred" (Participant 16).

Many participants reported raising the issue of family history with their GP on multiple occasions. On a return visit, one woman even brought her husband, and another woman broke down in tears, which succeeded in getting the referral that they wanted.

Women wanted to be referred for two reasons: 1) for mammographic screening and/or 2) to see a specialist to "have a chat" (i.e. a risk assessment) and maybe "a blood test" (i.e. a genetic test). One woman said:

> "The breast clinic where they examined me and gave me the mammogram made me feel better that way, they can actually see and they know they can't find anything. [The woman at the genetics clinic] was very, very good in talking to me and how she works and how she looks at the history. She helps mentally I suppose talking to her that way" (Participant 7).

2.4.5.1. Access to early mammographic screening

Participants felt that women with a family history of breast cancer should start being screened by mammography at an earlier age than usual. However, they were not sure at what age women in the UK are normally called for regular screening (estimates ranged from a woman's 30s to age 65 or 70). Nor did participants know what age would be appropriate

for them to begin being screened, although several had been told by their GP that they were too young.

Participants had some knowledge of the potential harmful effects of mammography for women under 50. However, despite this knowledge and even if participants were not at greatly increased risk, many wanted the reassurance of having regular mammography at least by the age of 40 and also wanted their daughters to be screened (one woman said as early as age 18). Women's views on the pros and cons of mammography are listed in **Table 2.6**.

Table 2.6: Women's views on the pros and cons of mammography

PROS	CONS
• Provides reassurance • Improves your chances of survival • Any abnormal changes are picked up earlier • Require milder form of treatment if cancer is found early • Doing something positive • Have an initial mammogram as a baseline for comparison	• The test is not a panacea, the findings are not absolute • Radiation exposure, possible risk to pregnancy? • Breast tissue more dense in women under age 50 • Feel like a misfit at the clinic due to your youth • Waiting time before learning results • Become neurotic thinking about it • May require further tests • Difficult when you do not know what to expect

However in the end, participants seemed convinced that the benefits of screening must outweigh the risks:

> "Maybe the x-ray is not that good for me, because you are taking on board a certain amount of radiation every time, aren't you? But, um, at the end of the day it's going to be better for me if I catch it early. I'd far rather it's done for peace of mind than not done, really. Just because of the family history" (Participant 21).

For this reason, they tried hard to get their GP to send them for a mammogram.

2.4.5.2. Access to risk assessment and gene testing

Women also wanted to be referred to obtain more information about their risks, and to find out about breast cancer gene testing. Women's views on the pros and cons of breast cancer gene testing are listed in **Table 2.7**.

Table 2.7: Women's views on the pros and cons of gene testing.

PROS	CONS
• Provides information for the future • One can be aware and careful • One can be under surveillance • Test can help in making decisions • Gene test can help research	• The test is complicated • There is a long wait for results • Test results are never 100% certain, even if a faulty gene is found • A positive test result may feel like "a time bomb" • Testing diverts funds from other health care needs • Implications for life insurance

On account of the novelty and complexity of this option, women felt that having adequate information and support would be essential in deciding whether or not to undergo the test.

2.5. Discussion

This study found that the main needs of women consulting their GP regarding a family history of breast cancer are information, reassurance, and access to secondary care. In particular, women wanted access for breast cancer risk assessment, gene testing and mammographic screening. The importance of information provision about breast cancer in the family prior to referral to secondary care is supported by previous

research [Chalmers K et al, 1996; Hallowell et al, 1997b; Williams T, 1999].

Women's experiences of breast cancer in the family, especially when it was their mother who had been diagnosed, and women's own perceptions of reaching the age when their relative was diagnosed with cancer, raised anxieties and influenced women's decision to consult their GP. Similar findings regarding the importance of the parent's illness in relation to the child's perception of their own risks have been found in other work [Decruyenaere et al, 1999; Richardson et al, 1994]. Furthermore, the finding that women decided to consult primary care under the influence of lay referral networks (such as friends or relatives who had been diagnosed with breast cancer) is also in keeping with previous findings [Cornford and Cornford, 1999].

Women presented to their GP about their concerns because they did not know where else to turn for information and support. It has been found elsewhere [Emery et al, 1998] that patients consider genetics to be a specialist area, which is another reason why the GP, the gatekeeper to secondary care, would be the first port of call.

However, women were not comfortable raising their family history concerns in primary care since they were not acutely ill and did not want to waste the GP's time. Often women's concerns were left unvoiced or were not fully dealt with, which can lead to dissatisfaction with care [Barry et al, 2000]. Also difficult for women was the transition from primary to secondary care. Women welcomed take-home information and the invitation to return to see their GP with further questions. Another qualitative study of patient experiences across the primary/secondary care interface [Preston et al., 1999] also found that information provision and continuity of care were extremely important for a successful referral process, without which patients may feel "left in limbo."

2.5.1. Limitations of the study

The study sample was limited to women who presented to their GP regarding their family history and were referred to a specialist, whereas many women who discuss breast cancer in the family with their GP will not be referred [Kahn, pers. comm.]. Thus study participants may be at higher risk, may have consulted GPs that tend to refer more readily, or may represent a somewhat more anxious and/or prevention-conscious group.

In trying to obtain participants at various stages in the referral process, it is possible that some women's recall of the GP visit may have been altered during the time elapsed since their referral, and for those who had seen a specialist, affected by what happened at the clinic visit. However, there were no apparent differences in primary care consultation needs reported by those who had already been seen by a specialist as compared to those who were still waiting to be seen.

2.5.2. Implications for primary care

More and more GPs are being faced with meeting the needs of women who have concerns about breast cancer in the family. Understanding that women's risk perceptions are shaped over time in relation to personal and emotional experiences of illness in the family combined with the increased media attention to cancer genetics is important. It is also worth noting that citing risk figures in a consultation may not be helpful without additional information regarding how that risk figure was arrived at, and some judgement as to whether the risk is high or low, and what the implications and options are.

Different women have different information and care needs, and these needs change over time. Particularly when first discussing the issue of family history in primary care, many women would appreciate being prompted about some of the key issues. This could be achieved by using a list of information needs identified by women in a similar situation as a guide (see **Table 2.3**). GPs could also play a large role in advising women on what to expect from referrals. For instance, there is very little chance of being offered gene testing by the genetics clinic, and due to an ongoing debate regarding mammography surveillance in women under 50 with little or no family history, there is a reluctance to offer screening, since in this group, it may do more harm than good [Thornton and Baum, 1999; Ubel et al, 1998]. Once again, using patient views of the pros and cons of the available options (see **Tables 2.6** and **2.7**) in offering such explanations could serve as a useful guide.

Standardising management guidelines and patient education materials nation-wide could greatly diminish the difficulties that arise from inconsistencies in information and care within families. As well, local or national networks for women with breast cancer in the family may make them less likely to feel "on their own." Most importantly, the provision of verbal information in primary care supported by take-home materials,

and the offer of an invitation to return for further discussions, could do a great deal to meet women's ongoing and changing information and care needs and promote patient reassurance, satisfaction, understanding and choice.

Qualitative methods were essential in eliciting the range of views and opinions that emerged in this study and this could not have been achieved by other means. In addition, this study provided the necessary data to develop the prospective descriptive study questionnaires as described in the following chapter.

3. Prospective descriptive study of experiences of women with a family history of breast cancer

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3.1. Introduction

As described in the previous chapter, qualitative methods were used to explore women's primary care consultation needs regarding a family history of breast cancer. Women's main consultation needs were for information, reassurance and access to specialist care.

Qualitative studies by nature are generally limited to small sample sizes and seek to explore people's subjective understanding of their experiences and why they feel the way they do [Pope and Mays, 2000]. Quantitative research is able to build upon the findings of qualitative work by quantifying the extent to which people share the same views or experiences, and therefore, for instance, may benefit from certain changes to current practice in health care provision. For this reason a prospective descriptive study was carried out to further define women's needs and experiences when consulting the health care system about a family history of breast cancer.

Whereas there have been many previous studies looking at the issues raised by familial breast cancer in secondary care (see **Chapter 1**), little work has focused on the primary care consultation in particular [de Bock et al, 1997 and 1999]. At the time this study began, no research had

looked at women's experiences of familial breast cancer in primary care, and in the intervening years, two studies have been published [Warner, 1999; Williams T, 1999]. With the growing number of women consulting their GP regarding breast cancer in the family, only a proportion of whom warrant referral to secondary care [Watson E and Lucassen, 1999], it was considered important to understand women's expectations and experiences of the GP consultation and the process of referral to secondary care.

This chapter describes the aims, methods and findings of a prospective descriptive study of women's experiences of consulting their GP and being referred to secondary care regarding a family history of breast cancer.

3.2. Aims and objectives

The aims and objectives of the prospective descriptive study were as follows:

1) To assess women's primary care and secondary care consultation expectations and experiences
2) To identify women's main information needs and how women would most like to receive this information

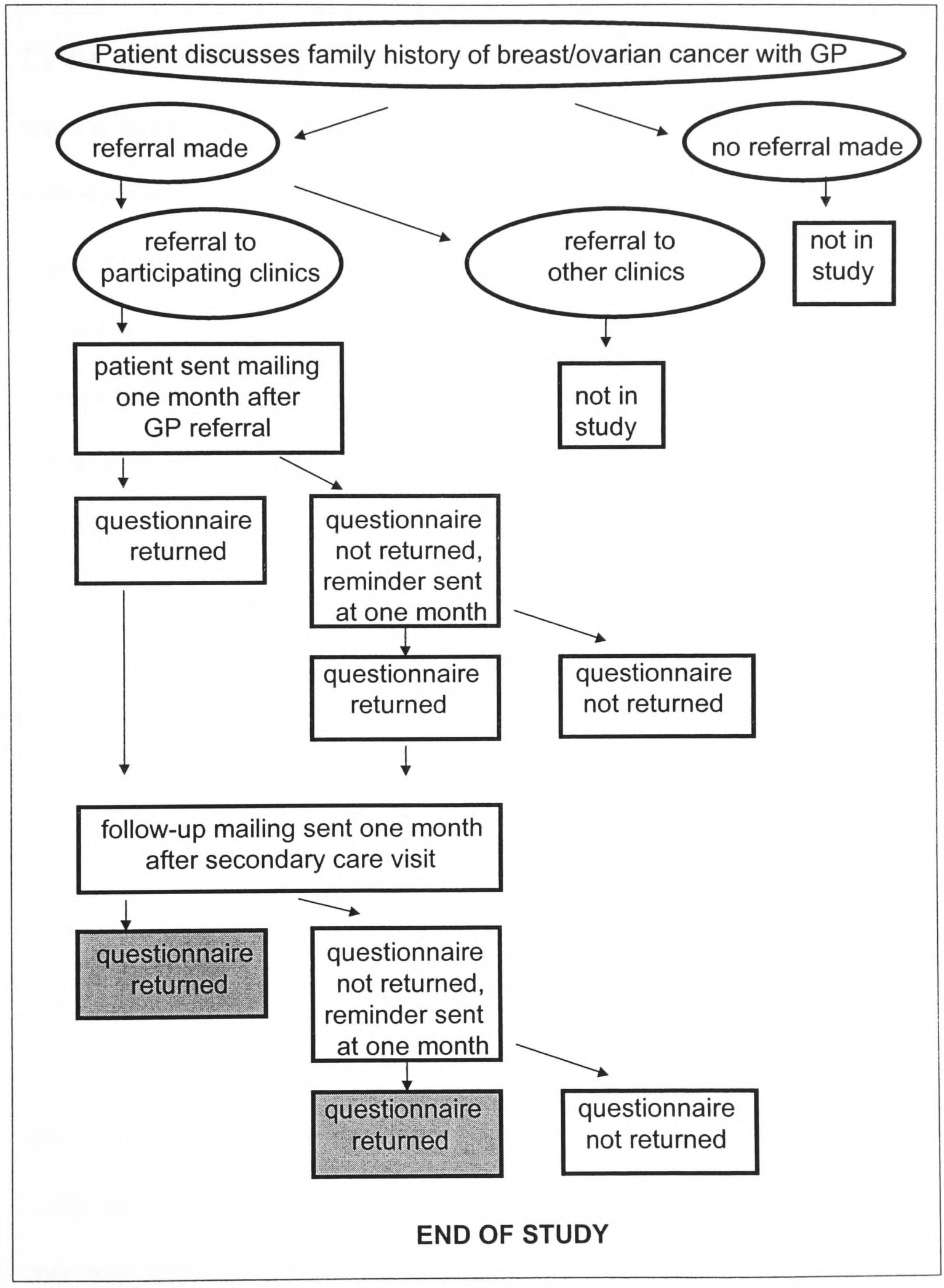
3) To identify the main sources of breast cancer information of women with a family history of breast cancer, including which of these sources are perceived as most reassuring and most worrying.
4) To assess the number of affected relatives and whether or not a woman's mother or sister had breast cancer to get a feel for the severity of the family history
5) To assess women's risk knowledge and perceptions regarding the chances of developing breast cancer
6) To assess women's breast cancer-specific worries
7) To assess women's desire for and understanding of mammography
8) To assess women's perception of the chances of harbouring an altered breast cancer gene and the desire for breast cancer genetic testing
9) To explore whether demographic and personal characteristics, as well as risk perception, cancer worries and preconceived desire for screening and genetic testing, are associated with the above knowledge, perceptions, concerns, needs, expectations and experiences

3.3. Methods

3.3.1. Study design

The study entailed recruiting women referred by their GP on the basis of a family history of breast cancer to secondary care clinics in Oxfordshire and Northamptonshire over a one-year period. Self-completion questionnaires were mailed to women following the GP referral and one-month after the secondary care visit. A schema of the study design is outlined in **Figure 3.1**. The study received research ethics committee approval. Full details of the participants and the self-completion questionnaires are described in this section.

Figure 3.1: Schema of prospective descriptive study design



3.3.1.1. Power and precision

As the aims of this study were descriptive in nature, it was important to have a large enough sample size to enable the estimates to be made with sufficient precision (i.e. to ensure narrow 95% confidence intervals). A pragmatic approach was taken in this respect, taking into account the limited time-frame of the study (i.e. no more than one year for the data collection phase) and the projected number of referrals that would be made in that time. It was estimated that the two cancer genetics clinics would receive approximately 250 breast cancer family history referrals in one year [Lucassen, pers. comm.]. Other clinics (i.e. the breast clinics) may expect only a small proportion of that number [Clarke, pers. comm.]. Thus, all of the clinics in Oxfordshire and Northamptonshire combined might have been expected to receive around 350 such referrals per year. Given the possibility that not all of the clinics would participate in the study (see **Section 3.3.1.2**), and that of the women invited to participate in the study, the expected response rate would be about 60%, a total of 180 responses were expected over a one-year period. This was considered a somewhat optimistic estimate as the pilot study response rate (see **Section 3.3.3**) was only 33%, but it was hoped that the alterations made to the questionnaire (see **Section 3.3.3.1**) would greatly improve the response rate. The number of respondents for

the follow-up questionnaire was estimated at about 50% of the initial number of respondents, taking into account a similar response rate, as well as losses to follow-up, for a total of about 90 women.

Even though there was no single main outcome in this study, calculations of power and precision were carried out using the program Power and Precision 1.0 to get a feel for the power of the study. For instance, the precision of a proportion of 0.50 (i.e. the 95% confidence intervals if half of respondents responded in the same way) would be 0.37-0.63 with 50 respondents, 0.40-0.60 with 100 respondents and 0.43-0.57 with 200 respondents. Thus increasing the sample size from 50 to 200 does not immensely affect the precision of the estimate. When looking for significant differences of a particular size, it is common practice to use 80% power to detect these differences and a two-sided value of alpha (α) of 0.05, (where α is the probability of Type I errors - rejecting the null hypothesis when the null hypothesis is in fact true) [Altman, 1991]. If, for instance, we used McNemar's test to detect a change in knowledge after the specialist visit as compared with before, 28 women would have had to respond at both time periods to detect a statistically significant difference of 30% (e.g. 50% responded correctly before the visit and 80% responded correctly after), 50 women would be

needed for a difference of 20% and 144 for a difference of 10%. Thus for a large effect size, even a small number of respondents would provide sufficient power to detect a difference.

Considering that the final number of respondents in this study was 128 for the first questionnaire and 47 for the second questionnaire (see **Section 3.4.1**), we can conclude that this study was reasonably precise and sufficiently powered to detect moderate differences.

3.3.1.2. Participating specialist clinics

Four secondary care clinics agreed to participate in the study: two breast clinics, one in Banbury (Oxfordshire) and one in Kettering (Northamptonshire), and two cancer genetics clinics, one in Oxford and one in Northampton. The two cancer genetics clinics are the sole clinical genetics centres in the two counties (i.e. Oxfordshire and Northamptonshire) and thus would be expected to receive all family history referrals to genetics clinics in this area. Two out of 4 breast clinics in the two counties did not participate in the study (and therefore referrals to these centres were not included). This was due in part to the fact that family history referrals constituted a small proportion of the

workload of these particular breast clinics [Clarke, pers. comm.]. Thus some busy breast surgeons were reluctant to join the study (especially as the start of the study coincided with the introduction of the NHS 2-week rule for urgent breast cancer referrals which led to breast clinics being overwhelmed with work).

3.3.1.3. Participant recruitment

As will be described in greater detail in **Section 3.4.1**, 193 women were invited to participate in the study via a letter from the consultant. The letter made clear that whether the woman decided to participate, or not, would have no effect on her subsequent care. This letter of invitation (see **Appendix 3.A**) formed part of a larger mailing that also consisted of:

1) An information sheet describing the study (see **Appendix 3.B**),
2) A questionnaire about breast cancer in the family (with different versions for women referred to a genetics clinic or to a breast clinic, see below **Section 3.3.2.3**), and
3) A reply-paid envelope.

Women were sent the initial mailing one-month after the GP referral was made. A single reminder (with only the covering letter altered, see **Appendix 3.C**) was sent to women who did not respond within a month. Given the sensitive nature of this subject area, it was felt that more than one reminder would be inappropriate, even if the response rate suffered as a result.

Respondents to the initial mailing (and reminder) were sent a follow-up mailing one month after their visit to the specialist clinic. Again, a reminder was sent to non-respondents at one month. The mailing consisted of:

1) A covering letter from the consultant (see **Appendix 3.D** and **3.E**),
2) An information sheet on continuing to participate (see **Appendix 3.F**),
3) A follow-up questionnaire (also with different versions for women referred to a genetics clinic or to a breast clinic, see below **Section 3.3.2.3**), and
4) A reply-paid envelope.

3.3.1.4. Inclusion / exclusion criteria

Women were included in the study if they fulfilled the following criteria:

1) Their GP had sent the clinic a letter of referral stating breast (or breast/ovarian) cancer in the family as the main reason for referral,
2) The referral letter was dated between March 15, 1999 and March 15, 2000, and
3) Less than 2 months had passed from the time the letter of referral was written to the time of recruitment into the study (i.e. the initial mailing). The timing was considered important as women's views of the GP consultation may change with time [Jung et al, 2000].

Women were excluded from the study if they had already been diagnosed with breast cancer, as their expectations and experiences may not be the same as those who have never had breast cancer.

3.3.2. Questionnaire design

3.3.2.1. Existing measures

When measuring such things as patient knowledge and satisfaction, it is preferable where possible to use an already existing, well validated measure rather than reinvent the wheel for every study [Fallowfield,

1995]. However, until recently, there were no well-developed disease-specific scales regarding patient knowledge and satisfaction in the area of cancer, let alone cancer family history [Bowling, 1995; Warner et al, 1999]. Potential questionnaires which had previously been developed for breast cancer family history-related research in the UK were sought by contacting researchers in the field (almost all of the studies were still in progress at the time) [Brain, pers. comm.; Broadstock, pers. comm.; Cull, pers. comm.; Kahn, pers. comm.; Salkovskis, pers. comm.]. Questionnaires were examined for their relevance to the aims of the prospective descriptive study (i.e. to assess women's expectations, experiences and information requirements when being referred from primary to secondary care, see **Section 3.2**). None of these condition-specific questionnaires regarding breast cancer family history addressed women's information needs and consultation expectations and experiences in a primary care setting. However, there were certain elements of these questionnaires that were relevant to this study in terms of reasons for raising family history concerns, levels of cancer worries and perceptions of breast cancer risks. A summary of the studies identified and the measures used are listed in **Table 3.1**. Where certain questions were adopted from these measures for use in the prospective descriptive study questionnaire (see **Section 3.3.2.2**) it was

necessary that these questions be piloted as part of the new questionnaire (see **Section 3.3.3**). The reason for this is that even if the questions adopted had previously been validated, that usually only applies to when the questionnaire is being used as a whole, not when one only uses selected parts of it.

Table 3.1: Measures used in previous breast cancer family history research in the UK

	Welsh Study [Brain, pers. comm.]	**BRCA1/2 Study [Broadstock, pers. comm.]**	**Aberdeen Study [Cull, pers. comm.]**	**Cambridge Study [Kahn, pers. comm.]**	**Oxford Study [Salkovskis, pers. comm.]**
Study Aim	To identify self-reported reasons for attending a familial breast cancer clinic	To evaluate the impact on psycho-social functioning of testing for the BRCA1/2 genes	To evaluate the effectiveness of nurse counsellors managing familial breast cancer	To explain why women want gene testing and the decision making process they use	To assess women's perceptions of risk, severity of outcome, and ability to cope with family history
Sample Measures					
Knowledge of cancer risks	• Population risks • Perceived risk - cancer/gene	• Population risks • Perceived risk - cancer/gene	• Population risks • Perceived risk - cancer only	• Perceived risk - cancer/gene	• Perceived risk develop cancer now, in future
Emotional State and Well-Being	• GHQ • CWS • STAI	• GHQ • CWS • IES	• STAI • HADS	• GHQ • CWS	• Anxiety/worry • Feelings • Coping ability
Behaviours and Intentions	• Breast self ex. • Clinical exam • Mammography	• Breast self exam • Clinical exam • Mammography	• Breast self ex. • Clinical exam • Diet/Exercise	• Breast self ex. • Clinical exam • Mammography	Not applicable
Counselling and testing issues	• MFHCQ • SGCQ	• Awareness • Expectations • Decision making	• SGCQ • Knowledge of heredity	• Desire for test • Decision • Reasons +/-	Not applicable

GHQ=General Health Questionnaire [Goldberg and Hillier, 1979], CWS=Cancer Worries Scale [Lerman et al, 1991b], IES=Impact of Events Scale [Horowitz M et al, 1979], STAI=State Trait Anxiety Inventory [Marteau and Bekker, 1992], FHCQ=Manchester Family History Clinic Questionnaire [Hopwood, 1997], SGCQ=Satisfaction with Genetic Counselling Questionnaire [Shiloh et al, 1990], HADS=Hospital Anxiety and Depression Scale [Zigmond and Snaith, 1983].

Generic measures used to assess patient satisfaction with the consultation process, especially in primary care, were also reviewed for their utility with regards to the prospective descriptive study [Baker, 1990; DiMatteo and Hays, 1980; Greenhow et al, 1998; Grogan et al, 1995; Kinnersley et al, 1996]. However, many of the items on these scales were not relevant to family history consultations in which the consulting individuals are in fact healthy with no physical signs or symptoms (e.g. Medical Interview Satisfaction Scale – "After talking with the doctor, I know just how serious my illness is"; Consultation Specific Questionnaire – "This doctor was very careful to check everything when examining me"; Patient Satisfaction Questionnaire – "This doctor always explains the reason for examination procedures or medical tests"). In general, the use of generic patient satisfaction surveys are not advisable when attempting to get at the issues that are important to patients [McIver, 1993b].

It would not be possible to include too many pre-validated measures in the questionnaire or there would be no room left to address the aims of the study. General psychological morbidity has not been found to differ among women with and without a family history [Lloyd et al, 1996]. Thus it was decided to use only the Lerman Cancer Worries Scale (1991b) as

this has been extensively used in related studies and was most relevant to the current study aims.

3.3.2.2. Constructing questions

Where appropriate, entire pre-validated measures were used (i.e. to measure cancer worries), and whenever possible, the wordings of questions that had been successfully used in other studies (see **Section 3.3.2.1**) were adopted to be piloted as part of the prospective descriptive study questionnaires. For instance, several of the previously developed questionnaires inquired whether a woman perceived her risk of developing breast cancer to be much lower, a little lower, about the same, a little higher or much higher compared to other women of the same age. This question was adapted for use in the present study.

Often there were no appropriate measures or questions available to use as templates for the questionnaire development (i.e. regarding information needs or expectations and experiences of the primary care consultation). In such cases, the questions were formulated based on the findings of the qualitative research regarding primary care information and consultation needs (see **Chapter 2**). Care was taken to

design intelligible questions by including only one concept or idea per question, keeping questions short and avoiding difficult language [Foddy, 1993; Meneer, 1976; Stone, 1993; Westrup and Jenkins, 1998a and 1998b; Woodward and Chambers, 1993].

The contents of the initial and follow-up questionnaires (see **Appendices 3.G and 3.H**) and the sources of the questions are summarised in **Table 3.2**.

Table 3.2: Contents and sources of study questionnaires

Study Aims	Nature of Questions	Source
To assess the extent of women's family history of breast cancer	If mother or sister had breast cancer, what age; total no. of 1st and 2nd degree relatives	Newly developed questions
To assess women's risk knowledge and perceptions regarding the chances of developing breast cancer	Knowledge of average lifetime risk and higher >50; perception of relative risk of developing breast cancer	Adapted from previous questionnaires (see 3.3.2.1)
To assess women's breast cancer specific worries	6-item Lerman Cancer Worries Scale	Lerman et al, 1991b
To identify the main sources of information of women with a family history of breast cancer, including which of these sources are perceived as most reassuring and most worrying.	Sources of information (e.g. family, GP, internet, etc.); which source provided the greastest amount, the most reassuring and the most worrying information	Newly developed questions, based on qualitative study findings
To identify women's main information needs and how women would most like to receive this information	If want to know more or know enough about various topics, most important topic and preferred information source	As above
To assess women's expectations and experiences of consulting primary care and being referred to secondary care regarding a family history of breast cancer	Expectations of primary care visit (e.g. information, refer) and actual experiences; expectations of secondary care (e.g. suggest gene test) and actual experiences	As above
To assess women's desire for and understanding of mammography	Understanding of frequency and most common age for false +/-; want mammogram	Understanding mammography study (Watson E, pers.comm.)
To assess women's perception of the chances of harbouring an altered breast cancer gene and the desire for breast cancer genetic testing	Perception of relative risk of harbouring an altered breast cancer gene; want gene test	Adapted from previous questionnaires (see 3.3.2.1)
To explore whether demographic or personal characteristics (such as risk perception) are associated with the above knowledge, perceptions, concerns, needs, expectations and experiences	Date of birth, marital status, number of boys and girls, age when finished full-time education, highest level qualification received, and ethnic group	As above

3.3.2.3. Questionnaire versions

Because the study population stemmed from two different groups, those referred to a genetics clinic and those referred to a breast clinic, where relevant, minor alterations were made to customise the questionnaires for each group. Mostly the changes were limited to one questionnaire that said "genetics clinic" while the other read "breast clinic." However, in a few rare instances, differences in practice between the two clinics meant that a question relevant to one group was not relevant to the other and was therefore omitted from that version. For instance, whereas women referred to a genetics clinic may be offered genetic testing, women referred to a breast clinic would not be offered such a test, but may have been referred to a genetics clinic for that purpose. Such differences between groups were reflected in the two versions.

Questionnaires were colour-coded to help distinguish between the versions when mailing and thus reduce administrative error. For the initial mailing, there was a yellow questionnaire (**Appendix 3.G**) to be sent to women referred to a genetics clinic, and an orange version (see **Appendix 3.I**) for women referred to the breast clinic. For the follow up questionnaires, a green questionnaire was sent to women following an appointment at the genetics clinic (**Appendix 3.H**) and a blue

questionnaire (**Appendix 3.J**) was sent following an appointment at the breast clinic.

A fifth version of the questionnaires was developed for women who were referred to the genetics clinic but were considered to be at low risk and therefore were not invited for an appointment at the clinic (**Appendix 3.K**). For obvious reasons it would not have been appropriate to send these women a follow up questionnaire that asked about women's experiences of the secondary care consultation. Thus the low risk questionnaire was a hybrid of the initial and follow-up questionnaires, and focussed on women's feelings of being referred but not being seen in secondary care, as well as any remaining information and reassurance needs that they may have had.

3.3.3. Pilot study

A draft of the questionnaire (see **Appendix 3.L**) was piloted with 30 women referred by their GP to the genetics clinic in Oxford regarding a family history of breast cancer. In accordance with the study protocol (see **Figure 3.1**), the questionnaires were sent one month following the GP referral to the clinic. Reminders were sent to non-responders at one month. There were only 10 responses one month after the reminders

had been mailed giving a response rate of 33%. Also, many of the questionnaires contained missing data, especially for multi-item questions (e.g. women's expectations of the GP and specialist consultations).

Well-designed postal surveys may expect about a three-quarters response rate [Berry and Romans, 1981]. Moreover, many strategies had been used in the pilot study to ensure a good response rate including using a covering letter on behalf of the consultant printed on the clinic's official letter-headed notepaper, enclosing a self-addressed pre-paid envelope for the return of the questionnaire, and sending a reminder mailing at one month [Streiner and Norman, 1989]. The low response rate in the pilot study and incomplete responses in several parts of the questionnaire reflected the fact that the questions may have been too difficult to understand or too distressing, and/or that for many of the women the questionnaire was too long and too time consuming to complete [Fitzpatrick et al, 1998]. Whatever the reasons, it was clear from the pilot study that the draft questionnaire was not acceptable to women.

3.3.3.1. Post-pilot alterations to the questionnaire

In an attempt to find out what was needed to improve the questionnaire (**Appendix 3.L**), a structured interview was carried out with one of the respondents to determine what she had found unclear or difficult to understand and whether in her opinion any important topics had been omitted from the questionnaire. The interview was very useful in identifying a more acceptable way of wording the questions. For instance, the respondent felt that she had not "discussed" the issue of family history with her GP (Question 46), although it may have been "mentioned" during the consultation. Minor changes to the wording of the questions can have a major impact on the responses made. According to the respondent, no major areas had been omitted from the questionnaire. However, the result of the pilot study indicated that the questionnaire did need to be shortened and reorganised.

Potentially worrying questions that ask about relatives being diagnosed with breast cancer (Questions 11-15) were reduced in number to 3 questions, and these questions were moved towards the end of the questionnaire to avoid discouraging women from completing the questionnaire from the very beginning [Foddy, 1993]. Likewise, questions about breast cancer risks and risk perceptions (Questions 16-

21) were also moved towards the end. The demographic data had originally been placed at the beginning of the questionnaire, but, after the pilot, this too was placed at the very end, as is usual practice in questionnaire design [Oppenheim, 1972]. Instead, the questionnaire began with questions about women's information needs, one of the main aims of the study and unlikely to be anxiety provoking. Rather than using the 4-point response scale (i.e. yes, no, unsure, already know) which women had found difficult and had therefore led to a great deal of missing data for the question about specific information needs, the question was altered to have two possible response items (i.e. "I want to know more" and "I know enough"). The questions regarding information needs were logically followed by questions about consulting one's GP about breast cancer in the family. Here too, some of the question layouts were changed to make it easier to respond to multi-item questions. Complex questions that produced too much missing data such as those including numerical statements about risk or likelihood, such as the number of women (e.g. one in a million) likely to have false negatives and false positives during mammographic screening, were also removed.

The new draft of the questionnaire was distributed to a number of women for further "fine-tuning" of the questionnaire. The final questionnaire was one third shorter than the original (reduced from 69 questions to 49 questions), with fewer potentially threatening or anxiety provoking questions, and with all such questions placed towards the end of the questionnaire (see **Appendix 3.G**).

3.3.4. Data entry and analysis

3.3.4.1. Data entry and data checking

The data from closed questions was coded and double entered independently by two individuals onto electronic data entry forms and verified for discrepancies using SPSS Data Entry Builder 1.0. Any discrepancies found were checked against the original questionnaire. Responses to open questions were transcribed verbatim into individual Microsoft Word files. A separate file was made for each question according to questionnaire type (e.g. Question 41, yellow questionnaires). All files were double-checked against the original questionnaires for possible errors.

3.3.4.2. Descriptive analysis

All statistical analyses were performed using SPSS 9.0. Binomial data was described as proportions and 95% confidence intervals. Categorical and ordinal data was described using frequencies, percentages and 95% confidence intervals. For data where the response items were "yes, no, don't know" (e.g. questions about consultation expectations), percent positive responses were calculated over a denominator of valid responses (i.e. after having omitted missing or spoiled data). Ordinal data regarding mammography and genetic risk knowledge was collapsed into fewer categories as appropriate. Continuous data was described using appropriate measures of centrality and spread. Written comments (from open questions) were grouped according to topic and described.

3.3.4.3. Tests of association

Following the descriptive analysis, variables were examined for associations with the following demographic and personal characteristics which, it was hypothesised at the design stage, may affect women's responses. These included:

1) Age,

2) Education,

3) Mother or sister ever had breast cancer,

4) Number of first- and second-degree relatives affected,

5) Perceived risk perception and actual genetic risk (the latter available for certain genetics clinic patients only),

6) Lerman Cancer Worries Scale overall score, and

7) Desire for mammography and/or breast cancer gene testing.

Ethnic group was not included in the analysis due to low variance. Education was measured as age when finished full-time education and highest level qualification obtained. In the analysis of highest level qualification obtained, the category "none of these" was excluded as it may have been taken to mean no qualification or another qualification not listed in the question.

Statistical tests used to test for associations are found in **Tables 3.3a and 3.3b**. Two sided p-values were calculated and 0.05 was taken as the cut-off point for significance.

Table 3.3a: Data types and statistical tests: Unpaired analysis

DATA TYPES	Binomial	Categorical	Ordinal	Continuous
Binomial	Chi-squared test	Chi-squared test	Mann-Whitney U test	t-test
Categorical		Chi-squared test	Kruskal-Wallis test	ANOVA
Ordinal			Spearman's correlation	Spearman's correlation

Table 3.3b: Data types and statistical tests: Paired analysis

DATA TYPES	Binomial	Categorical	Ordinal	Continuous
Binomial	McNemar's test			
Categorical		Wilcoxon signed ranks test		
Ordinal			Wilcoxon signed ranks test	
Continuous				Paired t-test

3.4. Results

Summaries of the main results are found at the beginning of each section (see **Boxes 3.1-3.9**).

3.4.1. Response rates

Box 3.1: Prospective study summary findings: Response rates

- 1st mailing: 75% response rate (145/193), 128 questionnaires analysed.
- 2nd (f/u) mailing: 74% response rate (56/76), 47 questionnaires analysed.

One hundred and ninety three (193) women were sent a questionnaire following a referral by their GP to one of the participating clinics (see **Figure 3.2**). Two of these women considered by a genetics clinic to be at low risk were sent a low risk questionnaire. In total, 145 women responded, providing a total response rate of 75%. Twelve women did not wish to participate and 5 questionnaires were excluded according to pre-determined criteria (see **Section 3.3.1.4**). In the case of low risk questionnaires, because there were too few to include in the analysis, these were also excluded from the analysis. One hundred and twenty eight (128) questionnaires were analysed (80 from genetics clinic referrals and 48 from breast clinic referrals).

Figure 3.2: Prospective descriptive study first mailing

Genetics clinics			Breast clinics	
A	B		C	D
102	28	**201** Breast cancer family history referrals from 4 clinics dated (03/99 to 03/00)	61	10
8	0	**8** not included (ovarian (7), not GP referral (1))	0	0
94	28	**193** women sent 1st Mailing	61	10
49	15	**98** responded	28	6
45	13	**95** reminders sent for 1st Mailing	33	4
25	5	**47** responded to reminder	16	1
74	20	**145** overall responses to 1st Mailing	44	7
6	3	**12** did not wish to participate	2	1
68	17	**133** questionnaires received	42	6
5	0	**5** excluded (low risk (1), had cancer (4))	0	0
63	17	**128** 1st Mailing questionnaires analysed	42	6

The 128 women who returned valid questionnaires from the first mailing were eligible to be sent a follow-up questionnaire one month after attending their appointment at the referral clinic (see **Figure 3.3**). Fifty-two (52) women were not sent a follow-up questionnaire largely because they had not yet attended the specialist clinic by May 1st 2000. The cut off date was imposed due to time restrictions regarding the completion of the study. This mostly affected women referred to the genetics clinics on account of the much longer waiting times at these clinics. Seventy-three (73) women who did attend their specialist clinic appointments

were sent a follow up questionnaire one-month after the appointment. A further 3 women were sent a low-risk questionnaire at this time because although they had previously completed a regular genetics clinic questionnaire, it later turned out that they were at low risk and were not going to be offered an appointment at a genetics clinic. Thus a total of 76 follow-up questionnaires were sent. In total, 56 women responded, resulting in a follow-up response rate of 74%. Three women did not wish to participate and 4 questionnaires were excluded due to clerical error. Once again, there were too few low risk questionnaires to include in the analysis. Forty-seven (47) follow-up questionnaires were analysed (19 from genetics clinic referrals and 28 from breast clinic referrals).

Figure 3.3: Prospective descriptive study 2nd (follow-up) mailing

Genetics clinics			Breast clinics	
A	B		C	D
32	13	**52/128** women not sent 2nd Mailing (had not attended clinic by 01/05/00 (45), clerical errors (7))	5	2
31	4	**76** women sent 2nd Mailing	37	4
14	1	**30** responded	12	3
17	3	**46** reminders sent for 2nd Mailing	25	1
8	1	**26** responded to reminder	17	0
22	2	**56** overall responses to 2nd Mailing	29	3
2	0	**3** did not wish to participate	1	0
20	2	**53** questionnaires received	28	3
2	1	**6** excluded (low risk (2), clerical error (4))	3	0
18	1	**47** 2nd Mailing questionnaires analysed	25	3

3.4.2. Demographics and personal characteristics

Box 3.2: Prospective study summary findings: Demographics

- The average age of respondents was 38 years (SD 10.0).
- Most were white (96%) and were married (80%) with children (74%).
- Most had a mother (81%) or sister (31%) diagnosed with breast cancer.
- They had a median of 2 affected relatives (inter-quartile range 1-4).
- About a third finished full time education over the age of 18 (30%) and had a university degree (30%).
- Women referred to a genetics clinic were younger, finished school at a later age and had higher level qualifications compared to women referred to a breast clinic. There were no other differences between the genetics clinic and breast clinic groups and thereafter the data of the two groups was considered together.
- There were no differences in terms of the demographic and personal characteristics of the 128 women who replied to the 1st mailing and the 47 women who responded to the 2nd (follow-up) mailing.

Demographic and personal characteristics of the 128 respondents are listed in **Table 3.4**. Of the 88% of women (n=112/128) with a mother or sister who had breast cancer, 81% (n=91/112) had a mother diagnosed with breast cancer and 31% (n=35/112) had a sister diagnosed with breast cancer (i.e. some women had both a mother and a sister affected). Six women had two affected sisters. Older women tended to have more affected first or second degree relatives (R=0.214, n=120,

p=0.019). Younger women reported finishing full time education at an older age (R=0.405, n=127, p<0.001), and women who finished school at an older age had higher level qualifications (R=0.636, n=102, p<0.001).

Table 3.4: Demographic & personal characteristics of respondents

Variable	Category	Number (n=128)	Percent (%)	95% CI of greatest proportion
Age	<20	2	2	
	20-29	21	16	
	30-39	50	39	30-48
	40-49	38	30	
	50+	17	13	
Marital Status	Married	102	80	73-86
	Single	12	9	
	Divorced/Separated	11	9	
	Widowed	2	1	
	Missing/Invalid	1	1	
Children	Have children	95	74	67-82
Education	<16 years	19	15	
	16-18 year	69	54	45-63
	19+	39	30	
	Missing/Invalid	1	1	
Qualification	O level	21	16	
	A level	11	9	
	Clerical/Commercial	29	23	
	College/University	39	30	22-38
	None of the above	28	22	
Ethnic group	White	123	96	93-99
	Other	4	3	
	Missing/Invalid	1	1	
Mother or sister diagnosed	Yes	112	87	82-94
	No	14	11	
	Missing/Invalid	2	2	
Number of affected first- or second-degree relatives	None	2	2	
	1	36	28	
	2-3	66	51	43-60
	4-6	16	13	
	Unsure/Invalid	8	6	

There were no significant differences between the genetics clinic data and the breast clinic data, with the exception of three related socio-demographic variables. Women referred to the genetics clinic were younger (on average 4.8 years younger than women referred to breast clinics, 95%CI 1.5 to 8.1 years; t=-2.880, df=119, p=0.005), left full-time education at an older age (U=1354, n=127, p=0.003; for example, 41% (n=32/79) left after the age of 18 in the genetics clinic group vs. 15% (n=7/48) in the breast clinic group) and obtained higher level qualifications (U=696, n=102, p<0.001; for example, 41% of women (n=33/80) referred to genetics clinics had a university degree vs. 17% of women (n=8/48) referred to breast clinics). For the remainder of the analysis, breast clinic and genetics clinic data was pooled (unless specified). The demographic profile of the subgroup of 47 women who completed a follow-up questionnaire was not significantly different from the profile of the 128 women whose questionnaires from the first mailing were analysed (i.e. no differences were found in terms of age, marital status, educational level, qualifications, ethnic group, whether first degree relative had breast cancer, total number of affected relatives, even risk perceptions and cancer worries).

3.4.3. Breast cancer information sources and needs

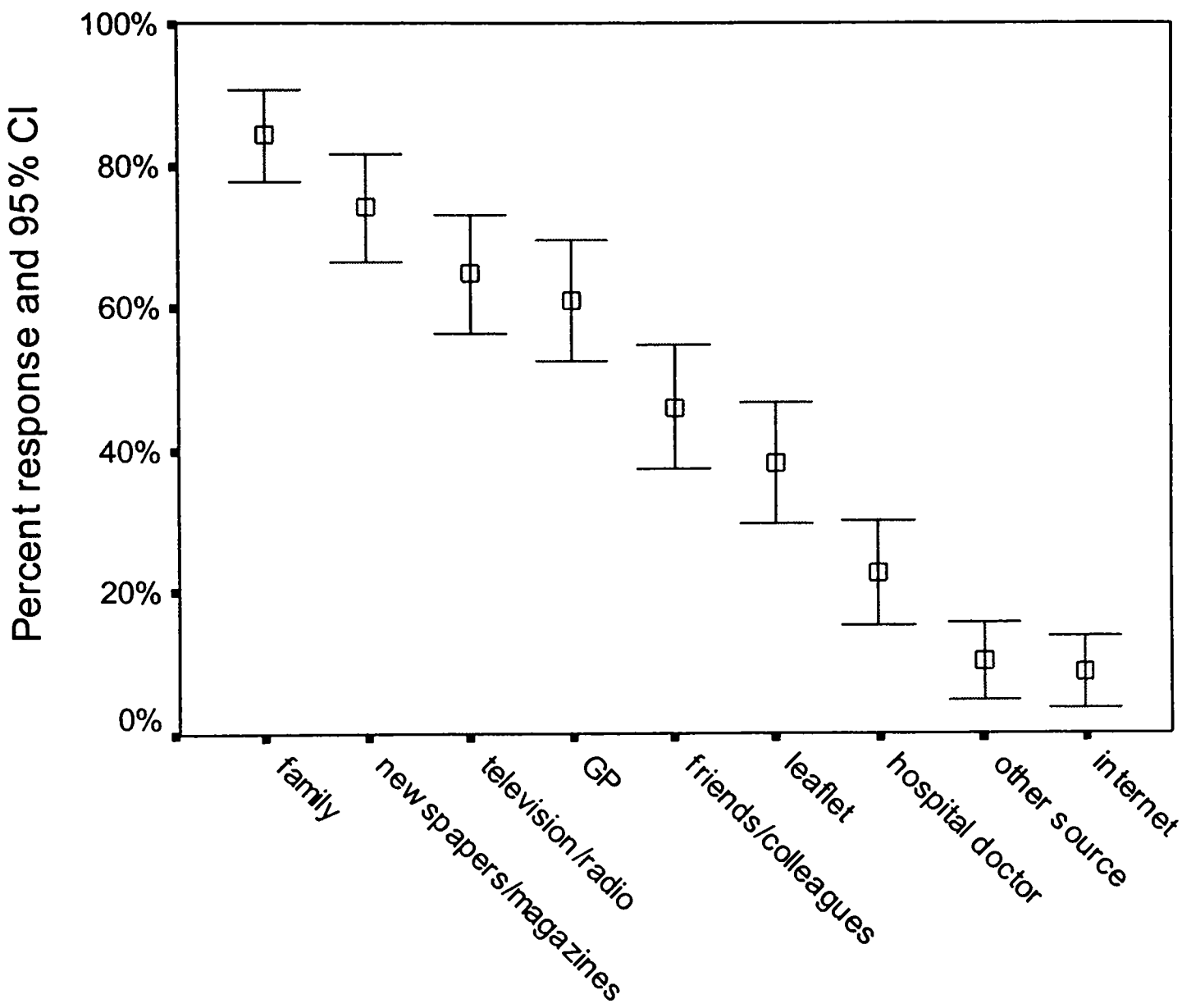
Box 3.3: Prospective study summary findings: Information needs

- Women had multiple sources of information about breast cancer. Their main sources were the media (85%), their family (84%), and their GP (61%). Only a few women (9%) used the internet.
- Women felt that they received the greatest amount of information from their family (35%), the most reassuring information from doctors (46%) and the most worrying information from the media (49%).
- Women wanted to know more about many different information topics.
- Over 90% of women wanted to know more about their risks of getting breast cancer, preventing breast cancer and breast cancer gene testing.
- Women most preferred getting information about breast cancer in the family by talking to a hospital doctor (60%), talking to a GP (22%) or reading a leaflet (6%).

Women cited a median of 4 sources of information that they had used in the past to find out more about breast cancer (inter-quartile range 3-5, absolute range 1-8). Women's main sources of information were the media (85% (n=109/128); 95%CI 79-91), their family (84% (n=108/128); 95%CI 78-91), and their GP (61% (n=78/128); 95%CI 52-70) (see **Figure 3.4**). Women also received information from friends and colleagues (46% (n=59/128)), leaflets (38% (n=49/128)), hospital doctors (23% (n=29/128)), and other sources (10% (n=13/128)), including nurses, books, journals, and cancer charities. The minority of

women who reported using the internet (9% (n=11/128)) tended to be more educated (U=360, n=127, p=0.008).

Figure 3.4: Women's main information sources about breast cancer



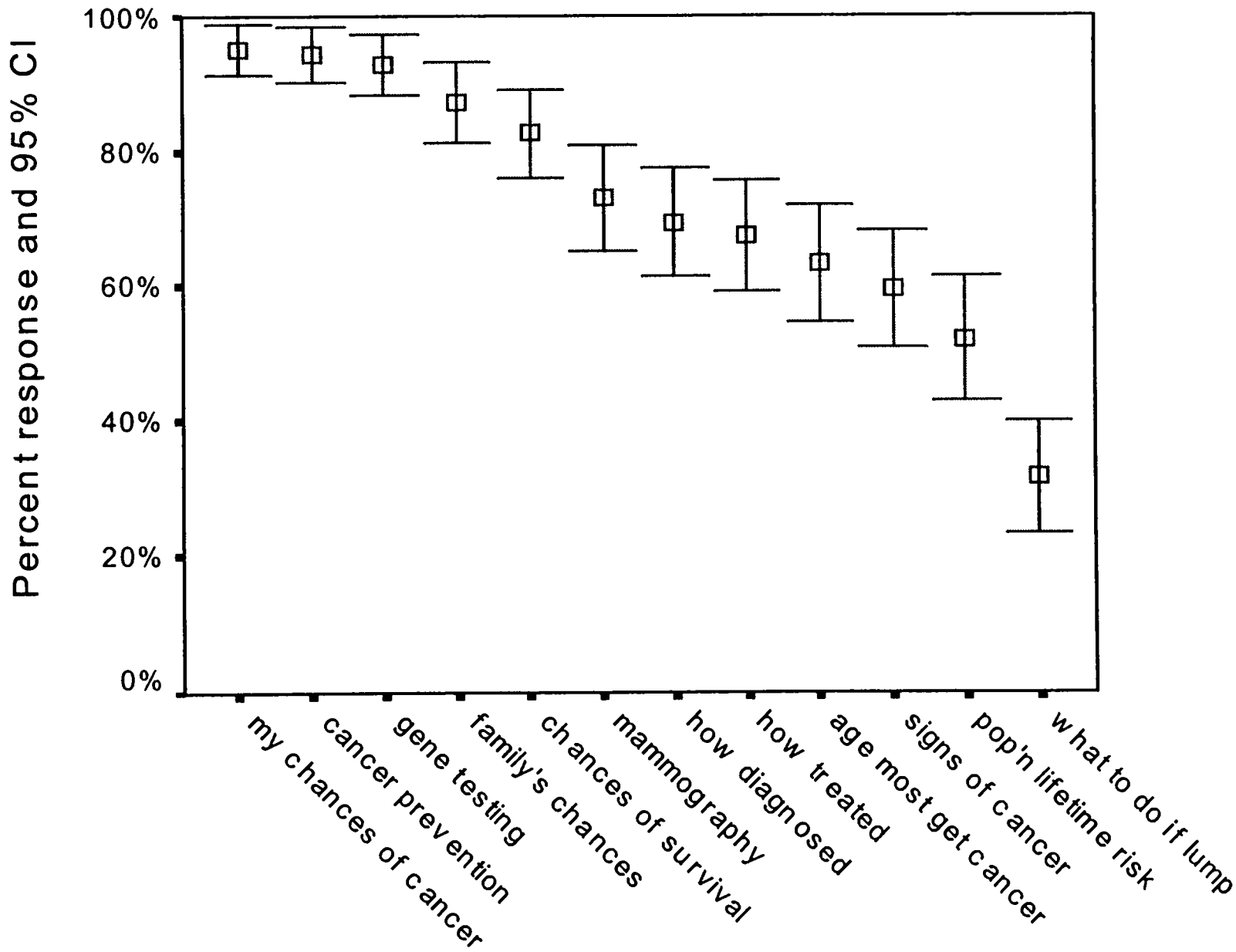
Women felt they received the greatest amount of information about breast cancer from their families (35% (n=38/108)), the media (29% (n=31/108)) and doctors (18% (n=19/108)). The most reassuring information came from doctors (46% (n=45/99)), although some said the

media (19% (n=19/99)) and families (n=15% (15/99)). Six percent of women (n=6/99) said they found no sources of information reassuring. The most worrying information was attributed to the media (49% (n=51/104)), but again families (20% (n=21/104)) and other sources (11% (n=11/104)) were also implicated. Women commented that what they found worrying was "not having the wright [sic] facts" (Respondent 48); "to [sic] much information" (Respondent 133); and "friends-colleagues with mis-information" (Respondent 44).

When asked whether they wanted to know more or whether they knew enough about 12 information topics, women wanted to know about a median of 9 topics (inter-quartile range 6-11), with younger women having been more likely to want more information (R=0.280, n=128, p=0.001). The majority of women wanted information about their chances of getting breast cancer (95% (n=118/124); 95%CI 91-99), preventing breast cancer (94% (n=116/123); 95%CI 90-98), and breast cancer gene testing (93% (n=118/127); 95%CI 88-97). They also wanted to know about their family's chances of getting breast cancer (87% (n=108/124)), the chances of surviving breast cancer (83% (n=104/126)), and who should have mammography (73% (n=91/125)). At least half of respondents were interested in how breast cancer is

diagnosed and treated, the age most women get the disease, possible signs of breast cancer and how common is breast cancer. About two-thirds of women (69% (n=85/124)) said they already knew enough about what to do if a change in their breast was noticed (see **Figure 3.5**). Only seven women commented that they wanted to know more about some other topic not included in the questionnaire.

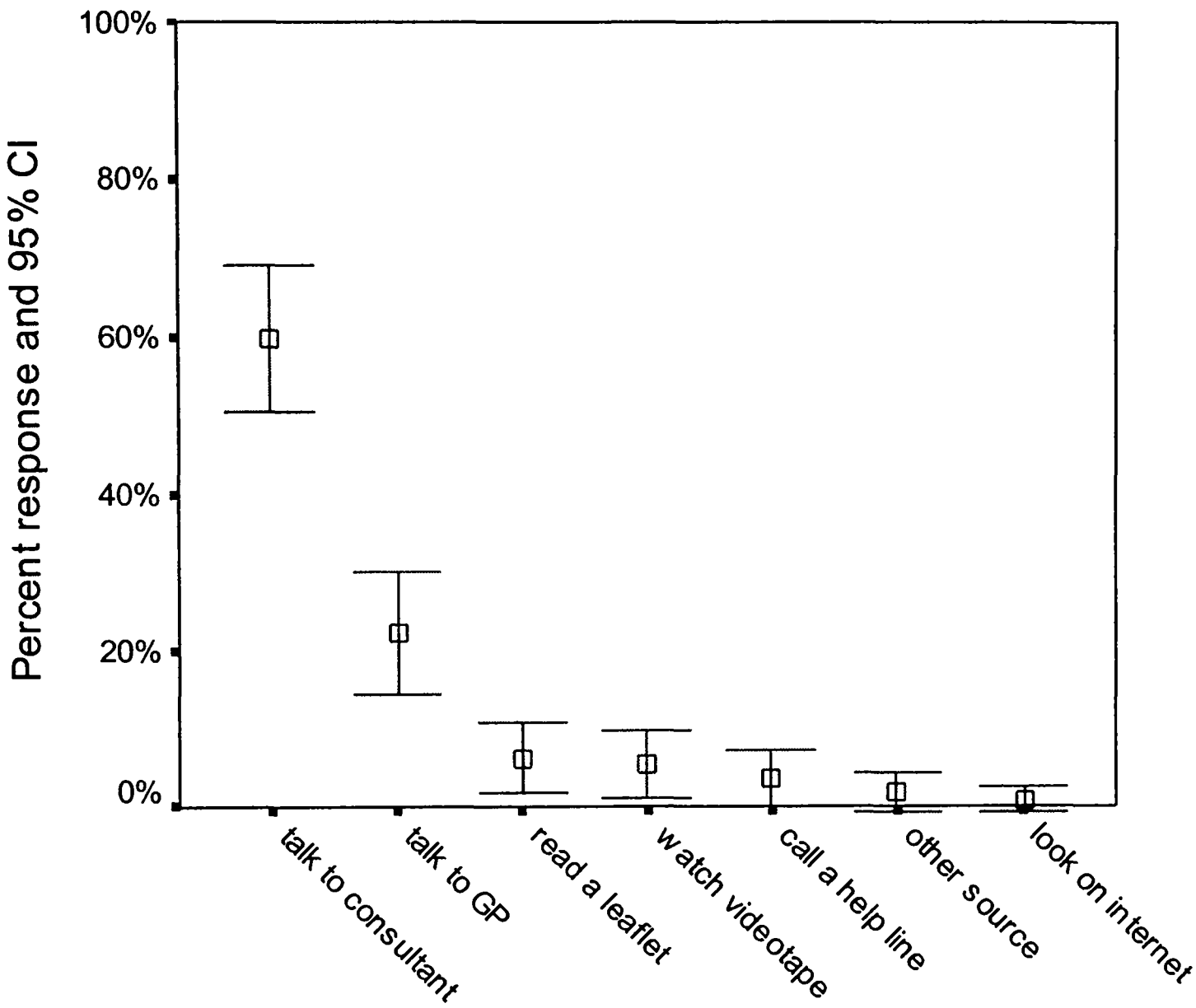
Figure 3.5: Information topics women wanted to know more about



The single piece of information the majority of respondents (46% (n=57/124)) most wanted to know about was their chances of getting breast cancer. Fourteen percent of women (n=17/124) most wanted to know who should have breast cancer gene testing and 9% (n=11/124) most wanted to know about some other topic. One woman most wanted to know "how to convince my GP that I feel something is wrong without appearing neurotic" (Respondent 57).

Women most preferred to get information about breast cancer in the family (see **Figure 3.6**) by talking to a hospital doctor (60% (n=67/112)), talking to their GP (22% (n=25/112)), or reading a leaflet (6% (n=7/112)). Five percent or fewer wanted to watch a videotape, call a help-line or search the internet. One woman would have wanted a researcher to give her the information (Respondent 7).

Figure 3.6: Preferred mode of receiving information



3.4.4. Consulting a GP about breast cancer in the family

Box 3.4: Prospective study summary findings: The GP consultation

- Over a third of respondents had previously seen their GP about a breast problem, but none had ever been diagnosed with breast cancer.
- The majority of women had mentioned breast cancer in the family with their GP many years ago (39%) and had raised the issue on multiple occasions (median 2 times, inter-quartile range 1-4).
- In almost all cases (94%) the patient raised the issue of breast cancer in the family, not the GP. Women's reasons for raising the issue included a recent breast cancer diagnosis in the family (36%), reaching the age when a relative was diagnosed (30%) or for some other reason (28%), most often specified as a recent death from breast cancer in the family. Few women were prompted to consult on the basis of something in the media.
- Women hoped their GP would offer them information (90%), discuss their risks of breast cancer (87%) and discuss mammography (80%).
- About half of women had not expected to be referred. Younger and more educated women were more likely to have wanted a referral and to have been referred.
- During the GP consultation, the GP most often asked the number (80%) and the ages (73%) of affected relatives.
- Prior expectations of the GP visit increased the likelihood of the event occurring. However, only a proportion of women (ranging from 32% to 71%) had their needs met, depending on what the need was.

Over a third of respondents (39% (n=50/128); 95%CI 30-48) had previously seen their GP about a breast problem that they thought may have been a possible sign of breast cancer. These women were

generally older than those who had not seen their GP about this (on average 5 years older, 95% CI 1.1 to 8.2 years; t=2.613 df=126, p=0.010). However, none of the women had ever been diagnosed with breast cancer (the four women who had breast cancer were excluded from the study in accordance with the exclusion criteria, since much of the questionnaire would not have been relevant to their situation).

3.4.4.1. Raising the issue at the GP visit

Thirty-nine percent (39%) of women (n=50/127) had first mentioned to their GP many years ago that a member of their family had breast cancer, and over a quarter had first raised the subject during their recent visit to the GP (28% (n=35/127)). A third brought up the issue sometime in between (33% (n=42/127)). Overall, women had raised the subject of breast cancer in the family with their GP a median of 2 times (inter-quartile range 1-4, absolute range 1-95). Some women explained that they raised the issue repeatedly due to moving house (Respondents 148 and 155), changing surgeries over the years (Respondents 163 and 37) and seeing different GPs (Respondents 15 and 37). However, one woman said that she had raised the issue with another doctor because

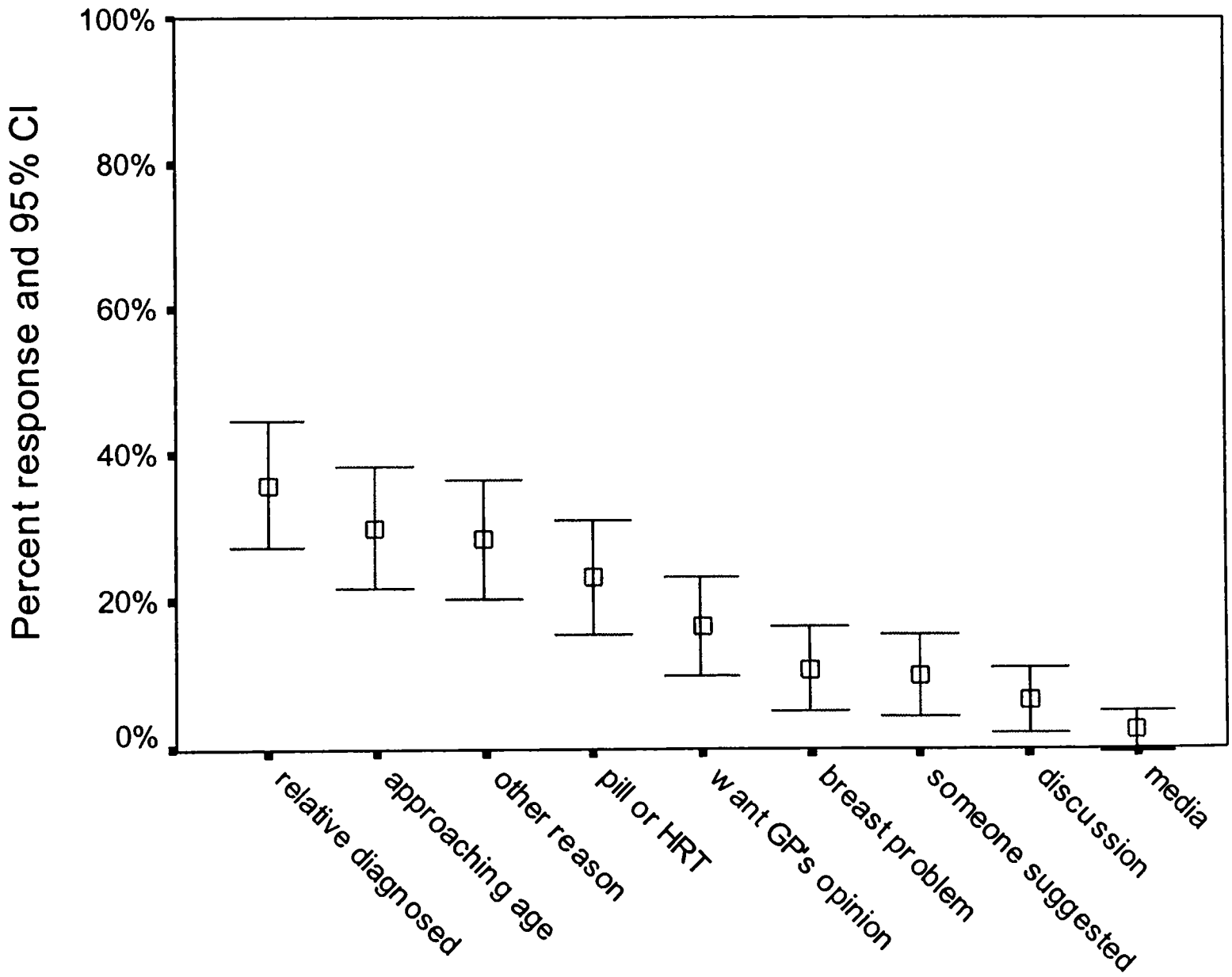
previous physicians that she mentioned her family history to were "not taking my word as serious" (Respondent 199).

At the most recent visit with a GP when breast cancer in the family was mentioned, in 94% of cases (n=120/128) it was the patient who raised the issue. Only 6% (n=8/128) said that their GP had raised the issue. Women who raised the issue with their GP were asked what had happened recently to prompt them to do so (see **Figure 3.7**). The most common reasons were because a relative had recently been diagnosed (36% (n=43/120); 95%CI 27-45), women felt they were approaching the age at which their relative developed breast cancer (30% (n=36/120); 95%CI 22-38) or for another reason (28% (n=34/120), 95%CI 20-37). Women most often specified these "other" reasons as a relative recently dying of cancer (9 responses), wanting a mammogram (3 responses), and following up on a previously made referral that had not yet materialised (2 responses).

Twenty-three percent of respondents (n=28/120) had a question about the pill or HRT, while 17% (n=20/120) wanted to know if their GP felt their family history was important. Eleven percent (n=13/120) said they had a breast problem, and 10% (n=12/120) said someone had suggest

they should raise the issue with their GP. Those who had made these suggestions included the affected relative's oncologist (3 responses), a practice nurse (2 responses), and the woman's mother (2 responses) or sister-in-law (2 responses). Only 7% of women (n=8/120) raised the issue after a discussion with friends and colleagues or because of something they recently saw or heard through the media (3% (3/120)).

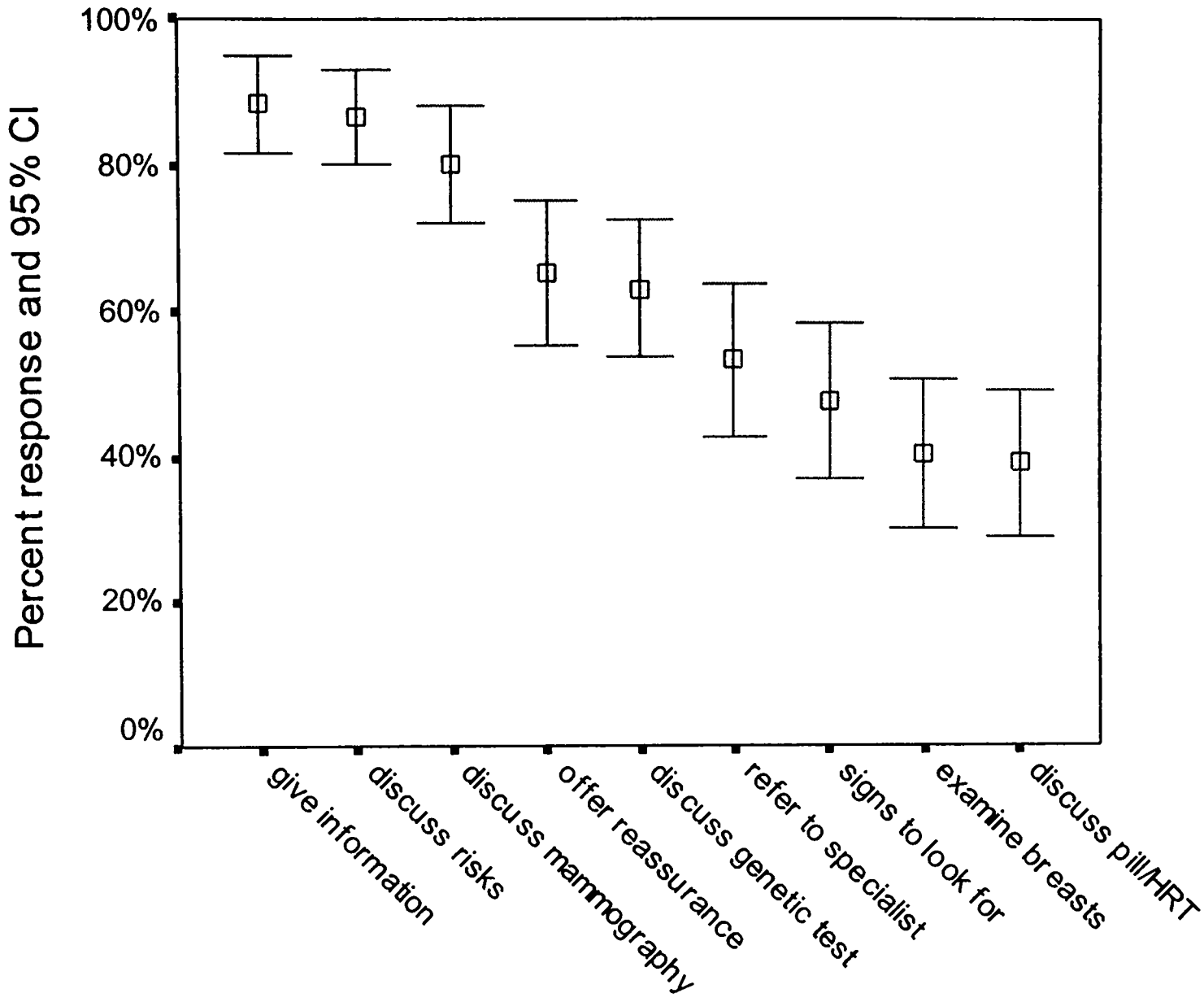
Figure 3.7: Triggers to raising family history in primary care



3.4.4.2. Women's expectations of the GP visit

Ninety percent of women expected their GP to give them information (n=84/95; 95%CI 82-95), 87% wanted to discuss their risks of getting breast cancer (n=91/105; 95%CI 80-93) and 80% wanted to discuss mammography (n=81/101; 95%CI 72-88) (see **Figure 3.8**). Two thirds of women also wanted to be offered reassurance (65% (n=62/95)) and to discuss genetic testing (63% (n=65/103)). Only half of women hoped for a referral to a specialist (53% (n=49/92)). Twenty-two percent (n=20/92) were unsure about whether they wanted a referral, and another 25% (n=23/92) had not hoped for a referral at all. Women who had hoped to be referred were younger (on average 4 years younger, 95%CI 0.08-8 years; $t=2.033$, $df=77$, $p=0.045$) and had more years of education ($U=461$, $n=79$, $p<0.001$). Less than half of respondents wanted to discuss the signs of breast cancer to look for (48% (n=41/86)), for their GP to do a clinical breast examination (40% (n=36/89)), or to discuss the pill or HRT (39% (n=36/92)).

Figure 3.8: Expectations of the primary care consultation

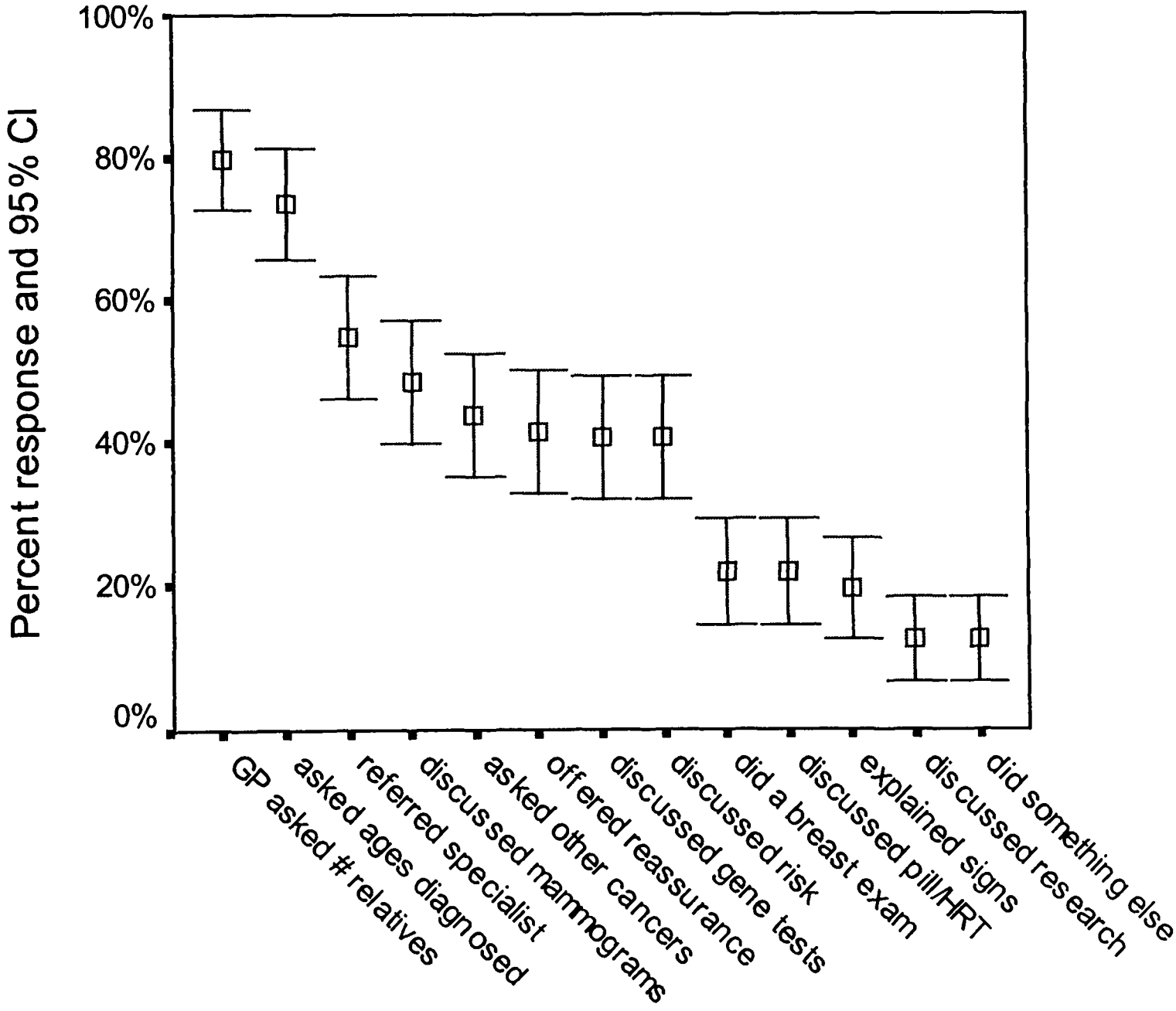


3.4.4.3. Experiences at the GP visit

When asked what actually happened during the recent GP visit (see **Figure 3.9**), women responded that GPs primarily asked how many of their relatives had been diagnosed (80% (n=102/128); 95%CI 73-87) and the ages at which their relatives had been diagnosed (73% (n=94/128); 95%CI 66-81). Fifty-five percent of respondents (n=70/128;

95%CI 46-63) said their GP referred them to a specialist (even though all participants were recruited from secondary care). Younger women (who were on average 5 years younger, 95%CI 2-9 years; t=2.826, df=104, p=0.006) and women with more years of education (U=1507, n=127, p=0.008) more often reported having been referred by their GP. Four women said they had to ask or insist for the GP to provide information or make a referral.

Figure 3.9: Experiences during the primary care consultation

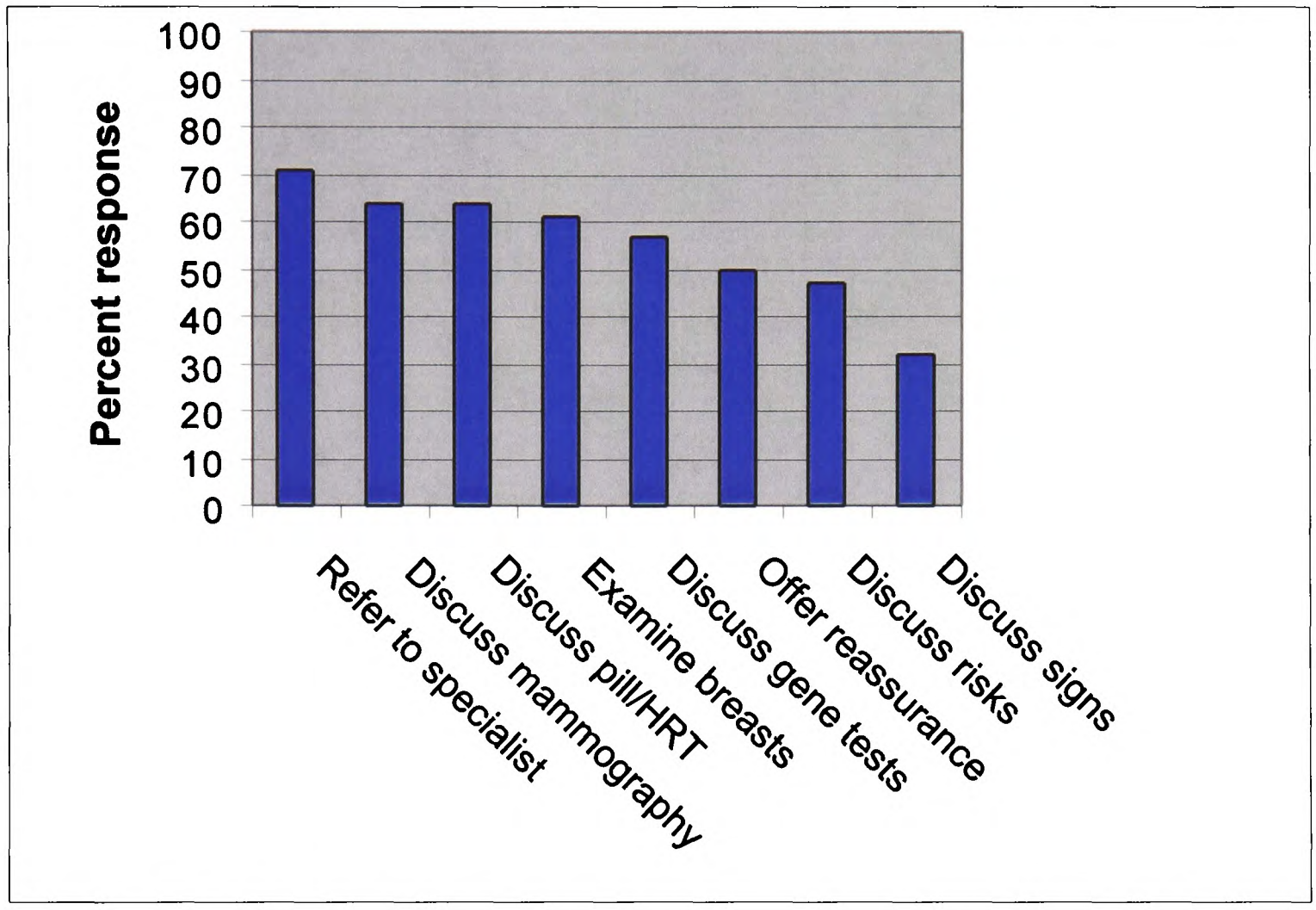


Less than half of respondents reported that their GP discussed mammography (48% (n=62/128)), asked about other cancers in the family (44% (n=56/128)), offered reassurance (41% (n=53/148)), discussed gene testing (41% (n=52/128)), or discussed the risks of breast cancer (41% (n=52/128)). About one fifth said their GP did a breast examination (22% (n=28/128)), discussed the pill or HRT (22% (n=28/128)), or discussed the signs of breast cancer to look for (20% (n=25/128)). Even fewer said their GP discussed research for preventing breast cancer (13% (n=16/128)) or did something else (13% (n=16/128)). One woman who was pleased with the GP visit said "He already had the information about my family in front of him and we discussed it. He is very helpful" (Respondent 163).

Prior expectations of the GP visit increased the likelihood of the event occurring during the consultation. For instance, 80% of women (n=81/101) had hoped to discuss mammography and 20% (n=20/101) had not; 64% (n=52/81) of those who had hoped to did, and only 15% (n=3/20) of those who had not hoped to also did ($p<0.001$). Nonetheless, only a proportion of women (ranging from 32% to 71%)

with prior expectations of the GP visit had their needs met (see **Figure 3.10**).

Figure 3.10: Expectations met at the GP visit



Forty-four percent (44%) of women (n=55/126) said that the GP consultation lasted a few minutes, 38% (n=48/126) reported 5 to 10 minutes. A minority said their appointment lasted more than 10 minutes (18% (n=23/126)). One woman said she spoke to her GP for "less than 1 [minute]!!" (Respondent 67). Only 9% of women (n=12/127) had

received a leaflet to take home entitled *Breast and/or Ovarian Cancer in the Family*. One woman said that was because her GP "had run out of leaflets" (Respondent 102). Women's views about the leaflet are described in **Chapter 5**.

3.4.5. Referral to a specialist for breast cancer in the family

Box 3.5: Prospective study summary findings: The specialist visit

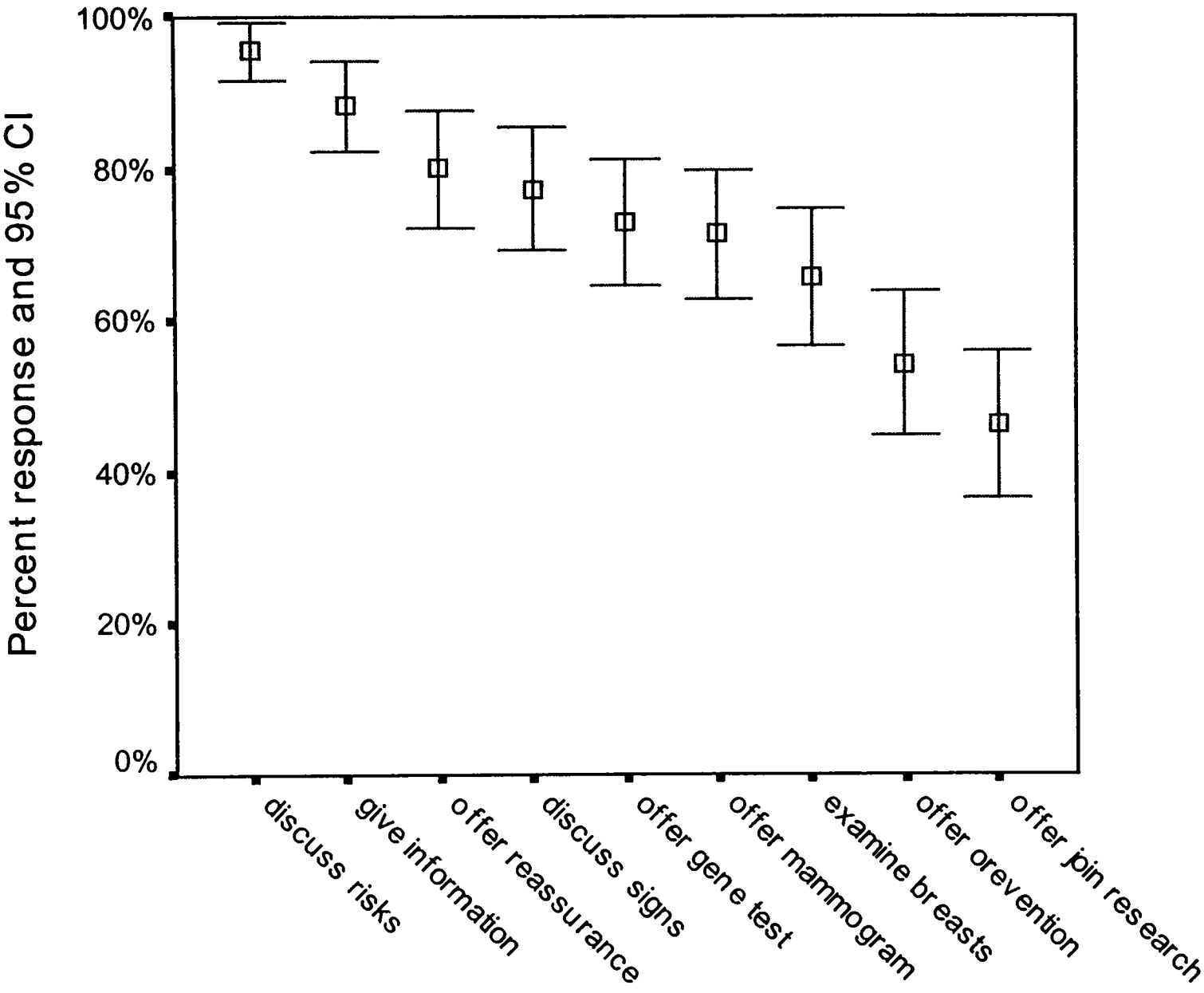
- The majority of women hoped the specialist would discuss their risks (96%), provide detailed information (88%) and offer reassurance (80%).
- Almost three-quarters of respondents hoped for gene testing (73%) or mammographic screening (71%), although some women were unsure (20% and 18%, respectively). In the case of mammography, younger women with higher levels of education were more likely to be unsure or opposed to it.
- About half of respondents wanted to join prevention studies (54%) or help with scientific research (46%). However, almost as many were uncertain about taking part in research (39% and 46%, respectively).
- 90% of women were first contacted by the specialist clinic within 3 months in response to the referral. Breast clinics were faster in responding than genetics clinics.
- At the clinic visit, 96% of women reported discussing their family history, 94% discussed their risks of breast cancer and 62% discussed their family's risks.
- 49% of women discussed gene testing with the specialist, but only 21% of women at the genetics clinic were offered testing. 40% of women both discussed and were offered mammographic screening. However, almost three-quarters of women had wanted these options prior to the clinic visit.
- Women attending the genetics clinics (who were significantly younger, more educated and had higher academic qualifications) were more likely than those at the breast clinics to discuss the pros and cons of mammography and gene testing, and to be advised to consider mammographic screening.
- As with the GP consultation, women's prior expectations increased the likelihood of their occurrence. Especially as regards discussing the risks of breast cancer, more women had their expectations met at the specialist visit as compared with the GP consultation and they also had more time in which to do so.
- Overall women found the specialist visit useful and reassuring.

3.4.5.1. Expectations of the specialist visit

Ninety-six percent of women (n=110/115; 95%CI 92-99) expected the specialist to discuss their risks of breast cancer in detail, and 88% expected detailed information about breast cancer (n=98/111; 95%CI 82-94) (see **Figure 3.11**). Eighty percent of women (n=84/105) hoped the specialist would offer reassurance and 78% percent (n=82/105) wanted to have the signs and symptoms of breast cancer explained (72/92, 78%). Seventy-three percent (n=83/114) were hoping to be offered a gene test, 71% (n=80/112) wanted a mammogram, and 66% (n=71/108) wanted a breast examination. About half of the women wanted to join a cancer prevention study (54% (n=58/107)) and to help with scientific research (46% (n=48/104)). However, 39% of women (n=42/107) were unsure about participating in prevention research and 46% (n=48/104) were unsure about helping with scientific research. One woman said she wanted to limit what research she would join "as this subject is very painful" (Respondent 199). Some women were also uncertain about having gene testing (20% (n=23/114)) and starting mammographic screening (18% (n=20/112)). Women with higher levels of education were more likely be unsure of or opposed to being offered mammography (KW=6.980, df=2, p=0.030). For instance, 24% of women (n=8/33) who left full-time education after 18 were unsure and

another 24% (n=8/33) did not hope for mammography compared to women who left aged 18 or younger where only 5% (n=4/78) were unsure and 15% (n=12/78) did not want mammography.

Figure 3.11: Expectations of referral to secondary care



3.4.5.2. Experiences at the specialist visit

Of the 47 women who returned the follow up questionnaire, 43% (n=20/47) reported first having been contacted by the secondary care

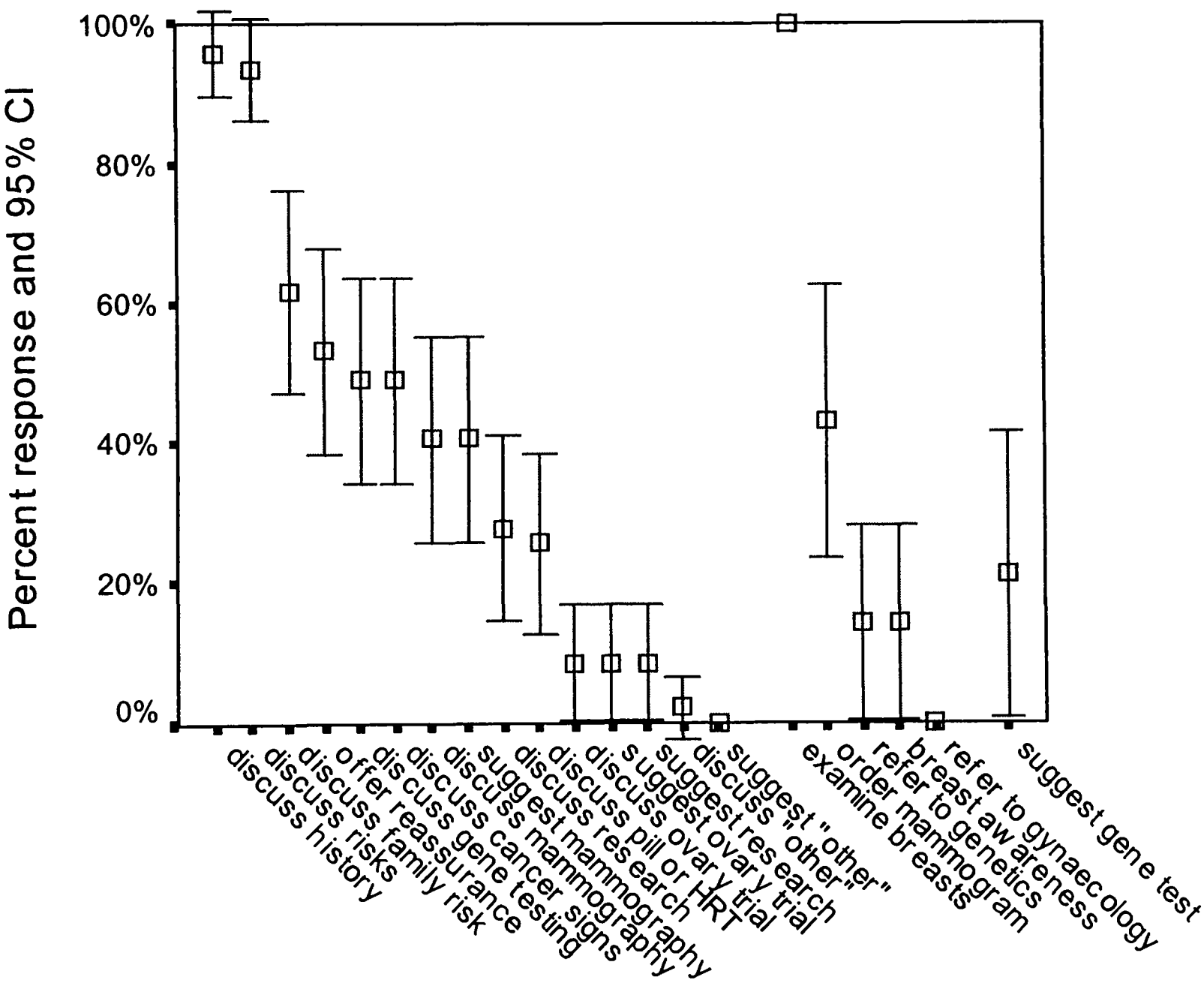
clinic regarding their referral less than one month after having been referred by their GP. Forty-seven (47% (n=22/47)) reported that they were first contacted between one and three months. Women referred to a breast clinic were contacted sooner than those referred to a genetics clinic (U=119, n=46, p=0.001; for example, 61% (n=17/28) were contacted within 1 month by the breast clinic vs. 17% (n=3/18) by the genetics clinic).

All but one of the women who attended a genetics clinic reported having been sent a form to complete about their family history (95% (n=18/19)). Of those who were sent a form, all thought the form was clear (n=18/18) but 75% (n=12/16) thought it was difficult to find the information the form asked for. Few women thought the form was worrying (2/15) or time-consuming (5/16).

Women were asked whom they spoke to about their family history during the clinic visit, and they were able to select more than one person. Seventy-two percent (72% (n=34/47)) reported having spoken to a doctor, 34% to a nurse ((n=16/47)), a few to "someone else" (6% (n=6/47)) and two were not sure with whom they had spoken (4%).

During the visit to the specialist, 96% of women (n=45/47; 95%CI 90-102) reported going over their family history, 94% discussed their breast cancer risks (n=44/47; 95%CI 86-101), and 62% discussed their family's risks (n=29/47; 95%CI 47-76) (see **Figure 3.12**).

Figure 3.12: Experiences of referral to secondary care



Fifty-three percent of women (n=25/47) were offered reassurance and 49% were told the signs of breast cancer to look and feel for (n=23/47). Forty-nine percent of women (n=23/47) said the specialist discussed the pros and cons of gene testing, but only 21% of the women at the genetics clinic said the specialist actually suggested it (n=4/19). Forty percent (40%) of women (n=19/47) reported that the specialist both discussed and suggested regular mammographic screening. About a quarter of women discussed taking part in research in general (28% (n=13/47)), taking part in ovarian screening trials in particular (9% (n=4/47), using the pill or HRT (25% (n=12/47)), or any other topics (2% (n=1/47)).

If attending the breast clinic, all women had a clinical breast examination (n=28/28), and almost half of the women had a one-off mammogram arranged for them (43% (n=12/28)). Women attending the breast clinic sometimes discussed breast awareness (14% (n=4/28)) or were referred to the genetics clinic (14% (n=4/28)).

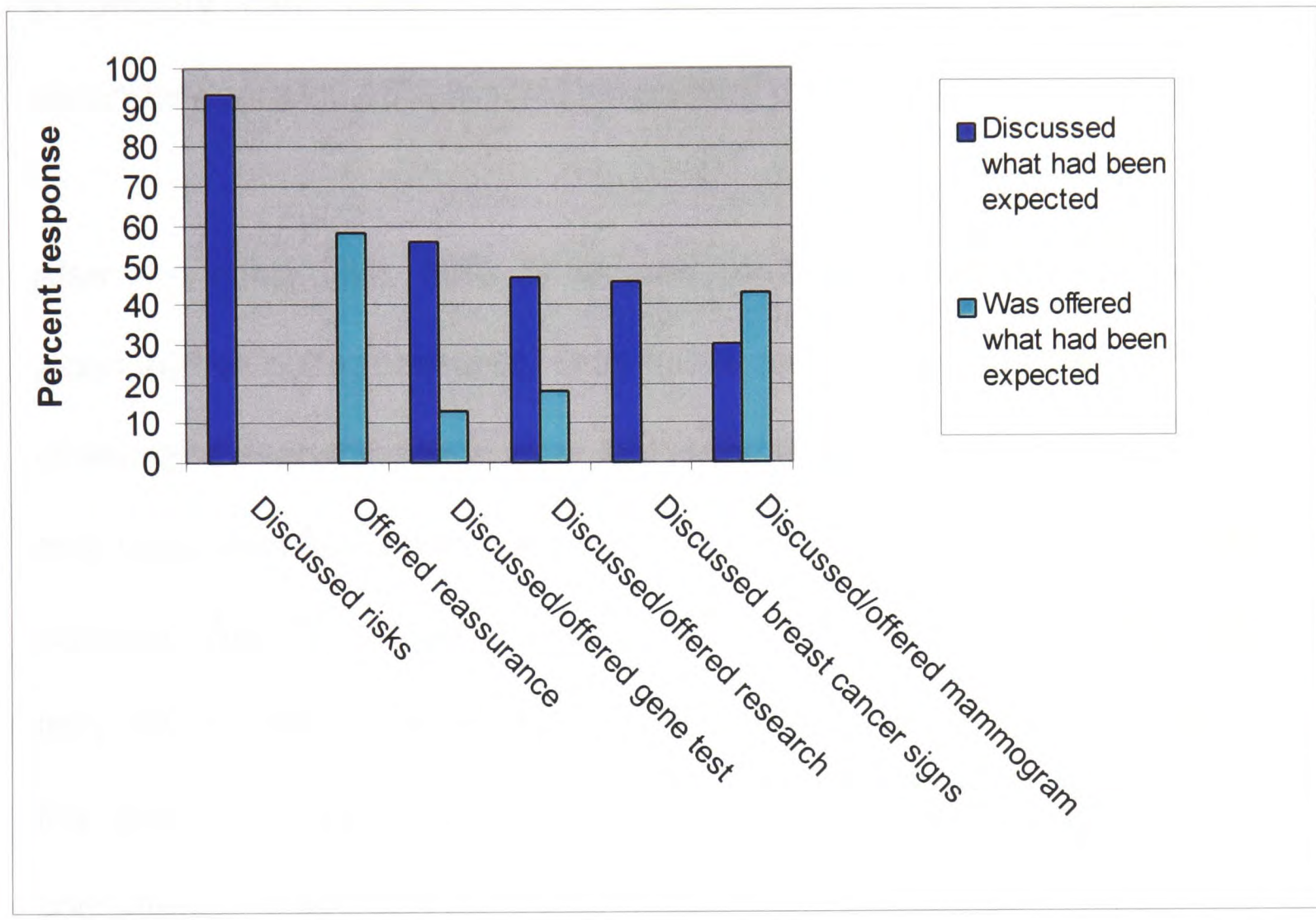
Women who attended a genetics clinic (who were significantly younger, more educated and had higher qualifications, see **Section 3.4.2**) were more likely than women referred to a breast clinic to discuss the pros

and cons of mammography (genetics clinic 74% (n=14/19) vs. breast clinic 18% (n=5/28); X^2=14.648, df=1, p<0.001) and to be advised to consider mammographic screening (genetics clinic 63% (n=12/19) vs. breast clinic 25% (n=7/28); X^2=6.843, df=1, p=0.009). Women referred to genetics clinics were also more likely than those at the breast clinic to discuss gene testing (84% (n=16/19) vs. 25% (n=7/28); X^2=15.881, df=1, p<0.001), as well as ovarian screening trials and other research.

As with the GP consultation (see **Section 3.4.4.3**), women's prior expectations of the specialist visit increased the likelihood of their occurrence, with the exception of wanting a genetic test, wanting to participate in research and wanting to know the signs and symptoms of breast cancer. Women's expectations of the specialist visit were met in a large proportion of cases when it came to discussing risks (93% (n=38/41), but somewhat less so in providing reassurance (58% (n=18/31)) and discussing mammography (30% (n=9/30)) and gene testing (56% (n=18/32)). Only a very small proportion of women had their expectations met in terms of being offered a genetic test (see **Figure 3.13**). However, the greatest difference between primary and secondary care was the proportion of women who felt they were able to

discuss their risks of developing breast cancer (93% (n=38/41) with specialist vs. 47% (n=43/91) with GP; p<0.001).

Figure 3.13: Expectations met at the specialist visit



In contrast with primary care, most women reported spending either 10 to 30 minutes (68% (n=32/47)) or more than 30 minutes (19% (n=9/47)) discussing breast cancer in the family during the secondary care visit. Only 13% of women (n=6/47) spent less than ten minutes. Women attending a breast clinic were significantly more likely to report spending

less time discussing their family history (U=151, n=47, p=0.002; for example, 21% (n=6/28) spent less than 10 minutes at the breast clinic vs. 0% (0/19) at the genetics clinic). Overall, however, women spent more time discussing their family history in secondary care as compared to primary care (87% (n=41/47) spent more than 10 minutes in secondary care vs. 15% (n=7/47) in primary care; p<0.001).

After the clinic visit, 86% of women (n=38/44) said they felt very reassured or quite reassured. Only four women (9%) said they did not understand everything they were told at the clinic. One woman said “my only query was how could someone possibly tell me I was in a ‘low’ risk category after 10 minutes” (Respondent 67). Only three women (7%) felt they did not find out all the information that they wanted to know from the clinic. Women's preference was to get that information by talking to a consultant (2 responses) or calling a help line (1 response).

Overall, almost all the women perceived the clinic visit to be either "very useful" or "quite useful" (96% (n=45/47)), with only 2 respondents finding it not very useful (4%). One woman said she was “very impressed by the detail which had been gone into re my family history” (Respondent 24). Overall women made very positive comments about their experiences at

the clinic. However, four women complained that the wait for an appointment was too long, three said there was no reception area and a long wait before being seen by the specialist, and two could overhear consultations in progress while waiting which was “very distressing to overhear” (Respondent 139). One woman felt her GP would have been able to do what was done at the referral clinic "provided he had the correct skills and knowledge" (Respondent 187).

3.4.5.3. Following the specialist visit

None of the women reported being back in touch with the clinic since their visit a month before. However, five women (11%) had been to see their GP. They spoke to their GP about mammography (n=5), breast checks (n=2), HRT (n=1) and what had happened at the clinic (n=1). One woman said that she and her GP discussed “the fact I was to have mammography every two years, and he said he would do checks twice a year at the surgery” (Respondent 33).

Almost half of respondents felt they had some choice in making decisions about their management with respect to having breast cancer in the family (47% (n=21/45); 95%CI 32-62). Only 5 women thought they

had no choice (11%) and 4 women were unsure (9%). About half of women felt that this amount of choice was "about right" (49% (n=22/45); 95%CI 34-64), and over a third that it was "not enough" (38% (n=17/45); 95%CI 23-53). One woman said “I can request regular screening but will it be made available?” (Respondent 21). Another woman felt there was a problem caused by a “lack of funding” limiting what screening is available (Respondent 6). A third woman pointed out that “only because breast cancer cannot be prevented, choices on offer do not guarantee prevention” (Respondent 15).

All but one woman said that they knew the signs and symptoms of breast cancer to look and feel for (98% (n=46/47)). However only 18% (n=8/44) felt very confident in recognising these signs and symptoms. About half felt quite confident (52% (n=23/44)), a quarter did not feel very confident (25% (n=11/44)) and 2 were not at all confident (5%).

3.4.6. Regular mammographic screening

Box 3.6: Prospective study summary findings: Mammography

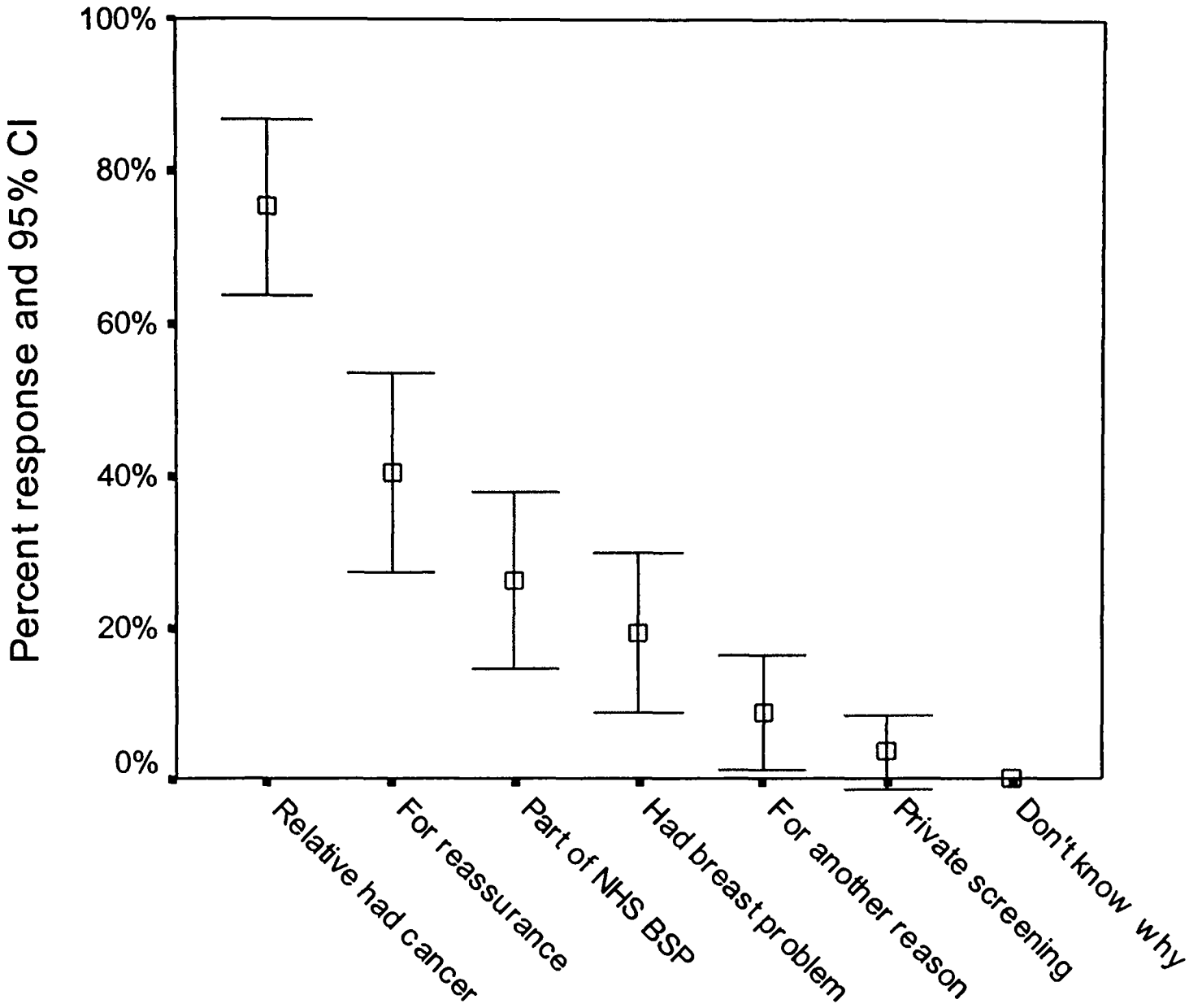
- 45% of women had already had a previous mammogram at the time of referral from their GP. 28% of these women were over the age of 50 and most of them were being screened through the NHS Breast Screening Programme (88%). However, the 41 women below the age of 50 had previously found other ways of having a mammogram and only two had gone privately.
- Overall, the reasons why women had previously had a mammogram were because a relative had had breast cancer (75%), for reassurance (40%), or because of a breast problem (19%).
- After the GP referral, 74% of respondents wanted to start regular mammographic screening. The minority of women (6%) who did not want screening were on average 10 years younger than the rest. After the specialist visit, 54% still wanted to begin regular screening, but this was significantly less than before (p=0.004).
- More women commented about the benefits than about the concerns of regular mammography for women their age. The most commonly cited benefits included early detection, reassurance and increased survival. The majority of those who commented on concerns felt they did not know enough about it. Most commonly mentioned concerns were radiation exposure, false positives and false negatives.
- Almost half of respondents correctly noted that false negatives and false positives occur sometimes or quite often (48% and 42%, respectively). Fewer were aware that these occur more commonly in pre-menopausal women (27% and 19%, respectively). One quarter to one half of women answered "don't know" to these questions. Women's knowledge increased, but not significantly, after the specialist visit.

At the time of referral, almost half of respondents said that they had already had a mammogram at some time in the past (45% (n=57/127);

95%CI 36-54). These women tended to be older (on average 12 years older, 95%CI 9-15 years; t=7.896, df=125, p<0.001). They also had more affected relatives (U=1307, n=119, p=0.012; for example, of those who had had a mammogram 49% (27/55) had more than 2 affected relatives compared to 22% (14/64) in those who had never had a mammogram). Sixteen of the women who had had a previous mammogram (28%) were over the age of 50, and 14 of the 16 (88%) were receiving screening through the NHS Breast Screening Programme. There were, however, 41 women (72%) who had previously had a mammogram but were below the age of 50, and these women must have had other means of being screened. Only two women of these women said that they had gone privately.

Overall, the reasons why women had previously had a mammogram (see **Figure 3.14**) were because a relative had had breast cancer (75% (n=43/57), for reassurance (40% (n=23/57)), or because of a breast problem (19% (n=11/57)). Nine percent of women (n=5/57) cited some other reason. One woman had wanted a mammogram as a "precautionary check up requested 20 years prior to relative's diagnosis" (Respondent 117).

Figure 3.14: Reasons for previously having had a mammogram



3.4.6.1. Desire for regular mammographic screening

After the GP referral, almost three-quarters of respondents wanted regular mammography (74% (n=93/125); 95%CI 67-82). Eleven percent (n=14/125) were already getting regular screening, 9% (n=11/125) were unsure whether they want to be screened and only 6% (7/125) did not want to start regular mammographic screening at that time. Similar to what was described previously, the women already receiving regular

screening as part of the NHS Breast Screening Programme were older and had more affected relatives. The 7 women who did not want to be screened were on average 10 years younger than the rest (95%CI 3-18 years; t=2.694, df=123, p=0.008).

After the specialist visit, just over half of respondents wanted regular mammography (54% (n=25/46); 95%CI 39-69), and one fifth were already receiving screening (20% (n=9/46); 95%CI 8-31). Nine percent (n=4/46) were unsure and 17% (n=8/46) did not want mammographic screening. There were significantly fewer women who wanted regular mammography after the clinic visit as compared to before (80% (n=36/45) post GP referral vs. 53% (n=24/45) post clinic visit; p=0.004). One woman wanted to start "at the appropriate age" (Respondent 102) and another woman complained that "I had already started mammograms, but now – due to my '10 minute chat' – I will not go again until I'm 50! I am 37!" (Respondent 67)

3.4.6.2. Benefits and concerns regarding mammographic screening

After the GP referral, 79% of women (n=101/128) commented on the benefits of regular mammography for women of their age, but only 45%

(n=57/128) noted any concerns (recalling that 87% of the overall number of respondents were younger than 50). Among the benefits of mammography that women most often cited, there was early detection and diagnosis (39% (n=39/101)) and reassurance and peace of mind (30% (n=30/101)). Women also felt that it would be important, especially for younger women, because of their family history (17% (n=17/101)), and because early treatment increased one's chances of survival (15% (n=15/101)). Some women felt mammography was better than or could supplement self-examination (6% (n=6/101)). One woman said that mammographic screening would help to ensure that she "lives to see my children grow and produce their own offspring which is something my mother did not see" (Respondent 191).

Four women commented that mammography has limited benefit in pre-menopausal women. Only two women wrongly believed that mammography could prevent cancer, and two others said they don't know much about it and need more information: "I cannot form any views until I have more information about the effectiveness of such screening for someone my age" (Respondent 154).

Of the 57 women who commented about possible concerns regarding regular mammographic screening, most said they “don’t know of any” or "don’t know enough about it" (14% (n=8/57)), or they simply had no concerns (14% (n=8/57)), and six women restated the benefits of mammography (11%). One woman said: “My concern is not knowing of any direct or indirect risk as a result of the mammography” (Respondent 149).

Women mentioned that they were concerned about the exposure to radiation (9% (n=5/57)) and false positive and false negative results (9% (n=5/57)). Examples of the latter included “being wrongly diagnosed and having unnecessary surgery” (Respondent 135) or “that a mammography may not detect early signs” (respondent 186). Some women wondered whether mammography triggers cancers (7% (n=4/57)). Others thought it may be a waste of time and money for young women if their breast tissue is too dense and if there is no change in mortality rate for that age group (7% (n=4/57)). A few women cited the pain and discomfort associated with mammography (5% (n=3/57)). One woman was concerned that mammography instills a false sense of security.

After the clinic visit, fewer women commented on the benefits of mammography (62% (n=29/47) after the visit vs. 80% (n=101/126) before), and about the same proportion voiced their concerns (40% (18/47) after the visit vs. 48% (n=57/120) before). Most of the comments made after the clinic visit closely reflected what had been said before the visit (see above). One woman wrote that mammographic screening gives one "a feeling of being in control" (Respondent 96). But another felt that "undue over vigilance causing worry" could also pose a problem (Respondent 108).

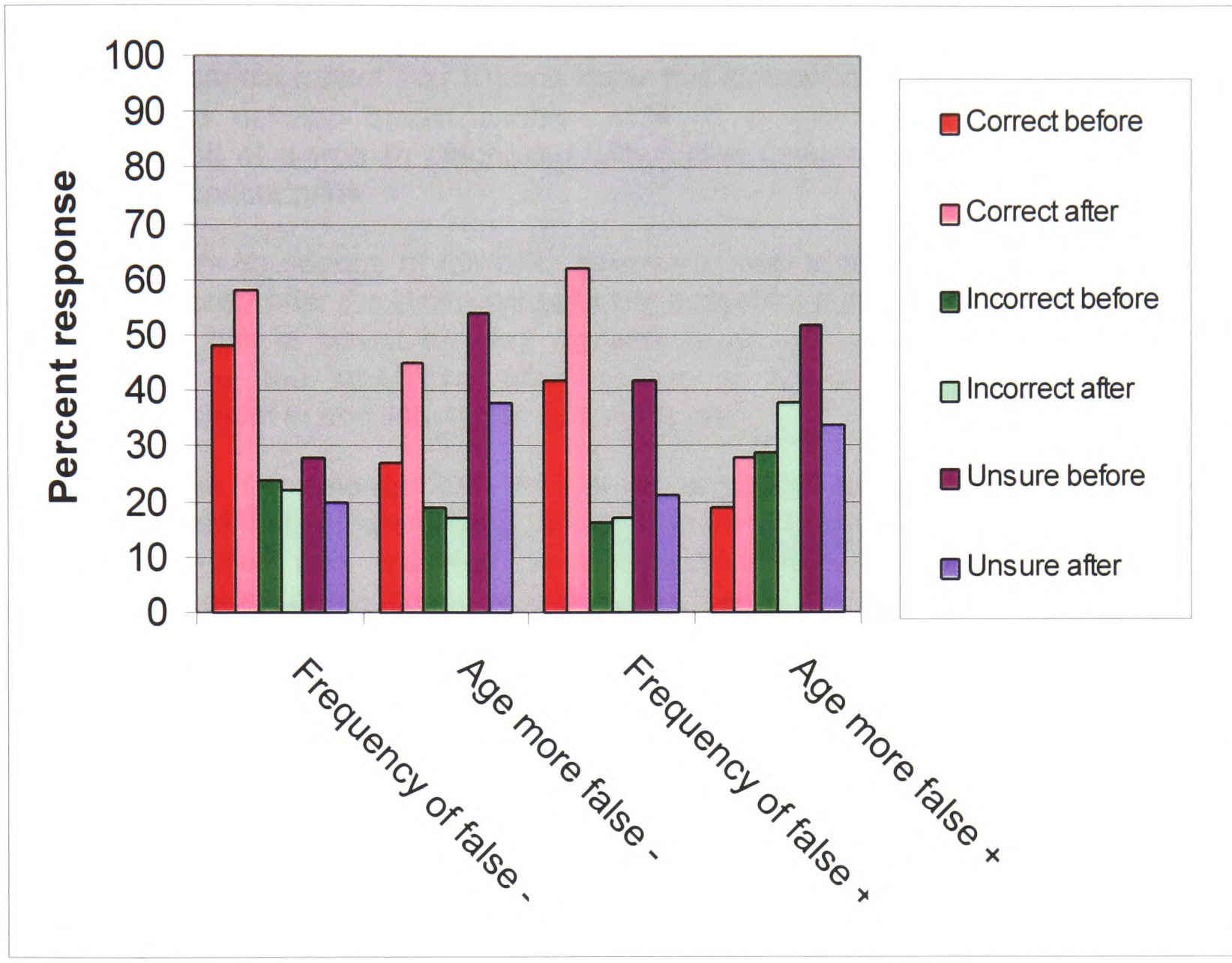
3.4.6.3. False negatives/positives associated with mammography

Before attending the specialist clinic, one quarter to one half of women responded "don't know" to each of the questions regarding the false negatives and false positives associated with mammography (see **Figure 3.15**). The majority of women (48% (n=61/127)) correctly noted that false negatives occur sometimes or quite often [Barratt et al, 1999; Kerkilowske and Barclay, 1997]. Over a quarter of women correctly noted that women under 50 are more likely to have a false negative (27% (n=35/128)) [Fletcher, 1997; Mushlin et al, 1998]. Likewise for the questions about false positives, 42% correctly identified that they occur

sometimes or quite often (42% (n=54/128)) [Kerkilowske et al, 1993]. Only 19% of women (n=24/128) thought that false positives occur more often in women under 50 [Fletcher, 1997; Kerkilowske and Barclay, 1997]. Women who wanted mammography were less likely to know the frequency of false negatives associated with screening compared with women who did not want mammography (42% (n=39/92) vs. 63% (n=20/32); X^2=3.849, df=1, p=0.05). However, they were more likely to correctly respond that false positives occur more often in women under 50 (24% (n=22/93) vs. 6% (n=2/32); X^2=4.649, df=1, p=0.031). Women already getting mammography were more likely to know the frequency of false positives associated with mammography (54% (n=31/57) vs. 33% (n=23/70); X^2=5.958, df=1, p=0.015).

Following the visit with the specialist, women's knowledge of false positives and false negatives improved, but not significantly. Likewise, fewer women answered "don't know" to all the questions, but this was only significant regarding the age at which women are most likely to have false positive results (57% (n=27/47) were unsure before the clinic visit vs. 34% (n=16/47) after; p=0.003).

Figure 3.15: Knowledge of false positives and negatives associated with mammography before and after attending a specialist clinic



3.4.7. Knowledge and perceptions of breast cancer risks

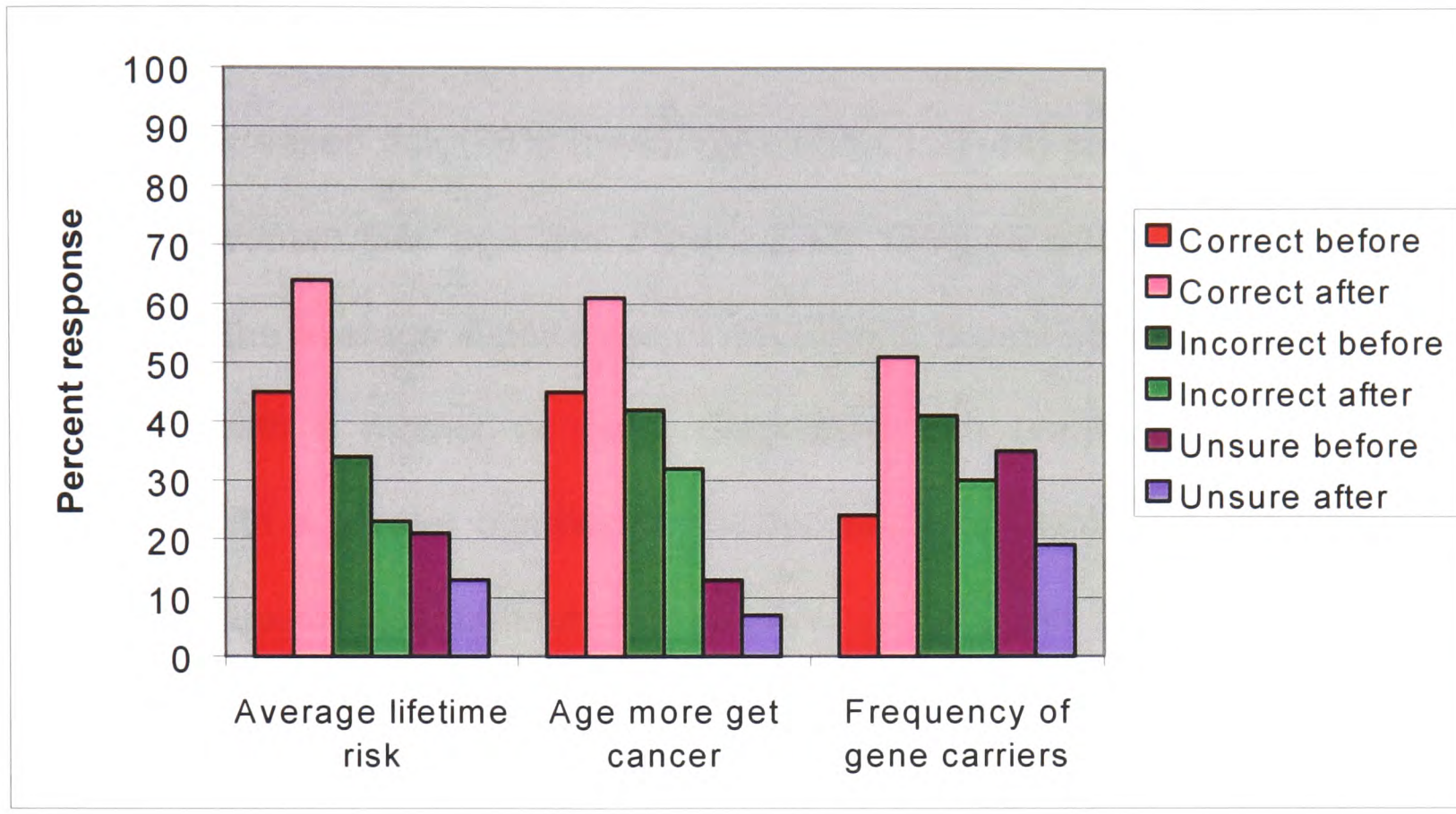
Box 3.7: Prospective study summary findings: Breast cancer risks

- After the GP referral, 45% of women knew the average lifetime risk of breast cancer (about 1 in 10) and knew that women over age 50 are more likely to develop breast cancer. 41% of women over-estimated the likelihood of a woman diagnosed with breast cancer carrying an altered breast cancer gene.
- Women's knowledge of the risks associated with breast cancer improved significantly after the clinic visit (with the exception of knowing the average lifetime risk of breast cancer). As well, fewer women responded "don't know" to the questions after seeing a specialist. However, the improvement in absolute terms was modest.
- After the GP referral, 87% of women perceived themselves to be at increased risk of developing breast cancer compared to the average woman their age. Elevated risk perceptions were related to having a mother or sister diagnosed with breast cancer, or having greater numbers of affected relatives.
- Although data was not available for all respondents, it appears that only a quarter of women (n=4/15) attending the specialist clinic were considered to be at high risk of carrying an altered breast cancer gene. Women's risk perceptions were not correlated with their "actual" risk as calculated by the specialist clinic.
- Overall, women's risk perceptions decreased significantly after the clinic visit, although there was no change in 64% of cases and 60% of women reported that their perceptions had not changed since the clinic visit. Similarly, after the clinic visit, only 28% of women thought they had an increased risk of carrying an altered breast cancer gene, and 63% of women felt their perceptions regarding their own chances of carrying an altered gene were about the same as before the secondary care visit.

3.4.7.1. Knowledge of breast cancer risks

After the GP referral, with the exception of the question regarding the proportion of gene carriers amongst women diagnosed with breast cancer, fewer women were unsure about the breast cancer risks questions as compared to the questions about false positives and false negatives associated with mammography (see **Section 3.4.6.3**). About half of women correctly identified the average lifetime risk of breast cancer as 1 in 10 (45% (n=57/127); 95%CI 36-54), and said that most women develop breast cancer after the age of 50 (45% (n=56/125); 95%CI 36-54) (see **Figure 3.16**). However, less than one quarter of respondents (24% (n=30/126)) correctly answered that women diagnosed with breast cancer sometimes, rarely or vary rarely carry an altered breast cancer gene that can be passed down in the family [Evans et al, 1994b]. Forty-one percent (n=52/126) over-estimated the chances of women diagnosed with breast cancer carrying an altered breast cancer gene, and believed that it occurred "quite often" or "very often".

Figure 3.16: Knowledge of risks associated with breast cancer before and after attending a specialist clinic

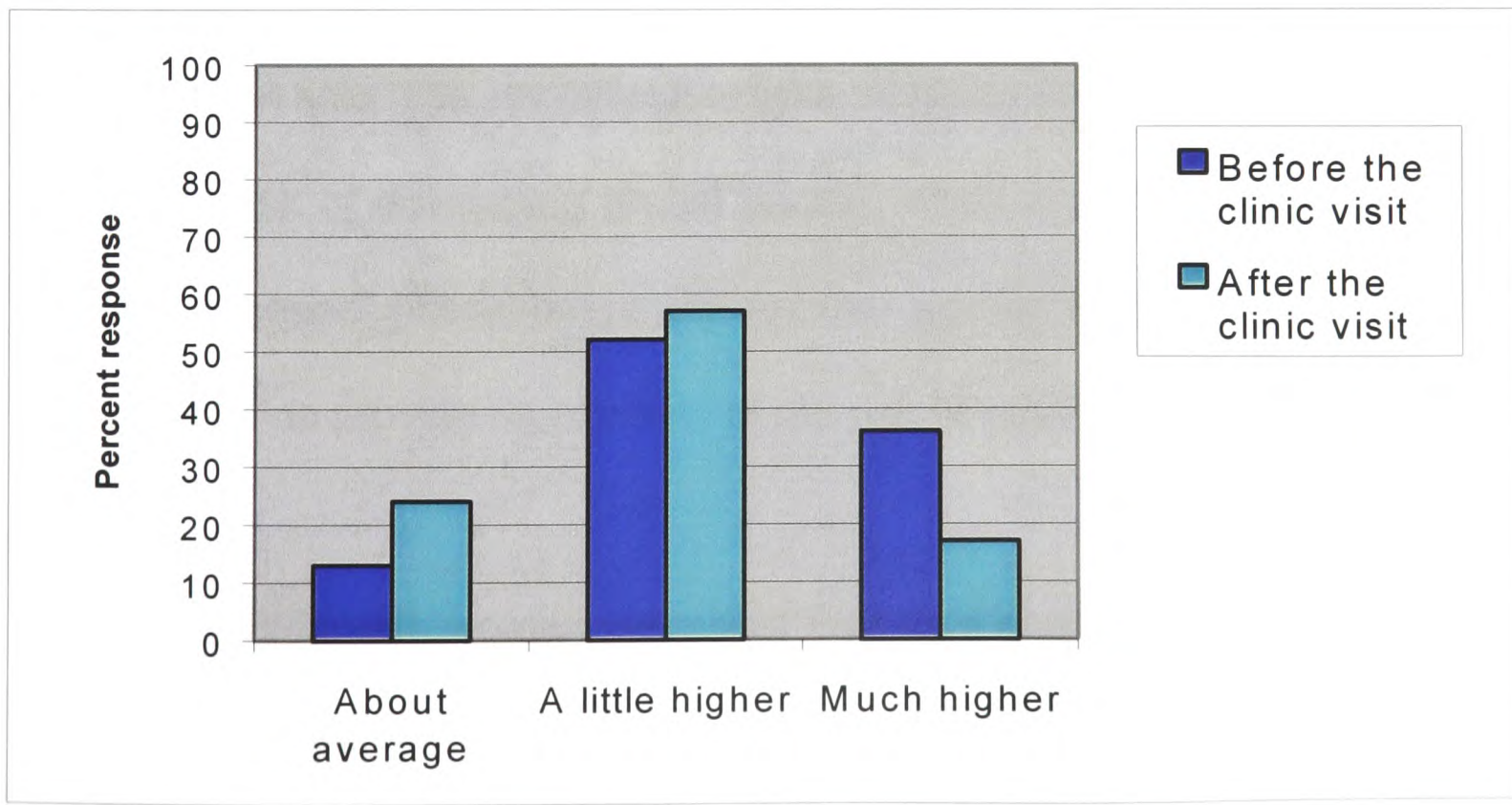


After the specialist visit, women's knowledge of the age when breast cancer is most likely to occur significantly improved (37% (n=17/46) correct answers before vs. 61% (n=28/46) post, p=0.001). Likewise, women's knowledge of the proportion of women with breast cancer who carry an altered breast cancer gene improved (28% (n=13/47) correct answers before vs. 51% (n=24/47) after, p=0.027). However, women's knowledge of the lifetime risk of breast cancer did not significantly improve (47% (n=22/47) correct answers before vs. 64% (n=30/47) after, p=0.077).

3.4.7.2. Perceptions of breast cancer risks

After the GP referral, most women perceived their risk of getting breast cancer to be slightly increased (52% (n=65/126); 95%CI 43-60) or greatly increased risk (36% (n=45/126); 95%CI 27-44) compared to the average woman their age (see **Figure 3.17**). Only 16 women (13%) felt they had the average lifetime risk of developing breast cancer (1 in 11). Women with a mother or sister diagnosed with breast cancer and women with a greater number of affected relatives were more likely to have increased risk perceptions (U=394, n=125, p=0.003; R=0.274, n=119, p=0.003)

Figure 3.17: Breast cancer risk perceptions before and after attending a specialist clinic



After the specialist visit, over half of respondents perceived their own lifetime risk to be a little higher than the average (57% (n=26/46); 95%CI 42-71). Twenty-four percent (24%(n=11/46)) thought their risk was about the same, and 17% (n=8/46) thought it was much more than average. Only one woman thought her risk was less than the average lifetime risk. Overall, women's perceptions of their lifetime risk of breast cancer compared to other women their own age decreased after the clinic visit (W=-2.977, n=45, p=0.003), although in 64% of cases (n=29/45), women's responses did not change before and after. This is closely reflected by the fact that 60% of women (n=28/47) responded that their risk perceptions were about the same as before they attended the secondary care clinic. Twenty-three percent (n=11/47) believed their risk perceptions to be lower, and 11% (n=5/47) thought they were higher. One woman said "it is still difficult to take on board only a slight increase [in one's risk of developing breast cancer] when my identical twin has been diagnosed" (Respondent 21). Another woman was "awaiting gene test results" to provide an estimate of her risk (Respondent 92).

After the clinic visit, women perceived their own chances of carrying an altered breast cancer gene as about average (41% (n=19/46); 95%CI

27-56) or high to very high (28% (n=13/46); 95%CI15-42). Fewer thought their chances were low or very low (20% (n=9/46)). One woman said that if the question was "asking me to compare my chances with the chances of an 'average' person – if so I'm very high. Or are you asking me to put my chances into words, in which case low" (Respondent 37). Sixty-three percent (63%) of women (29/46) felt their perceptions regarding their own chances of carrying an altered gene were about the same as before the secondary care visit. Twenty-six percent (n=12/46) thought their perceptions were now lower and only 4% (n=2/46) thought they were higher. One woman said she was "reassured that the gene would probably not be passed down in the family" (Respondent 117).

Statistical estimates of a woman's risk of carrying an altered breast cancer gene as calculated in the specialist clinics using Cyrillic software was available for only 15 of the 47 women (32%) who responded to the study questionnaire mailed after the clinic visit. Only 4 of these women (27%) had a risk of carrying an altered breast cancer gene above 25%, and were therefore categorised by the specialist clinic as being at high risk. Overall, women's perceptions of their gene carrier status and

chances of developing breast cancer were not correlated with their calculated risks.

3.4.8. Breast cancer gene testing

Box 3.8: Prospective study summary findings: Gene testing

- After the GP referral, 77% of women wanted a breast cancer gene test. Only 17% were unsure and 6% did not want to be tested. Desire for testing was associated with women's perceived risks of developing breast cancer.
- Women wanted more information about the appropriateness of gene testing in their situation. Some women were torn about whether or not to be tested, whereas others felt it would provide much needed reassurance.
- It was considered unethical to ask women after the clinic visit whether they wanted gene testing since most would not have been offered a test (see **Figure 3.13**).

After the GP referral, over three-quarters of women said they wanted a breast cancer gene test (77% (n=96/125); 95%CI 69-84). Seventeen percent (n=22/125) did not know whether they wanted to be tested and only 6% (n=7/125) said they did not want to be tested. Desire to have a gene test was associated with increasing perceived lifetime risk of developing breast cancer (U=823, n=124, p=0.001).

Regarding women's reservations about being tested, women felt they needed more information as they had not yet discussed all the implications (n=7). One woman said she had an "overwhelming feeling of ignorance" (Respondent 7). Another said: "I would like to be given advice on appropriateness of gene testing to my situation" (Respondent 197). Women were "divided" about whether or not to have the test, what would happen if it the test came out positive, could they live with the consequences (n=6). One woman wrote: "I'm a little torn – part of me adheres to the 'ignorance is bliss theory' – such knowledge from a test can be worrying. Part of me wants to know the reality so that I can make the most of my life" (Respondent 154). Five women felt that having the test would provide reassurance and stop them worrying: "I do worry and get depressed so it would reassure me" (Respondent 1).

3.4.9. Cancer specific worries

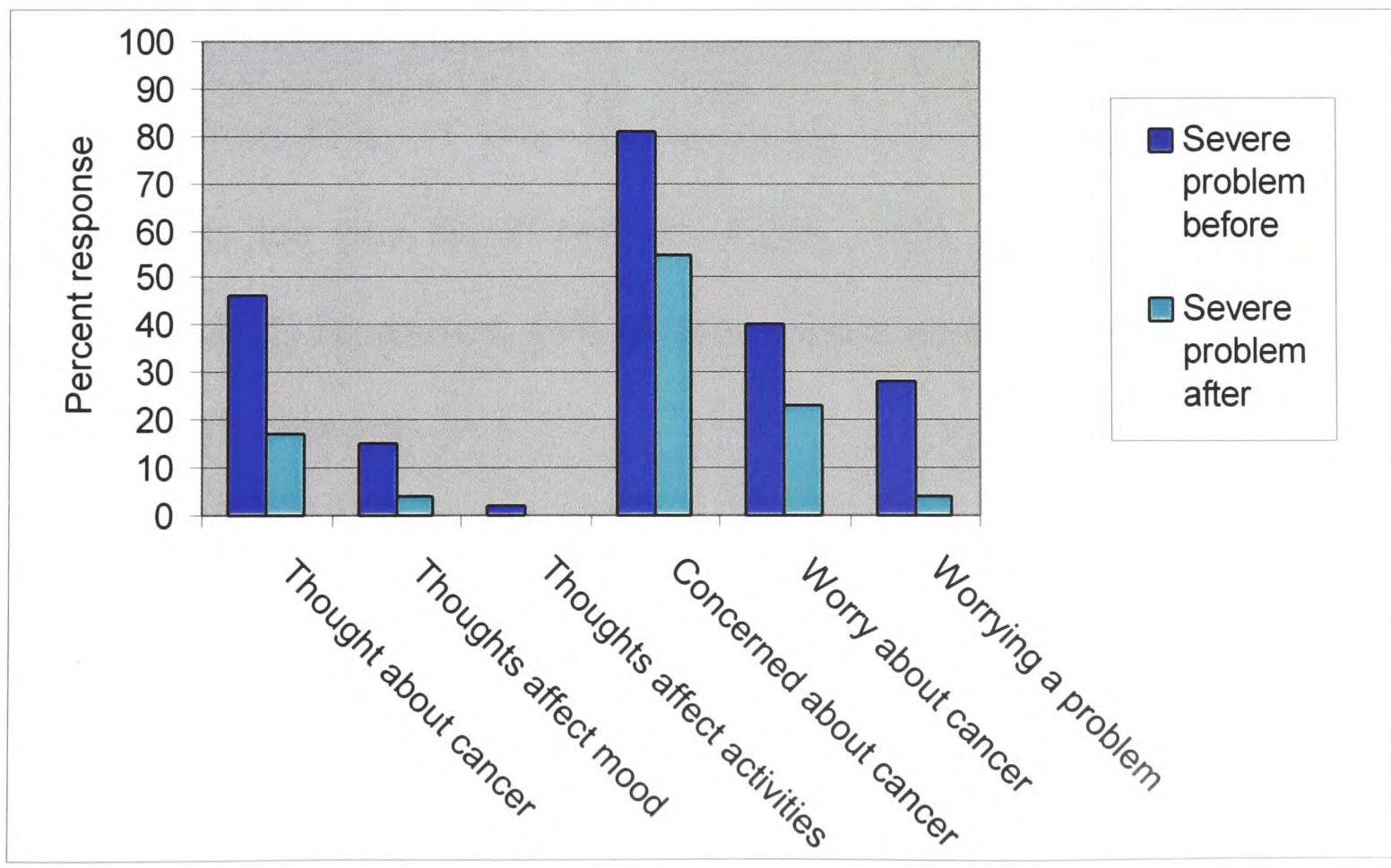
Box 3.9: Prospective study summary findings: Cancer worries

- After the GP referral, 46% of women thought about their chances of developing breast cancer often or almost all the time. Although these thoughts were not likely to affect their mood or interfere with daily activities, 81% were moderately or very concerned and 40% worried frequently or even constantly, especially younger women. For 28% worrying about getting breast cancer was a definite or severe problem. The median Cancer Worries score after the GP referral was 13.
- Cancer worries were correlated with perceived risks of developing breast cancer, but not "actual" risks calculated using Cyrillic in specialist clinics.
- After the clinic visit, all but one of the Cancer Worries Scale items decreased in severity, and the median score was reduced from 13 to 11.
- Women's coping strategies for dealing with their worries included talking to family and friends (38%), witnessing the experiences of relatives who had been diagnosed with breast cancer (19%), being proactive (18%) and seeing their GP (11%).

After the GP referral, almost half of respondents had thought about their chances of developing breast cancer "often" or "almost all of the time" during the previous month (46% (n=59/127)) (see **Figure 3.18**). Thoughts about their chances of getting breast cancer were not likely to affect their mood (15% (n=19/127) responded that their mood was affected "often" or "almost all of the time"). Nor did these thoughts affect their ability to perform daily activities (2% (n=3/127) responded that activities were affected "often" or "almost all of the time"). Nonetheless,

81% of women (n=101/124) considered themselves to be "moderately" or "very concerned" about the possibility that they may get breast cancer someday, and 40% (n=51/127) said they worried about it "frequently" or even "constantly." Younger women were more likely to respond that they worried more (R=0.303, n=127, p=0.001; for example, 31% of women under 40 (n=39/127) said they worried "frequently" or "constantly" compared to 9% of women over 40 (n=12/127)). For 28% of women (n=35/125) worrying about breast cancer was definitely a problem for them, if not a severe problem.

Figure 3.18: Breast cancer worries before and after attending a specialist clinic



Out of a minimum score of 6 on the Cancer Worries Scale, where none of the items posed a problem, to a maximum score of 24 where all 6 of the items posed a severe problem, before the clinic visit, women scored a median of 13 (inter-quartile range 11-16, absolute range 6-24). Women's Cancer Worries scores were strongly correlated with their perceived risk ($R=0.358$, $n=122$, $p<0.001$), but not with their risk calculated at the specialist clinic using Cyrillic ($p=0.663$).

After the clinic visit, all but one of the items on the Cancer Worries Scale (i.e. all items except worrying about getting breast cancer) had decreased in severity. Overall, the median Cancer Worries Scale score decreased from 13 to 11 (inter-quartile range 9-13, absolute range 6-16), and this too was significant ($W=-4.245$, $n=44$, $p<0.001$; 73% of scores ($n=32/44$) decreased, 18% ($n=8/44$) remained the same and only 9% ($n=4/32$) increased).

3.4.9.1. Coping with worries

Women had a number of ways of coping with their worries. Many women found information and reassurance by talking to their family and friends (38% (n=32/84)), and especially to husbands (n=6), sisters (n=5) and mothers (n=3). Almost one fifth of respondents felt that witnessing the experiences of their relatives with breast cancer, visiting them in hospital, seeing the modern treatments available, the survival rates of their relatives and seeing how they have coped, helped respondents to cope with their own worries (19% (n=16/84)). One woman said "having had a relative suffer and die from breast cancer, has eased worries and helped me to understand it a lot better, and that the earlier the treatment the better" (Respondent 19). Women felt that being proactive and the prospect of screening, and early detection, diagnosis and treatment helped them to cope (18% (n=15/84)). One woman said that she wanted to be "doing something positive about it – so I don't have any nagging doubts that I could have done something" (Respondent 198).

Some women found that their GP helped them to cope with their worries (11% (n=9/84)). Telling their GP about their family history, making their GP aware of the issue, and having a "patient, understanding and reassuring" GP were all considered helpful. Some women felt that

nothing helped them to cope with their worries (11% (n=9/84)). One woman said: "Nothing has really helped. I would have liked to discuss this with my GP but he was very busy and skirted around the subject" (Respondent 9).

There were women who tried not to think about their worries by keeping busy and pushing these thought to "the back of their mind". One woman said: "Getting lost in work is all I can do. V.v. [very, very] frightened about this" (Respondent 178). Whereas others adopted a pragmatic and positive attitude that it was not worth worrying about getting breast cancer (10% (n=8/84)). One woman said: "I'm an optimist by nature and although I have some concern I take the view that most women don't get breast cancer" (Respondent 113).

3.5. Discussion

This prospective descriptive study has shown that women with breast cancer in the family who present to primary care perceive themselves to be at increased risk (regardless of their actual risk). Women also have considerable cancer-specific worries that are correlated with their perceived risk of developing breast cancer. These findings are in keeping with results of previous research and experience regarding the

psycho-social implications of hereditary diseases, and of familial breast cancer in particular [Biesecker et al, 1993; Black et al, 1995; Evans et al, 1993; Kash et al, 1995; Lerman and Croyle, 1994; Lerman et al, 1995a; Lynch et al, 1994; Murday, 1994; Ryan, 1997; Ryan and Skinner, 1999; Saunders et al, 1999; Watson M et al, 1998 and 1999; Williams T, 1999; Wright et al, 1999]. Moreover, the way in which the question on risk perception was asked in this study (i.e. by comparing one's risk to the average woman rather than using numbers) has been shown to be a more accurate way of assessing women's true perceptions [Woloshin et al, 1999].

A particularly important finding was that wanting preventive and screening options were also correlated with risk perceptions, and this has also been found in other studies [Geller et al, 1999]. The strong desire to engage in mammographic screening and genetic testing, which in practice are only appropriate for and offered to a limited number of women, may also be related to women having little knowledge about these issues (for instance, not knowing that women under 50 undergoing mammographic screening are more likely to have false positives and false negatives, or even knowing about any potential negative consequences of mammography) [Domenighetti et al, 2000;

Sarfati et al, 1998; Savalescu, 1997]. Thus reducing risk perceptions and cancer worries must be combined with providing information about women's risks and options so that they can make more informed choices about their care.

Women's main information need was to learn more about their chances of developing breast cancer. Women most wanted to learn this information by talking to a consultant. Even if GPs are women's first port of call regarding breast cancer worries [de Bock et al, 1997], that they are not necessarily women's first choice as information providers is supported by previous research in this area [Audrain et al, 1998; Gross et al, 2000].

Previously women's main sources of information about breast cancer had been multiple, including family and friends, the media and health care professionals. The greatest amount of information had come from their family, the most reassuring from doctors and the most worrying from the media, which is in keeping with previous findings [Johnson J and Meishcke, 1992; Rowan and Bowcott, 1998]. Despite the drive towards web-based health information [Cochrane, 1999; Ferguson,

1997; Jadad, 1999; Shepperd et al, 1999], very few women cited the internet as one of their sources of information about breast cancer.

Women had often mentioned the issue of breast cancer in the family on multiple occasions with their GP, and it was most often women themselves who raised the issue. Health anxiety has previously been associated with repeated self-initiated general practitioner consultations [Conroy et al, 1999], and may be linked to patients normalising and not voicing their problems resulting in their anxieties not being detected or addressed by the physician [Barry et al, 2000; Kessler et al, 1999].

Women's reasons for presenting to primary care included a recent cancer diagnosis or death of a relative and reaching the age at which a relative was diagnosed. This fits well with previous research that found that deciding to seek medical care is associated with an individual's feeling of vulnerability and the perceived severity of the condition which they feel they are at risk of developing [Campbell and Roland, 1996].

Women's expectations of the primary care visit were to discuss their risks and to be provided with information, often about mammography and gene testing in particular, as well as to be offered reassurance.

Women's expectations were met in part. However, most often women reported that the GP would ask about the number of relatives diagnosed and the ages at which they were diagnosed, and would refer to a specialist. Although this is in keeping with clinical guidance for GPs [Watson E and Lucassen, 1999], it may not be sufficient in reassuring women at the time of consultation (especially for women who are not referred). Previous research has found that patients feel more reassured when they feel that their problems have been properly acknowledged [Donovan and Blake, 2000]. Research has also shown that about 80% of GPs refer women with concerns about a breast cancer family history, not all of whom are at increased risk [de Bock et al, 1999; Suchard et al, 1999]. A referral may be sufficient in addressing a patient's concerns in some cases, but for others, it may be insufficient in meeting women's needs. It has been further argued that even meeting expectations is insufficient, it is important to involve patients and to inform them of what is in store [Greenhow et al, 1998].

It has been suggested elsewhere that there is a potential mismatch between the aims of specialists who wish to discuss genetic risk information in detail and the aims of women who may view a referral regarding their family history as a means of receiving screening

[Richards M, 1993]. The findings of this research has shown that although many women wanted mammographic screening or genetic testing, women primarily (or at least initially) hoped the specialist would discuss their risks, provide information and offer reassurance. Such findings have also been found elsewhere [Brain et al, 2000; Hallowell et al, 1997b; Williams T, 1999], and in practice women often considered that these needs were addressed.

The true imbalance lay in the fact that women referred to genetics clinics were on average younger, more educated and more qualified than women referred to breast clinics. Although, the entire sample was a well educated one, this may have something to do with the fact that breast cancer is more common in women of higher social classes [Cancer Research Campaign, 1996]. However, with regards to referral patterns, the women being seen at the genetics clinics were more likely to spend more time at the clinic and to discuss the pros and cons of various screening and testing options with the specialist. Some women may prefer a breast clinic where they are examined as opposed to a genetics clinic where there is greater opportunity for in-depth discussion. However, the findings of this study suggest that there may exist inequalities in the referral and management of women with a family

history of breast cancer, as have been shown to exist within the health care system in general [Acheson, 1998; Benzeval et al, 1995]. With regards to breast cancer care, ranging from breast cancer screening to treatment and follow-up, it has been shown that women from more affluent groups tend to ask more questions, be better informed and to demand better access to services than women from more deprived backgrounds [Davey et al, 1999]. There is scope for future research in this area regarding familial breast cancer. In this instance, it is possible that more educated women may be doing themselves more harm than good in being referred, as delving into risks estimates and the associated options is fraught with uncertainty.

Following the secondary care visit, women's perceptions of their own risks decreased significantly, as did their cancer worries. This correlation was found in previous studies [Hopwood et al, 1998; Kent G et al, 2000]. However, over half of women had no change, and accordingly the absolute reductions in risk perceptions and cancer worries were modest. Women coped with their worries by discussing the issue with others, learning from the experiences of their relatives, and being proactive in attempting to join early detection programmes. Once again, reinforcing that women's desire for mammography and gene testing may be a form

of coping mechanism for women to deal with their worries in the face of heightened risk perceptions.

After the clinic visit, women said they had understood everything they had been told by the specialist. However, this study as well as others [Evans et al, 1993; Watson M et al 1998] have found that women's risk knowledge did not always increase, nor were women able to recall actual risk figures [Watson M et al, 1999]. Although, risk knowledge was not associated with risk perceptions and cancer worries, it is a pre-requisite for informed choice. The knowledge that is currently being measured in research studies (e.g. risks expressed in numerical terms) may not be the kind of knowledge women need to make informed choices. Thus more work may be needed in constructing research questions about risk knowledge worded in ways that are best understood and most useful to women in deciding about their options.

A high proportion of women wanted mammographic screening and gene testing, even though, or perhaps because, many had limited knowledge about them. It has been shown elsewhere that women in general, as well as those with a family history of breast cancer, tend to over-estimate the effectiveness of screening [Barratt et al, 1999; Black et al ,

1995]. About one third of women who undergo breast screening over a ten year period will have a false positive result [Elmore et al, 1998; Fletcher, 1999], with all the psychological consequences that entails [Lerman et al, 1991a; Ong et al, 1997]. However, a recent American study showed that the majority of women do not want to take false positives into account when deciding about screening [Schwartz L et al, 2000]. Women's sense of duty to do something may cause them to choose screening options despite potential negative consequences, because simply doing nothing may not be considered an option [Charles et al, 1998; Hallowell, 1999; Marshall, 1995]. A previous study had also found that many women referred to family history clinics had already been screened for cancer at some time prior to their referral [Richards M et al, 1995].

3.5.1. Limitations of the study

As in another study [Greenhow et al, 1998], this research may be criticised for measuring patient expectations and needs following the primary care consultation. Ideally, it would have been of great interest to obtain the views of women who consult primary care and are not referred. However, logistically this was not possible as the number of breast cancer family history cases that any one GP sees over the

course of the year is very small (for a GP with an average list size of 2000 patients, about 18 patients will have a first degree relative with breast cancer and approximately 14 will consult their GP each year) [de Bock et al, 1997; Johnson N et al, 1995]. Thus although women who are referred represent only a proportion of those who consult their GP [Kahn, pers. comm.], and those referred may represent a group with greater cancer-specific distress [Peshkin and Lerman, 1999], recruitment from secondary care was the best possible option.

Recruiting women from the specialist clinics also had its difficulties in that the busy administrative staff were relied upon to identify incoming letters of referral and to provide the details of when clinic appointments had been scheduled. Unfortunately, as a result, only 73% of the referral letters (n=201/277) were passed on to the researchers and 7 appointments were not made known to the researchers in time. However, there does not appear to have been any systematic omissions of referrals to this study as can be seen from later comparing the number of women omitted and included, who were considered by the specialist to belong to different risk groups (low, moderate and high). What did not occur, however, was timely flagging of low risk referrals, and thus many were sent the regular version of the questionnaire, often

these women also were not seen in clinic and therefore were not sent a follow-up questionnaire.

In terms of the analysis of the study, many statistical tests were performed to assess whether there was an association between age, education, and degree of family history with women's attitudes and experiences. It was felt that performing these tests might provide valuable information that could be useful for health care practitioners. However, from a statistical point of view, performing many statistical tests increases the possibility of Type I errors (i.e. obtaining a significant result and rejecting the null hypothesis when the null hypothesis is in fact true) [Altman, 1991]. For this reason, the results of these tests of association should be interpreted with caution.

3.5.2. Implications for primary care

This prospective descriptive study has shown that women with a family history of breast cancer have information needs that they would prefer to be addressed by a specialist, but should also be addressed and reinforced in primary care. Women's main expectations of the GP consultation are to receive information and to discuss their risks of breast cancer. Although it is good practice for GPs to assess a woman's

family history by asking the number of affected relatives and the ages at which they were diagnosed with cancer, this should not preclude discussion of women's concerns and provision of information during the consultation. As well, because women may have a long wait before being seen at the specialist clinics, and at the genetics clinics in particular, the provision of verbal and written information within primary care takes on an even greater importance.

4. Development of an information leaflet for women with a family history of breast and/or ovarian cancer

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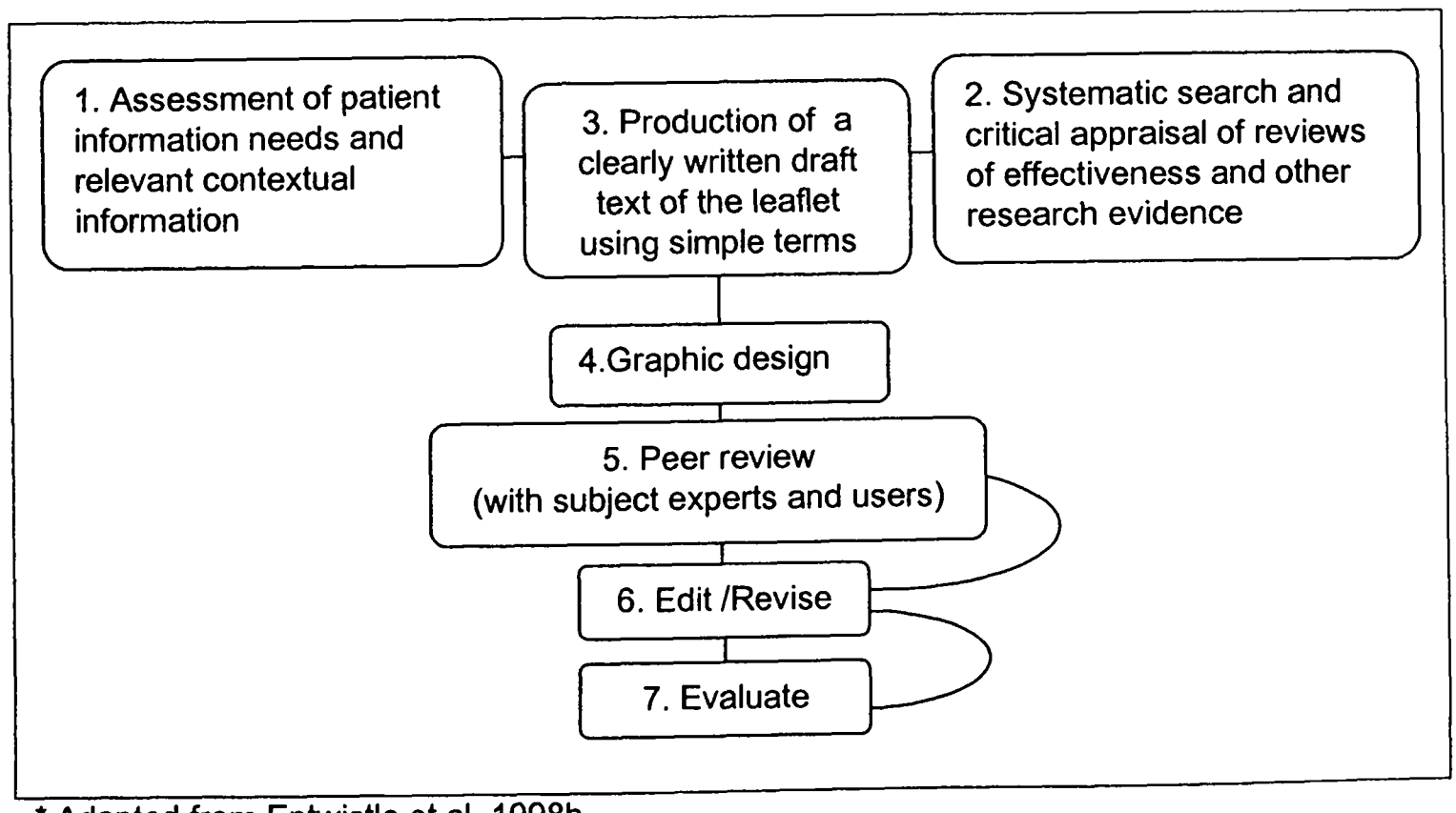
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4.1. Introduction

As a result of the recent consumer movement in health care, the provision of high quality patient information has become a priority in today's health service [Department of Health, 1999; National Health Service Executive, 1996]. There are several guidelines, some very recent, on how to produce quality information that meets patient needs [Austoker et al, 1997; Broadstock, 1993; Centre for Health Information Quality, 1998; Duman, 1998; Duman and Farrell, 2000; US Department of Health and Human Services, 1992]. The basic process of producing patient information is illustrated in **Figure 4.1**.

Figure 4.1: The basic process of producing patient information*



* Adapted from Entwistle et al, 1998b.

The three important first steps of the information production process are:

1) Involving consumers from the outset to address the issues which are important to them,
2) Finding and appraising evidence-based information from randomised trials, systematic reviews and meta-analyses, and
3) Clearly communicating the information in ways that make sense to the intended audience [Centre for Health Information Quality, 1999a].

Previous chapters of this thesis have demonstrated that women with a family history of breast cancer who are referred from primary care have unmet information needs and would like additional take-home information. There is growing evidence that patients are generally unable to access the information they need [Coulter et al, 1998]. The provision of written information about breast cancer and breast cancer screening has been shown to decrease patient anxiety and to increase patient satisfaction with their care [Austoker and Ong, 1994; Vetto et al, 1996]. Our research, as well as other studies [Coulter, 1998; Vahabi and Ferris, 1995; Weinman, 1990], have found that patients want written

information to complement, but not to replace, verbal explanations provided by health care professionals.

This chapter describes the initial three steps (see **Figure 4.1**) in the development of a patient information leaflet to meet the needs of women consulting their GP regarding their family history of breast cancer.

4.2. Aims

The primary aims in developing an information leaflet for women with a family history of breast cancer who consult primary care are:

1) To complement the information provided during a GP consultation
2) To provide useful, accurate and reliable information
3) To cover the topic areas that women consider relevant and important
4) To present the information in a way that is caring and easy to understand

The more far-reaching goals of the leaflet that are less straightforward to evaluate include:

1) To provide reassurance
2) To improve patient understanding

3) To suggest options and assist in the decision-making process

4) To facilitate communication with physicians and family members

5) To promote patient choice

4.3. Methods

4.3.1. Previously developed patient information

To avoid any unnecessary replication prior to developing a new information leaflet, and to identify any wording that may be particularly useful in explaining difficult concepts, a systematic search was carried out to determine what breast cancer family history patient information is already in existence or in preparation.

Systematic searches were carried out in seven electronic databases using the search strategy outlined in **Figure 4.2**.

Figure 4.2: Template for systematic searches of databases*

No.	Records	Request
1	124046	BREAST
2	912579	NEOPLASMS
3	83539	BREAST NEOPLASMS IN MESH
4	124046	BREAST
5	428537	CANCER*
6	88988	TUMOUR*
7	473524	TUMOR*
8	60569	BREAST near (CANCER* or TUMOUR* or TUMOR*)
9	93121	#3 or #8
10	237957	FAMILY
11	39717	FAMILIAL
12	34187	HEREDITARY
13	942636	GENETIC*
14	1116100	FAMILY or FAMILIAL or HEREDITARY or GENETIC*
15	372939	RISK
16	1435938	#14 or #15
17	22274	#16 and #9
18	1847735	PATIENT*
19	11806	CLIENT*
20	19812	CONSUMER*
21	25173	USER*
22	208646	WOMEN
23	2007448	PATIENT* or CLIENT* or CONSUMER* or USER* or WOMEN
24	294409	EDUCATION*
25	207901	INFORMATION*
26	482947	EDUCATION* or INFORMATION*
27	5818	LEAFLET*
28	8486	BOOK*
29	334	BROCHURE*
30	25731	VIDEO*
31	26951	AUDIO*
32	14092	TAPE*
33	39074	WEB*
34	3378	INTERNET*
35	119188	LEAFLET* or BOOK* or BROCHURE* or VIDEO* or AUDIO* or TAPE* or WEB* or INTERNET*
36	584935	#26 or #35
37	70135	#23 near #36
38	789	#17 and #37
39	656985	PATIENT
40	275664	EDUCATION
41	85134	ATTITUDE
42	716036	HEALTH
43	77935	(PATIENT EDUCATION IN MESH) OR (ATTITUDE TO HEALTH IN MESH)
44	210	#38 and #43

* Used for searching Medline, slightly modified for use in other databases.

The electronic databases searched included Medline, EMBASE, CINAHL - the nursing and allied health literature database, Sigle - the grey literature database, PsycLIT - the psychological literature database, AMED - the allied and complementary medicine database, and Sociofile - sociological abstracts.

Databases of reviews (i.e. Best Evidence and the Cochrane Library) and of theses (i.e. Aslib Index to Theses and Dissertation Abstracts) were also searched, as were internet-based cancer literature databases (e.g. OncoLink and CancerLit) [Cotterill, 1999]. The index lists of the three journals most relevant to this topic were hand-searched: *The Journal of Cancer Education* for the period 1996 to 1999, *The Health Education Journal* from 1990 to 1999 and *Health Expectations* from 1998-1999. References of the articles retrieved from these searches were inspected to potentially identify further relevant publications.

However, details of the development and evaluation of patient information materials often remain unpublished. Therefore patient literature databases of the following organisations were searched for actual documents: the Scottish Health Education Board, the Health Education Authority for England and Wales, the National Cancer

Institute in the USA, the Patient UK database and the Patient Information Projects Exchange Register (PiPER) at the Centre for Health Information Quality in Winchester.

In addition, experts in the field including clinical geneticists, breast surgeons, GPs and academic researchers were personally contacted, as were the breast cancer information organisations, such as CancerBACUP, Breast Cancer Care and the Women's Nationwide Cancer Control Campaign. Individuals were asked about their knowledge of any breast cancer family history patient information materials currently in use, any unpublished materials or works-in-progress, and the names of other experts in the field who may be useful contacts in this respect.

Once the patient information documents were collected, they were categorised and critically appraised according to QUICK and DISCERN guidelines [Health Education Authority and Centre for Health Information Quality, 1999; Charnock et al, 1999].

4.3.2. Patient information needs

Regardless of what patient information is already in existence, one cannot assume that it addresses the issues that are important to patients. Therefore needs assessment research is now considered essential when developing new information resources [Amos, 1993; Centre for Health Information Quality, 1999a].

Women's information needs were assessed using qualitative and quantitative methods as described in previous chapters of this thesis. In addition, a systematic search was carried out to identify any further research in this area by employing a similar search strategy to the one used above to identify the relevant patient literature (see **Section 4.3.1.**).

Articles retrieved were critically appraised according to accepted methods [Greenhalgh, 1997]. This involved assessing whether the results of the studies were valid, what the actual study results were, and whether those results were relevant to the development of a leaflet for women with breast cancer in the family who present to primary care.

4.3.3. Evidence in support of the information

All patient information should be supported by research evidence, and whenever possible, by secondary research (i.e. systematic reviews, meta-analyses and economic evaluations) [Centre for Health Information Quality, 1999b]. Where there are gaps in the evidence, or where the evidence is based on anecdote or opinion as opposed to well-designed randomised trials, this should be made explicit.

With this in mind, the search for the evidence in support of the information to be included in the leaflet (i.e. lifetime cancer risks, etc.) focussed on the contents of the Cochrane Library and the Best Evidence database (the latter consisting of *ACP Journal Club* and *Evidence Based Medicine* contributions). As well, *Effective Health Care Bulletins* produced by the NHS Centre for Reviews and Dissemination and Cancer Research Campaign *Fact Sheets* were used as reliable sources of evidence-based information. The findings taken from the above sources have already been through a process of critical appraisal.

Where these sources of evidence were not appropriate (i.e. for questions regarding the consultation process and referral process), key informants were used.

4.3.4. Developing the draft leaflet

On the basis of the methods described in this chapter, and by following guidelines for the clear communication of medical information [Doak et al, 1996; Vahabi and Ferris, 1995], a draft leaflet was developed. This leaflet was sent to specialists in the field for comment including consultant geneticists, a genetics nurse and breast surgeons.

4.4. Results

4.4.1. Previously developed patient information

The systematic searches of electronic databases, databases of reviews and databases of theses, as well as hand-searching three highly relevant journals, identified several articles, but only one report of patient educational materials for women with a family history of breast cancer intended for use in a community-based or primary care setting [Warner et al, 1999]. To obtain a copy of the materials the authours were contacted by e-mail but they responded that the draft information

was still under evaluation and the final version would only be available by the year 2001.

The patient information literature does contain a number of educational tools intended for use immediately before, after or during genetic counselling consultations. These include educational counselling strategies [Evans et al, 1994a; Kash et al, 1995; Lerman et al, 1996b, 1997a and 1999; Watson M et al, 1999], videotapes [Cull et al, 1998], written summaries [Hallowell and Murton, 1998] and a shared decision-making program [Stalmeier et al, 1999]. Other educational strategies for which the setting is not specified include a risk assessment tool [Lippmann et al, 1992], greater involvement of nurses in educating at-risk individuals [Fitzsimmons et al, 1989], a telephone helpline breast cancer risk analysis service [Kelly, 1987] and an interactive computer program [Green M and Fost, 1997]. One study explores the information that women receive via the media, which can in itself be considered an educational strategy [Gerlach et al, 1997]. There are also a number of psycho-therapeutic interventions [Alexander et al, 1996; Esplen et al, 1998; Schwartz M et al, 1998], and a physician-affect intervention [Shapiro et al, 1992], intended to assist women with a family history in assimilating breast cancer risk information.

Searching the patient information document databases did not produce any materials specifically regarding breast cancer family history. Using the internet-based cancer information sites did identify some American materials, however these were almost entirely limited to genetic testing issues [National Action Plan on Breast Cancer, 1997; University of Pennsylvania Cancer Center, publication date unknown] and to the use of tamoxifen in preventing breast cancer [National Cancer Institute, 1998].

By far the most successful approach was contacting various experts in the field and national organisations in a number of countries. Two general booklets on breast cancer in the family, one from Australia [National Breast Cancer Center, 1997], and one from the UK [Jackson, unpublished(a)]; two general leaflets, one published [Mackay, 1997], and one unpublished [Jackson, unpublished(b)]; leaflets produced by individual secondary care clinics [Breast cancer family history clinic, publication date unknown; Lucassen, unpublished] and a booklet sponsored by the media [Dixon and Bryan, 1997] were identified in this way. Two of the above materials and a further fact sheet on familial

cancers [Imperial Cancer Research Fund, 1999] were listed in the new Macmillan Directory of information materials [Dickens, 1999].

An appraisal of the materials identified indicated that none were appropriate for use with a general population of women with breast cancer in the family (ranging from general population risk to high risk women) who present to primary care (see **Table 4.1**). The most important DISCERN and QUICK criteria that were not met (see **Table 5.2**) were the relevance to consumers and the clarity of the information being presented.

There was some evidence that the booklets were too long and detailed. They were beyond the scope of women's initial needs, and even inappropriate and potentially anxiety provoking for women at low risk since not all patients want extensive information about their condition at all stages of their medical journey [Leydon et al, 2000]. There were materials that, although written in a well-balanced way, focussed to a large extent on genetic testing and surgical options that are only relevant to a very small proportion of the population.

Critical appraisal of the leaflets also revealed that these could be improved upon as most were too scientific and technical (especially those written by scientists and specialists) or included too many details of referral criteria that have not yet been nationally accepted. Most materials did not have any information on the referral process itself, and one leaflet that did [Breast cancer family history clinic, publication date unknown], used a very complicated flow chart to describe the process.

Table 4.1: Suitability of previously developed materials on breast cancer in the family for primary care

Title of patient information materials	Strengths and weaknesses	Patient informed and evidence based	Suitable for primary care
Breast cancer and family history: What you need to know (Booklet, 12pp) [National Breast Cancer Centre, 1997]	• Clearly written and well designed • Too much information that the majority of women may never need (i.e. details of genetic testing, p 11). • Too much information that women may find confusing (i.e. table of risk and referral criteria pp. 7-8)	Yes, based on needs assessment with patients. [Williams T, 1999]	No.
Breast cancer in families (Booklet, 22pp) [Jackson, unpublisheda]	• Clearly presented, includes useful Question & Answer section • Too much information that the majority of women may never need (i.e. details of genetic testing, pp. 14-16). • Too much information that women may find confusing and not directly relevant (i.e. section called "what are genes?" pp. 3-4)	Unsure.	No.
Cancer Genetics (Leaflet, A4) [Mackay, 1997]	• Clear description of the importance of family history • Too much information that the majority of women may never need (i.e. details of gene testing) • Too much information that women may find confusing and not directly relevant (i.e. details of referral criteria for bowel and ovarian cancer)	Unsure.	No.
Breast cancer in families (Leaflet, A4) [Jackson, unpublishedb]	• Clearly written and well designed, includes details of GP consultation and referral process • Too much information that women may find confusing (i.e. includes referral criteria which is problematic as they are complex, and more importantly, are only now being agreed upon nationally)	Unsure.	No.

Table 4.1 cont.: Suitability of previously developed materials on breast cancer in the family for primary care

Title of patient information materials	Strengths and weaknesses	Patient informed and evidence based	Suitable for primary care
BRCA genes and breast cancer - Questions and answers for patients (2-sides of A4) [Lucassen, unpublished]	• Written in a Question & Answer style • Too much information that the majority of women may never need (i.e. details of gene testing) • Too much information that women may find confusing and not directly relevant (e.g. "BRCA1 or 2 are genes that make a protein that is important for the normal function of cells…")	Unsure.	No.
Breast cancer family history clinic information leaflet (Leaflet, A4) [Breast Cancer Family History Clinic, date unknown]	• Clearly written • Too much information that women may find confusing (i.e. details of clinical trials and referral criteria, and an especially complex schema of the referral process)	Unsure.	No.
Breast cancer genes: The decision (Booklet, pp. 16) [Dixon and Bryan, 1997]	• Clearly written and well designed, includes list of further resources for women • Too much information that the majority of women may never need (i.e. details of gene testing pp. 7-8) and information that is potentially anxiety-provoking (i.e. surgical options pp. 10-12)	Unsure.	No.
Family cancers (4 sides of A4) [Imperial Cancer Research Fund, 1999]	• Clearly written • Too much information that women may find confusing (e.g. "cancer is due to a series of genetic errors which occur in a cell in the body…"), not directly relevant and potentially anxiety provoking (i.e. information about ovarian, bowel, retinoblastoma and skin cancers).	Unsure.	No.

Most importantly, it was apparent that the identified materials had not been designed based on any research evidence of women's information needs, nor evaluated with potential users, with the exception of the Canadian materials [Warner et al, 1999] and the Australian booklet [National Breast Cancer Center, 1997; Williams T, 1999].

None of the materials identified through the systematic search both met the quality criteria and were suitable for the primary care setting. The Canadian materials appear to be the most suited, however they are not yet available, and even once available, they may not be transferable to the UK setting. The Australian booklet, although researched and evaluated, was considered too lengthy and beyond the scope of women's general information needs when consulting their GP.

Thus it was decided to develop a new leaflet combining the merits of the previously developed materials but with the primary intention of addressing the information needs of women who consult their GP about breast cancer in the family.

4.4.2. Patient information needs

The information needs of women with a family history of breast cancer who present to primary care identified by the two studies reported in previous chapters of this thesis are listed in **Table 2.3** and **Figure 3.5**.

Systematic searches of the literature identified further research regarding the information needs of women with breast cancer in the family, however these studies mostly focused on the genetic counselling consultation [Audrain et al, 1998; Hallowell et al, 1997a and 1997b; Lloyd et al, 1996; Moller et al, 1999; Napoli, 1997; Ryan and Skinner, 1999; Thirlaway et al, 1996] or genetic testing in particular [Geller et al, 1997 and 1998; Tessaro et al, 1997].

The main findings of this research relevant to a primary care leaflet were that most women did not feel prepared for the genetics clinic visit, and that although women expected to discuss their risks and risk management options in secondary care, they often did not know what else to expect. It has been recommended that women referred due to their family history would benefit from written information prior to being seen in secondary care. Such information should describe what will occur at the genetics clinic, what topics will be discussed, as well as

background information about breast cancer and heredity [Hallowell et al, 1997b].

The most relevant research regarding women's information needs in a community-based or primary care setting include the Canadian study of the development of an information aid [Warner et al, 1999] and the Australian study which led to the development of the information booklet [Williams T, 1999]. Both of these studies based the development of their educational materials on qualitative research with women. However in the Canadian study only one of their four focus groups involved women with a family history, whereas the Australian study demonstrated that there are differences in the findings between community based samples and samples of women with a family history. Both studies also used reviews of the literature and key informants in the development of their materials for identifying information needs of women.

The information topics that the Canadian researchers chose to include in their patient information materials were: an overview of breast cancer, breast cancer risk factors, hereditary breast cancer, a personal family history checklist, lifestyle and screening recommendations, a glossary of terms and a list of further resources [Warner et al, 1999].

The information topics chosen to be included in the Australian brochure were: what is breast cancer, why does it occur, what is hereditary breast cancer, what are the main risk factors, what is meant by a family history, how does family history affect one's risk of breast cancer, risk assessment information, options for women with a strong family history, genetic testing and breast cancer, important issues in genetic testing, and what can be done about breast cancer risk [Williams T, 1999].

The information needs found to be important by the Canadian and Australian studies are quite similar to the results of the two studies reported in previous chapters of this thesis (**Table 2.3 and Figure 3.5**). All of these results, as well as the relevant findings from the studies obtained by systematically searching the literature, were synthesized. Seven main topics to be addressed by the new patient information leaflet were thus identified and are listed in **Table 4.2**.

Table 4.2: Patient information needs to be addressed by leaflet

- **Breast and ovarian cancer in general**
  - Risk of developing cancers
- **Hereditary breast and/or ovarian cancer**
  - Risk of breast cancer in the family being hereditary
  - Cancer-predisposing genes
- **The GP consultation**
- **Breast awareness and care**
- **What to expect from a referral to secondary care**
  - At the breast clinic
  - At the genetics clinic
- **Screening and prevention**
- **Further sources of information**

4.4.3. Evidence in support of the information

The evidence in support of each piece of information that women wanted to know about (**Table 4.2**) is described in this section.

The population lifetime risk of developing breast cancer is 1 in 11 [Cancer Research Campaign, 1998]. Family history is a well-established risk factor for the development of breast cancer [Pharoah et al, 1997]. The link between breast and ovarian cancer exists in *BRCA1*-positive families [Castilla et al, 1994; Ford et al, 1994]. Therefore certain

information regarding ovarian cancer is included in the leaflet, but only in relation to the assessment of breast cancer risks. It is estimated that the two known dominantly-predisposing breast cancer genes are responsible for only 4-5 percent of breast cancer cases, 10-15 percent are likely hereditary non-*BRCA1* and non-*BRCA2* cases, and over 80% of breast cancer cases are sporadic [Evans et al, 1994b].

UK guidelines for risk assessment and referral of women with a family history of breast cancer have only recently been published [Eccles et al 2000], however there is still no national consensus. The process of consulting a GP about a family history of breast cancer involves taking a family history and making a preliminary risk evaluation. For those women not at increased risk, obtaining reassurance, practising breast awareness (see Austoker, 1994a) and attending mammography screening after the age of 50 is recommended [Hoskins et al, 1995]. For women at moderate to high risk, a referral to a specialist is usually indicated [Pharoah et al, 1998a]. A visit to a breast clinic may involve a more detailed risk evaluation and arrangements for mammography surveillance if appropriate [Clarke, pers. comm.]. A visit to a clinical geneticist is likely to involve a more lengthy discussion of risks and options, and a referral for mammography surveillance if appropriate,

however gene testing is usually only offered to a very small minority of women with a very strong family history (i.e. 4 or more relatives on the same side of the family with breast and/or ovarian cancer) [Lucassen, pers. comm.].

There is currently no strong evidence that mammography screening decreases breast cancer mortality in women under 50 [Cancer Research Campaign, 1997; Daudt et al, 1996; Goodwin, 1995; Mushlin 1993; Willett, 1996], and there may be some evidence of harm [Royal College of Radiologists, 1998]. Nonetheless, some feel that the evidence in favour of screening women under 50 is becoming stronger, and that the benefits of screening women with a family history would outweigh the risks [Pharoah et al, 1998b].

Similarly, there is also no strong evidence that chemoprevention, prophylactic surgery, increased exercise, low-fat/high-fibre diets and the avoidance of exogenous hormones lead to a reduction in mortality from breast or ovarian cancer, although with continued research, these options may in the future be shown to be effective [Bruzzi, 1998; Cancer Research Campaign, 1996; Clarke, 1998; Hartmann et al, 1999; Woodman, 1999].

4.4.4. Developing the draft leaflet

Based on the above information needs and evidence in support of this information, a draft leaflet was developed (see **Appendix 4.A**). Preliminary comments on this draft were favourable and only minor revisions were made. The revised leaflet was then sent to a graphic design artist and printer to produce a high-quality version for evaluating with the intended audience (**Appendix 4.B**).

4.5. Discussion

The development of the patient information leaflet for women with a family history of breast cancer who present to primary care was patient informed and evidence based and led to the production of a draft leaflet in which the information is clearly explained to the intended audience. Producing a leaflet that is informed by patients entailed conducting qualitative and quantitative research as well as a systematic search, appraisal and synthesis of the literature. Ensuring that the information contained in the leaflet is evidence based involved systematically searching the secondary literature of meta-analyses and reviews. Finally, producing information that can be understood by the intended audience involved following guidelines for good communication.

The final step in the development of the leaflet is the evaluation of the leaflet to see whether it is acceptable to those who will ultimately be making use of it. The leaflet evaluation study is described in the following chapter.

5. Evaluation of the leaflet for women with a family history of breast and/or ovarian cancer

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5.1. Introduction

The initial development of the leaflet entitled *Breast and/or Ovarian Cancer in the Family: Learning more about your risks and options* is described in detail in the previous chapter. To determine whether the leaflet will be understood and well received by the target population, it needs to be evaluated. There is a long-standing and rapidly growing literature on the evaluation of patient information [Arthur, 1995; Barnes, 1996; Bishop et al, 1997; Burklow et al., 1988; Coulter et al, 1998; Duman and Farrell, 2000; Entwistle et al, 1998a; Estey, 1991; Frank-Stromborg, 1985; Gene Therapy Advisory Committee, 1995; Moore, 1983]. Readability formulae are widely-used as a means of assessing the clarity of written materials. Several information assessment tools have recently been developed to promote simple and systematic appraisals of the content of patient information [Centre for Health Information Quality, 1997; Charnock, 1998; Health Education Authority and Centre for Health Information Quality, 1999; Health Promotion Wales and Welsh School of Pharmacy, 1996; Meiman, 1996]. However, the most effective and all-encompassing way of evaluating educational materials is by formal assessments with the intended audience.

In this chapter, the use of three methods to evaluate the *Breast and/or ovarian cancer in the family* leaflet is described:

1) Readability formulae,
2) Patient information assessment tools, and
3) Formal evaluations with patients using:
    a) The leaflet evaluation study
    b) Pertinent sections of prospective descriptive study (**Chapter 3**)

5.1.1. Readability formulae

There are many different readability formulae [Centre for Health Information Quality, 1998] that have long been used to assess the clarity of written information. One of the oldest and most well known formula is the Flesch Reading Ease Test [Flesch, 1948] which is commonly used with the Flesch-Kincaid Grade Level. In general, readability formulae produce favourable scores for written information that has fewer words per sentence and fewer syllables per word.

The Flesch reading ease score ranges from 0 (practically unreadable) to 100 (easy for any literate person). The Flesch-Kincaid grade level predicts the approximate educational level a person must have to understand written information (see **Table 5.1**). The UK reading age

required to understand written text is obtained by adding 5 to the grade level [Ong et al, 1998]. The aim is for written materials to have a Flesch reading ease score of 70 or higher, a Flesch-Kincaid grade level of 7 or less and a UK reading age of 12 or less.

Table 5.1: Flesch reading ease scores*

Reading ease	Grade level	Description of text	Typical Text	Estimated % understand
90-100	5	Very easy	Comics	97
80-90	6	Easy	Tabloids	95
70-80	7	Fairly easy	Popular	90
60-70	8-9	Standard	Magazines	90
50-60	10-12	Fairly hard	Broadsheets	77
30-50	college	Difficult	Academic	31
0-30	graduate	Very hard	Scientific	7

*adapted from Flesch, 1948 and Ong et al, 1998.

5.1.2. Information assessment tools

Information assessment tools have recently been developed to assist in judging the quality of the content of written information. Two widely recognised tools are DISCERN [Charnock, 1998] and QUICK [Health Education Authority and Centre for Health Information Quality, 1999]. The DISCERN tool is evidence based and has undergone extensive evaluation with patient groups. The QUICK tool is a more general

information assessment tool, originally intended for use with web-based information.

5.1.3. Formal evaluations with patients

The most important step in the development of a leaflet or any other form of patient information is evaluating it with the intended audience. One may wish to assess the effect of the educational intervention on patient reactions (i.e. satisfaction with the intervention), learning (i.e. knowledge or skills acquired), behaviour change and/or decision-making [Entwistle et al, 1998a; Frank-Stromberg, 1985; Hutchinson, 1999; Spear, 1983]. As the *Breast and/or ovarian cancer in the family* leaflet contains different information that may be more or less relevant to women at various levels of risk, and as there is no behaviour in particular that this leaflet intends for women to adopt, the evaluation focused on whether women were glad to have received the leaflet and whether they were satisfied with the contents and presentation.

5.2. Aims

The specific aims in evaluating the leaflet are:

1) To determine whether the leaflet is written for the average reading age (i.e. 12 year old reading age level)

2) To determine whether the leaflet has clear aims and contains the necessary elements important in patient information
3) To determine whether women were glad to have received the leaflet
4) To assess whether the leaflet covers the information women want to know and to identify any additional information women may want
5) To assess whether the information is clearly and effectively communicated
6) To assess whether the presentation and layout are acceptable to women and to identify any changes to the leaflet women may recommend
7) To determine whether women find the leaflet reassuring and useful
8) To explore at what point women would most like to receive the leaflet (i.e. during, prior to or following the consultation with their GP)

The first aim can be addressed using readability formulae, the second with information assessment tools, but the rest require the direct input of the target population for whom the information was developed.

5.3. Methods

5.3.1. Readability Formulae

Ease of readability of the *Breast and/or ovarian cancer in the family* leaflet was assessed using the Flesch Reading Ease Test and the

Flesch-Kincaid Grade Level. To calculate the Flesch reading ease score, several samples of the leaflet text were used, each sample being 100 words in length. The average number of syllables per 100 words was calculated (*wl*). Then the average number of words per sentence in the 100 word samples was calculated (*sl*). Reading ease was calculated using the formula: 206.835 - 0.846(*wl*) - 1.015(*sl*) [Flesch, 1948]. The Flech-Kincaid Grade Level was obtained by converting the reading ease score into the US grade level required by the reader to understand the written information (see **Table 5.1** in **Section 5.1.1**).

5.3.2. Information assessment tools

The quality of the contents of the *Breast and/or ovarian cancer in the family* leaflet was assessed using the QUICK assessment tool criteria. The DISCERN tool was not used because DISCERN was primarily developed to judge the quality of publications about one particular treatment choice and therefore many of the DISCERN criteria (see **Table 5.2**) were not relevant to the evaluation of this leaflet. The QUICK tool was chosen because it is more useful in assessing a broad range of information types, and, in addition, it covers most of the non-treatment related issues included in the DISCERN tool.

Table 5.2: Quality criteria of information assessment tools

DISCERN (www.discern.org.uk)	QUICK (www.quick.org.uk)
1. Have explicit aims 2. Achieve its aims 3. Be relevant to consumers 4. Make sources of information explicit 5. Make date of information explicit 6. Be balanced and unbiased 7. List additional information sources 8. Refer to areas of uncertainty 9. Describe how treatment works 10. Describe the benefits of treatment 11. Describe the risks of treatment 12. Describe outcome without treatment 13. Describe effects quality of life 14. Make clear treatment choices 15. Support shared decision-making	1. Is it clear who wrote the information? 2. Are the aims of the site clear? 3. Does the site achieve its aims? 4. Is the site relevant to me? 5. Can the information be checked? 6. When was the site produced? 7. Is the information biased? 8. Does the site tell you about choices open to you?

5.3.3. Formal evaluations with patients

To obtain women's views of the leaflet, it was evaluated with a group of patients who had consulted their GP regarding their family history of breast cancer and had been referred to a specialist. The evaluation was carried out in two ways. First, women who received the leaflet from their GP and subsequently participated in the prospective descriptive study (**Chapter 3**) were asked questions as part of this study regarding the usefulness of the leaflet. This provided women's views about the leaflet in a true clinical situation. However, it was anticipated that the number of women who would receive the leaflet prior to participating in the descriptive study would be small and the scope of questions that could

be asked as part of the larger study questionnaire was limited. Thus, a second, independent leaflet evaluation was also carried out. This second study is the principal way in which the leaflet was evaluated. The methodology of this study is described here in detail.

5.3.3.1. Leaflet evaluation study - Study design

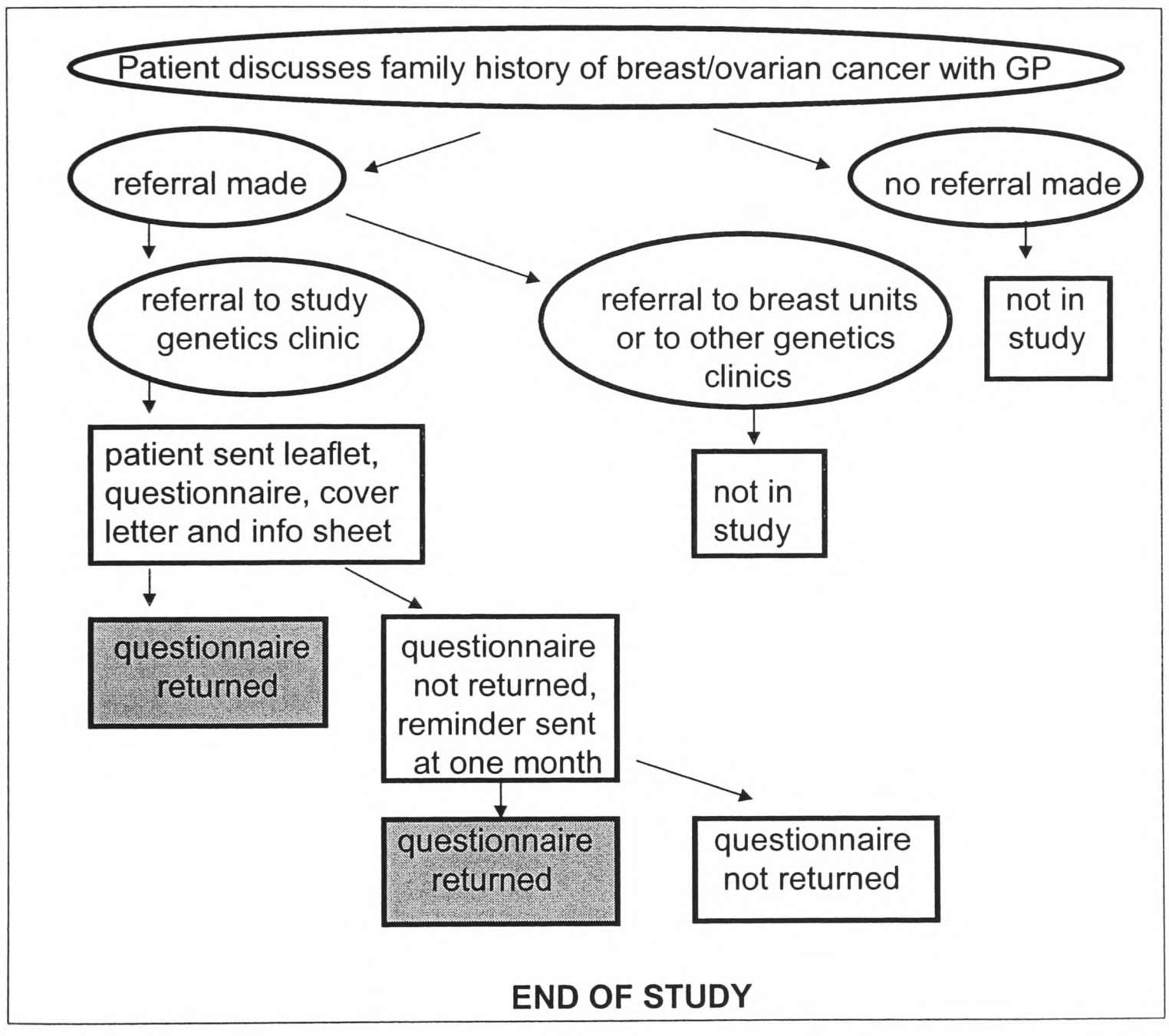
All women referred to the Cambridge breast/ovarian cancer family history clinic who were still on the waiting list, having not yet been seen by the specialist, were eligible to participate in the leaflet evaluation study. Starting at the end of the waiting list (i.e. with the most recent referrals), two hundred women consecutively listed on the waiting list were selected for recruitment into the study. Ten women were excluded as they had already participated in the pilot study (see **Section 5.3.3.3**). Mailings were sent to 190 women with a single reminder mailing at one month. The mailings consisted of the following:

1) An invitation letter to participate in the study from the consultant (**Appendix 5.A**),
2) A study information sheet (**Appendix 5.B**),
3) The *Breast and/or Ovarian Cancer in the Family* leaflet (**Appendix 4.B**),

4) A 4-page self-completion questionnaire (**Appendix 5.C**).

A schema of the study design is found in **Figure 5.1**. Ethics committee approval was obtained for the study.

Figure 5.1: Schema of leaflet evaluation study design



5.3.3.2. Leaflet evaluation study - Questionnaire design

The questionnaire entitled *Your Views About the Leaflet* (see **Appendix 5.C**) was developed by drawing from topics areas that have been assessed in previous evaluations of written patient information. A literature review revealed four main topic areas (i.e. content, presentation, access and delivery and outcomes) that are common to many patient information evaluation studies [Bishop et al, 1997; Coulter et al, 1998; Gray R et al, 1998; Haefner et al, 1998; Kennedy et al, 1999; Madden et al, 1994; McGuire, 1990; Rippen, 1997; US Department of Health and Human Services, 1992; Vetto et al, 1996]. These topic areas are outlined in **Table 5.3** and, where relevant, the topics were incorporated into the study questionnaire.

Table 5.3: Topic areas assessed in evaluating patient information

Content	• **Utility:** Relevant / Novel / Key Message • **Amount of Information:** Complete / Not too much • **Type of Information:** General overview / Causes / Consequences / Treatment options / Diagnostic interventions / Risks, benefits and probabilities / Lifestyle changes / Coping strategies / Knowledge gaps • **Promotes patient choice:** Balanced View / Accurate
Presentation	• **Language:** Comprehensibility / Readability / Style / Tone / Explains Technical Terms / Plain English • **Visual Appeal:** Impact / Colour / Illustrations / Layout / Sign-posting / Typeface Quality
Access and Delivery	• **Primary care:** GP Waiting Room / GP Visit • **Secondary care:** Specialist • **Other**
Outcomes	• **Satisfaction / Knowledge / Psychological consequences** • **Ability to share information** • **Increased choice and/or control**

The most important topics for the purpose of this study were whether the leaflet was wanted, how it should be delivered, whether it was useful, covered women's information needs, explained the information (and any technical terms) clearly and in a visually appealing way, and whether additional information was required.

5.3.3.3. Leaflet evaluation study - Pilot study

A pilot study was conducted to evaluate the usefulness and clarity of the questionnaire in eliciting women's views about the leaflet and to ensure that no ambiguities were present. The questionnaire was piloted with 30

women who were waiting to be seen at the breast/ovarian cancer family history clinic in Cambridge. Only two sub-parts to two questions appeared to be unclear or irrelevant and were omitted in the final study questionnaire.

5.3.3.4. Leaflet evaluation study - Data analysis

The data was double entered independently by two researchers onto electronic data entry forms and verified for discrepancies using SPSS Data Entry Builder 1.0. Any discrepancies found were checked against the original questionnaire.

A descriptive analysis was carried out. All statistical analyses were performed using SPSS 9.0. Binomial data was described as proportions and 95% confidence intervals. Categorical and ordinal data was described using frequencies, percentages and 95% confidence intervals (the latter obtained by generating dummy variables for each category). Ordinal data from 4-point Likert scales (1="very much" to 4="not at all") was collapsed into positive ("very much" and "somewhat") and negative ("not very much" and "not at all") categories. Percent positive responses were calculated. Continuous data was described using appropriate

measures of centrality and spread. Written comments (from open questions) were grouped according to topic and described.

5.4. Results I - Readability formulae

The leaflet consists of 959 words with an average of 1.6 sentences per paragraph, 21.3 words per sentence, and 4.3 characters per word. There is an average of 156 syllables per 100 words (*wl*) and an average of 5.6 sentences in approximately 100 words (*sl*). The Flesch reading ease score for the leaflet is 69. This falls into the score category of 60 to 70 out of a possible 100 and corresponds to the verbal description of "standard" language that one might find in magazines (see **Table 5.1** in **Section 5.1.1**). It is estimated that 90% of readers would understand information at this level. The Flesch-Kincaid Grade Level is estimated at 8th or 9th grade (secondary school level). The UK reading age corresponds to that of a 13 or 14 year old.

5.5. Results II – Information assessment tools

The findings of the leaflet appraisal using the QUICK information assessment tool are shown in **Figure 5.2**.

Figure 5.2: Leaflet appraisal using the QUICK assessment tool

1. Is it clear who wrote the information? The names of the authors, and their affiliations, are clearly marked at the back of the leaflet.
2. Are the aims of the leaflet clear? The aims of the leaflet are to help women with breast and/or ovarian cancer in the family to learn more about their risks and options. These aims are clearly written on the front cover.
3. Does the leaflet achieve its aims? The leaflet describes the general population risks of developing breast and ovarian cancers, as well as when family history is likely to increase a woman's genetic risk of developing these cancers. Women's options are detailed according to whether they are at low risk (i.e. breast awareness and breast screening over the age of 50), moderate risk (i.e. referral to a breast clinic) or high risk (i.e. referral to a genetics clinic). Discussing the pros and cons of early screening and prevention options is beyond the scope of the leaflet, but all the currently available possibilities are flagged under "Issues related to breast and/or ovarian cancer in the family that might be discussed with a doctor."
4. Is the leaflet relevant to me? The leaflet is relevant to women who have had a relative diagnosed with breast and/or ovarian cancer (as will be shown later in this chapter by the formal evaluation with patients).
5. Can the information be checked? The information contained in the leaflet can be verified by contacting the authors. As there were too many sources of evidence used in the development of the leaflet (see **Section 4.4.3.**) it was not appropriate to list them as part of the leaflet.
6. When was the leaflet produced? The leaflet was first published in 1999. The publication date is clearly marked on the back of the leaflet.
7. Is the information biased? The referral patterns are described and the various options are outlined, however, the information does not favour any particular option and therefore does not contain bias.
8. Does the leaflet tell you about choices open to you? As above, the leaflet is all about women's choices, what to expect from being referred to a breast clinic or to a genetics clinic, and what further options then emerge.

5.6. Results IIIa – Leaflet evaluation study

5.6.1. Response rate

Of the 190 questionnaires sent out, 144 were returned, giving a response rate of 75.7%.

5.6.2. Demographics and personal characteristics

Demographic and personal characteristics of the 144 respondents are summarised in **Table 5.4**.

The ages of respondents ranged from 25-68 years, but most were in their 30s or 40s (mean age 42 years, SD 8.9). A third had a college or university degree. Almost all respondents described themselves as white and had a mother or sister diagnosed with breast cancer. Respondents had a median of 2 first- or second-degree relatives diagnosed with breast cancer (inter-quartile range 1-3), with a minimum of no affected relatives and a maximum of 6. Eight percent of respondents were unsure how many relatives had been diagnosed with breast cancer or included relatives who were more distantly related (e.g. great aunts, cousins, etc.).

Table 5.4: Demographic & personal characteristics of respondents

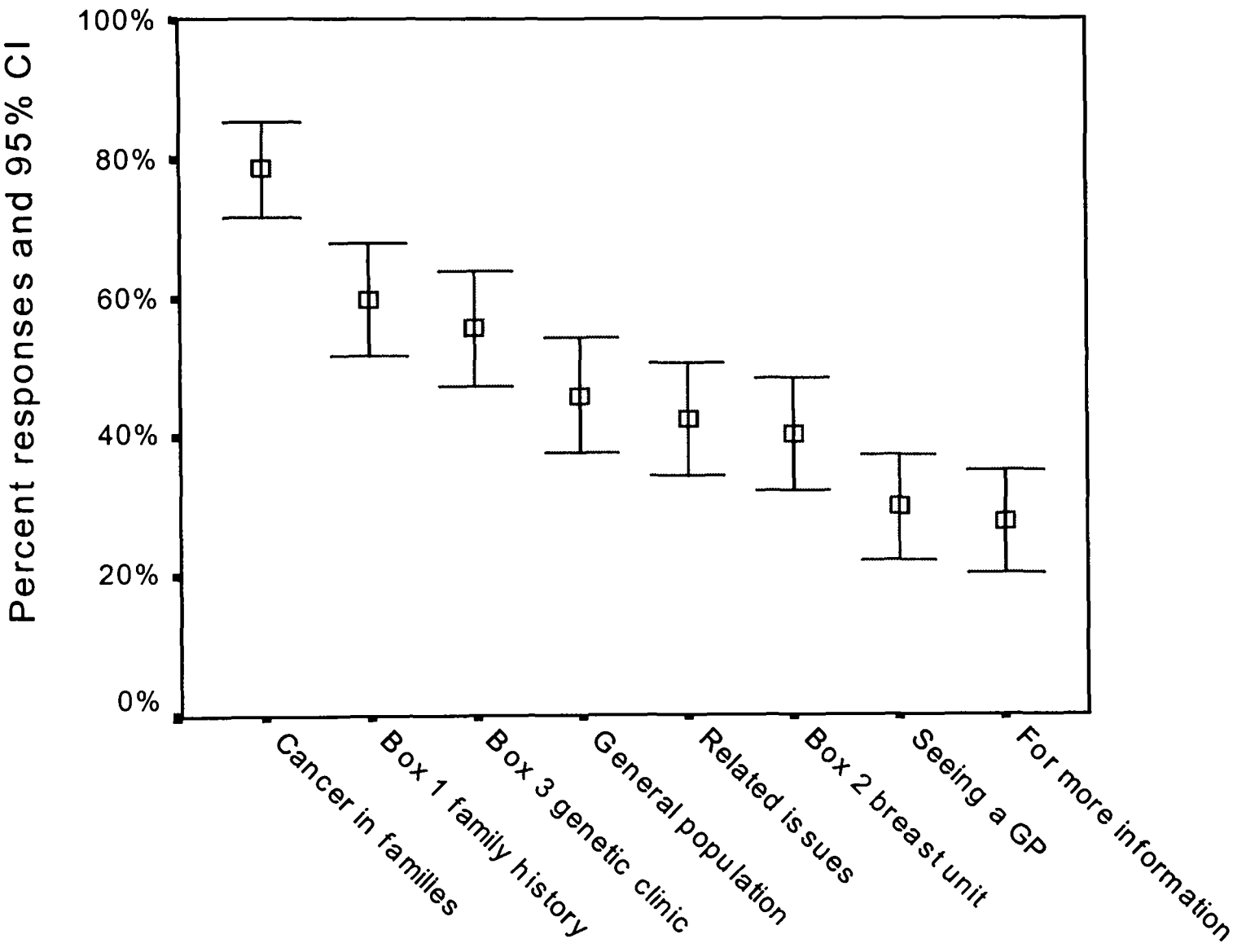
Variable	Category	Number (n=144)	Percent	95%CI
Age	20-29	11	7	
	30-39	50	35	
	40-49	56	39	31-47
	>50	27	19	
Education	O level	34	24	
	A level	12	9	
	Clerical/Commercial	15	10	
	College/University	46	32	24-40
	None of the above	22	15	
	Missing/Invalid	15	10	
Ethnic group	White	141	98	96-100
	Chinese	1	1	
	Other	2	1	
Mother or sister diagnosed	Yes	120	83	77-89
	No	23	16	
	Don't know	1	1	
Number of affected first- or second-degree relatives	None	5	4	
	1	42	29	22-37
	2	42	29	22-37
	3	27	19	
	4	9	6	
	5	6	4	
	6	2	1	
	Unsure/Invalid	11	8	

5.6.3. Perceived usefulness of individual sections

All but 4 respondents stated having read the entire leaflet prior to completing the questionnaire (97% (n=140/144); 95%CI 95-100). The sections of the leaflet considered most useful by over half of respondents included the section on "breast cancer in families" (78%

(n=113/144); 95%CI 72-85), the box about family history (60% (n=86/144); 95%CI 52-68) and the box about the genetics clinic (56% (n=80/144); 95%CI 47-64) (see **Figure 5.3**). Each of the sections was considered "most useful" by at least 30% of respondents.

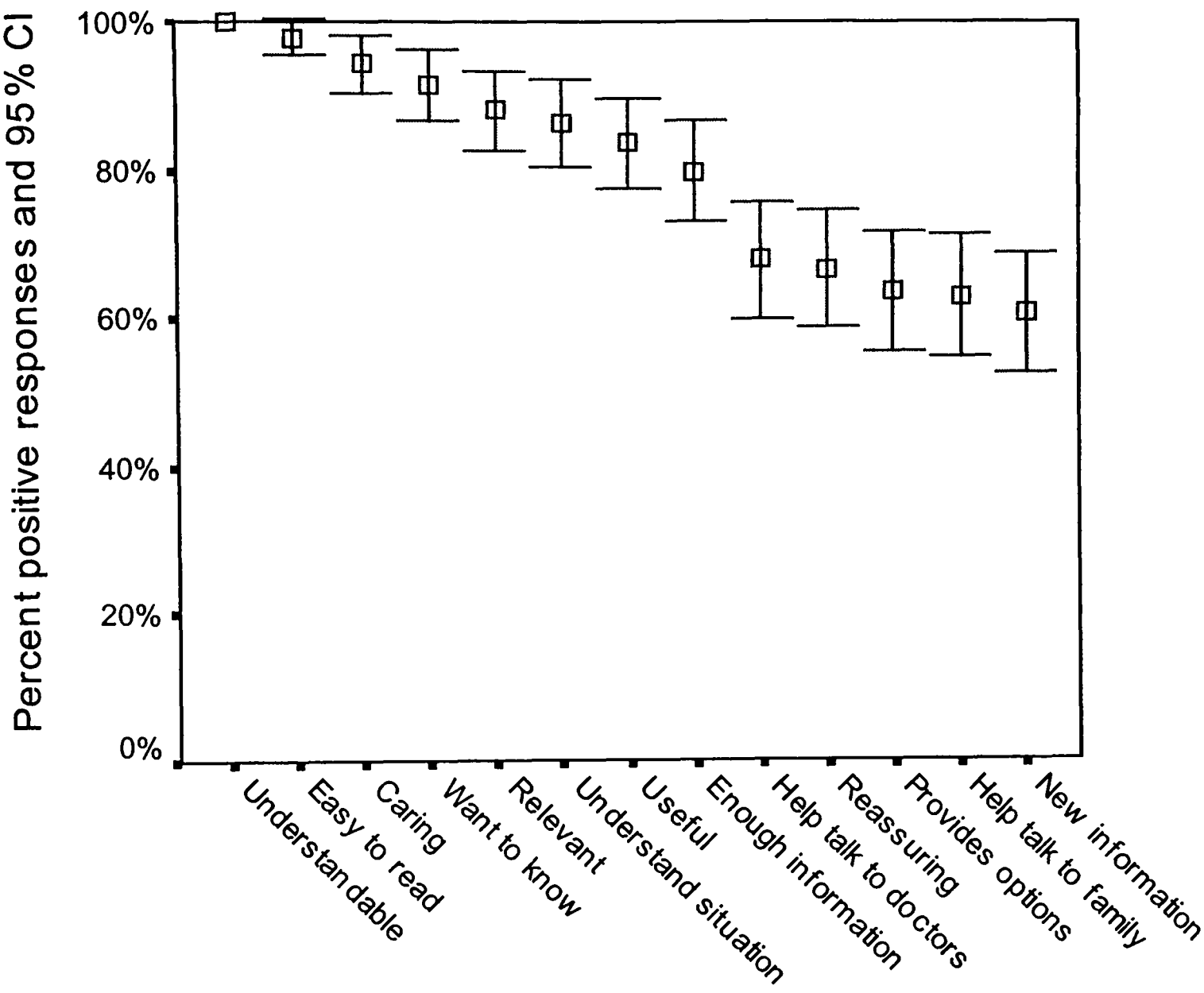
Figure 5.3: Perceived usefulness individual sections of the leaflet



5.6.4. Perceptions of relevance, content, clarity and utility

Using a 5-item scale (1="very much", 2="somewhat", 3="not very much", 4="not at all", 5="don't know"), patients were asked how they found the leaflet overall (see **Figure 5.4**).

Figure 5.4: Perceptions of leaflet relevance, content, clarity & utility



Women felt most strongly that the leaflet was written in a way they could understand (positive responses 100% (n=144/144)), was easy to read (98% (n=138/141); 95%CI 95-100), was written in a caring way (94% (n=134/142); 95%CI 91-98), and covered what they wanted to know (92% (n=130/142); 95%CI 87-96). They also felt very strongly (positive responses ranging from 80%-90%) that the leaflet was relevant to their

present needs, helped them to understand their situation, was useful to them and provided enough information. Women agreed, although slightly less strongly (positive responses ranging from 60%-70%), that the leaflet helped them to talk to doctors, was reassuring, provided them with options, helped them to talk to family members and provided information that was new to them. For each item, the minimum number of positive responses was 60%.

Fifteen women (10%) made specific comments regarding the leaflet's relevance, content, clarity and utility. Comments could be categorised as general positive or negative statements and specific suggestions.

General positive comments included that the leaflet was relevant, valuable and not "scary." Women felt that it raised awareness about breast cancer family history, it legitimised women coming forward to discuss these issues with their GP, and it identified available support systems. One woman also noted that the leaflet "treats me as an intelligent person" (Respondent 013). The leaflet was considered by many as "a first step" for someone with worries. In consequence, a couple of women found the leaflet too simplified. One woman wished she had received the leaflet earlier.

General comments which could be considered somewhat negative included that the use of percentages made the leaflet seem "clinical as opposed to caring", and that the leaflet raised even more questions to be brought up with one's GP.

Specific suggestions for improvement included making the leaflet more legible for women with visual impairments (for instance by removing the logo motif background) as well as making the leaflet more understandable for women who are not native English speakers. One woman wanted clarification regarding whether having breast cancer at an early age necessarily means that an inherited gene is involved. A few women also wanted more mention of the benefit of diet and lifestyle changes and further information about breast awareness.

5.6.5. The desire for information not included in the leaflet

About a third of women (39% (n=55/140); 95%CI 31-47) wanted more information, often about several different topics (see **Table 5.5**). However, there was no single topic in particular that was of interest to a majority of respondents.

Table 5.5: Information topics of interest to at least 5 respondents

Genetics and genetic testing (n=11/55) – gene names, pros and cons of testing, options if result positive, implications for insurance, time required for test results, procedure if no affected relatives available, reasons why testing should be restricted to a small minority.
Ovarian cancer (n=9/55) – symptoms, screening, pros and cons of screening.
Access to further information (n=8/55) - how to find other leaflets, books, & contact numbers.
Breast awareness (n=6/55) – signs/symptoms, see GP fast, needs more emphasis.
Cancer statistics (n=6/55) – treatment success rates for breast and ovarian cancer; risk of breast, ovarian or secondary cancers; risk of HRT or the pill causing cancer.
Breast screening (n=5/55) – how to get onto a screening programme, pros/cons.

Topics each of interest to about 5 to 10 women (i.e. about 10-20% of the 55 respondents) included genetics and gene testing, ovarian cancer, how to access further information, the risks of cancer and the chances of successful treatment, breast awareness and breast screening. A few women (less than five in each case) wanted more information about implications of family history for children and family members (n=3), issues related to HRT and the pill (n=3), and prevention through diet and exercise (n=2). One woman thought "it would be helpful to have some sort of guide of procedures (i.e. got to our doctor who will then discuss and refer you)" (Respondent 199). Other individuals wanted to know

more about Cowden's disease, risks to identical twins and risks associated with IVF (in-vitro fertilisation).

5.6.6. Aspects of the leaflet perceived as difficult or unclear

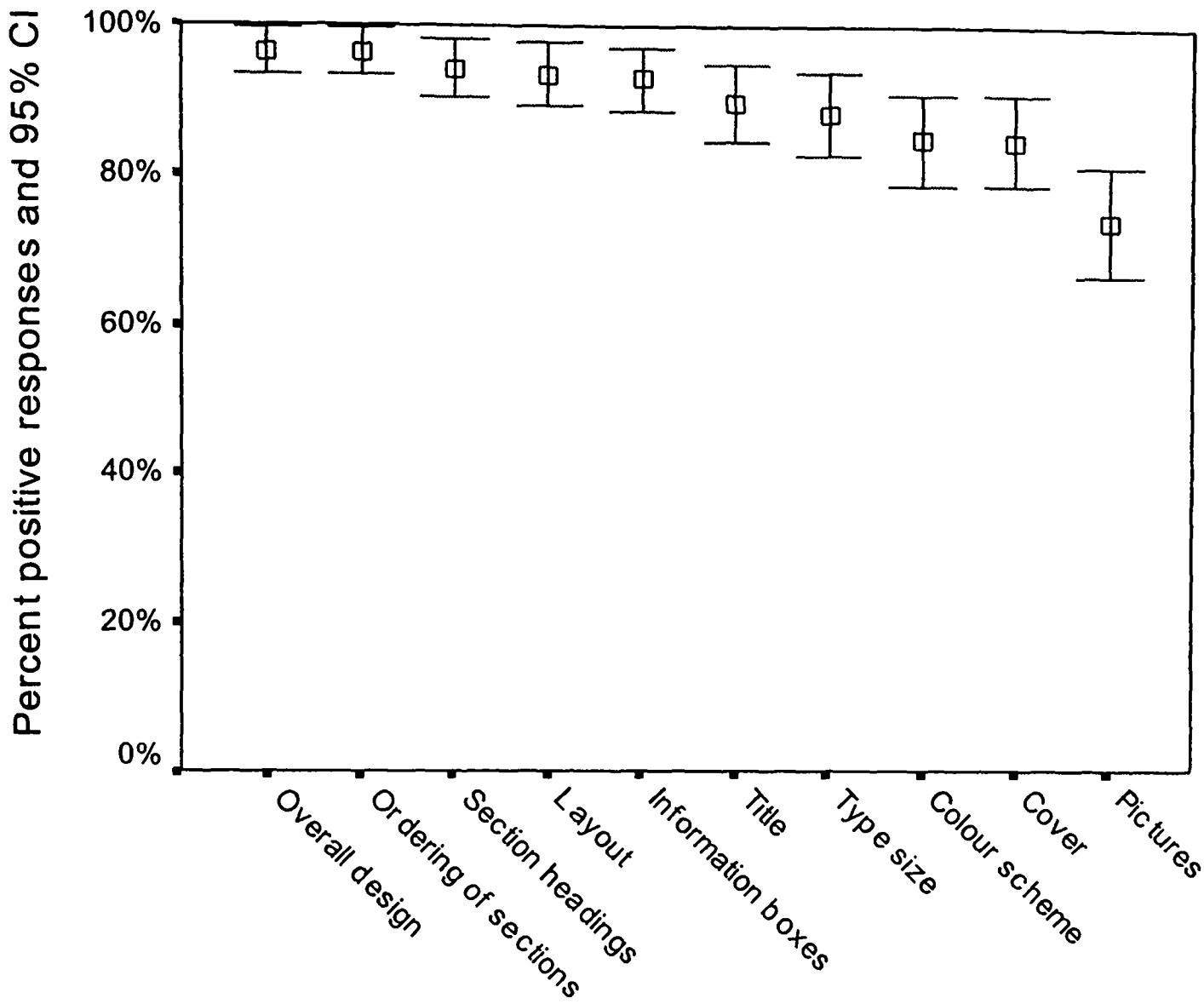
A very small minority of women (3.5% (n=5/141); 95%CI 0.5-7) found anything unclear or difficult to understand in the leaflet. Two respondents wanted more details in the section entitled "Issues related to breast and/or ovarian cancer." Another respondent (199) wanted headings in the "For more information" section to highlight "in which capacity each organisation can help (i.e. information on breast care or support or other such headings)." One woman commented that the leaflet is "just very 'matter of fact' and too 'blunt' – not very reassuring to a worried woman" (Respondent 153). Another wondered whether the leaflet would be "clear enough/simple enough for everyone" (Respondent 118). However, most women wanted clarification about specific topics such as the link between breast and ovarian cancer "if you've had one, are you at high risk for the other one?" (Respondent 166); the way risks are described " 'In approximately 50% of families…' What is the bit in the brackets referring to?" (Respondent 149); oral contraceptives "should these be avoided or is it a protection?"

(Respondent 88R); and genetic testing "how can a blood test tell if you are at high risk or not?" (Respondent 172).

5.6.7. Impressions of leaflet layout and design

Using the same 5-item scale used to assess the leaflet content, clarity and utility (1="very much", 2="somewhat", 3="not very much", 4="not at all", 5="don't know"), women were asked whether they liked specific aspects of the leaflet layout and design (see **Figure 5.5**).

Figure 5.5: Appeal of specific aspects of leaflet layout and design



Women were very positive about the overall design of the leaflet (positive responses 96% (n=135/140); 95%CI 93-100). They very much liked the ordering of sections (96% (n=135/140); 95%CI 93-100), the section headings (94% (n=132/140); 95%CI 90-98), the layout (94% (n=131/140); 95%CI 89-98), the information boxes (93% (n=131/141); 95%CI 89-97) and the title (90% (n=123/137); 95%CI 85-95). Women were also very positive about the type size, the colour, and the cover

(percent positive responses ranging from 85%-90%). They were somewhat less positive about the pictures (74% (n=102/138); 95%CI 66-81). Twenty percent of respondents did not like the pictures very much, and 4% did not like them at all (2% were unsure).

Only six percent (6%) of women (n=9/140) made specific comments about the leaflet layout and design. Most of these comments concerned the cover (n=4), the colour scheme (n=3) and the type size (n=3). The cover was described by the four women as "dull and bland" and the title was not prominent enough so "people don't often read them. A lot of money is spent on them. A stunning front cover helps people to pick it up!" (Respondent 126). As for the colours, one woman commented that "the colour blue denotes 'coldness' to most people, peach/pink would be better" (Respondent 006R). Another woman felt that the "blue is okay... [but] the pinky colour is odd" (Respondent 118) and one woman felt that a "bolder blue front" would be better (Respondent 126). The type size was considered by three women to be small and perhaps difficult for some to read. Other comments were that "the background [logo motif] obscures the text" (Respondent 118), the section heading and information boxes needed to be bolder (Respondent 126) and the layout could be better (Respondent 93). On the positive side, two women

remarked that the leaflet was "clear and simple" (Respondent 87) with "no waffle" (Respondent 13).

5.6.8. Desire to remove or change something in the leaflet

One fifth of respondents (21% (n=29/141); 95%CI 14-27) said that they would remove or change something in the leaflet. Consistent with women's impressions of the leaflet layout and design, most comments about what to change or remove concerned the cover (n=9), the pictures (n=5), and the background logo (n=4). Several women (n=8) also wanted more information.

Comments regarding the cover highlighted that it needed to be more eye-catching (see **Section 5.6.7**). One woman also suggested making "the title of the cover larger and more bold" (Respondent 71). Three women commented that the pictures should be removed altogether. Whereas two women thought perhaps the pictures could be altered. Several women (n=4) also wanted to remove the background logo motif that they called a "pink blob design" or "pink cell". Other suggestions included making the information boxes look bolder, and altering the title of the third section ("Seeing a GP...") that was considered "too long winded" (Respondent 149). As well, it was suggested to express risks as

words or numbers but not both thus avoiding too many "brackets dotted about" (Respondent 149).

Of the eight women who wanted more information included in the leaflet, one woman wanted more information about genetic counselling (Respondent 90) and another wanted to "warn readers of the likelihood of a very long wait for genetic counselling" (Respondent 14). One respondent suggested the addition of "a phone number someone can ring if they are alarmed and need to speak to someone fast or for more than educated calming! Cancer and genes do alarm us. I expect such a service is unrealistic?" (Respondent 13). Two women wanted more information in the "Issues related to breast and/or ovarian cancer" section.

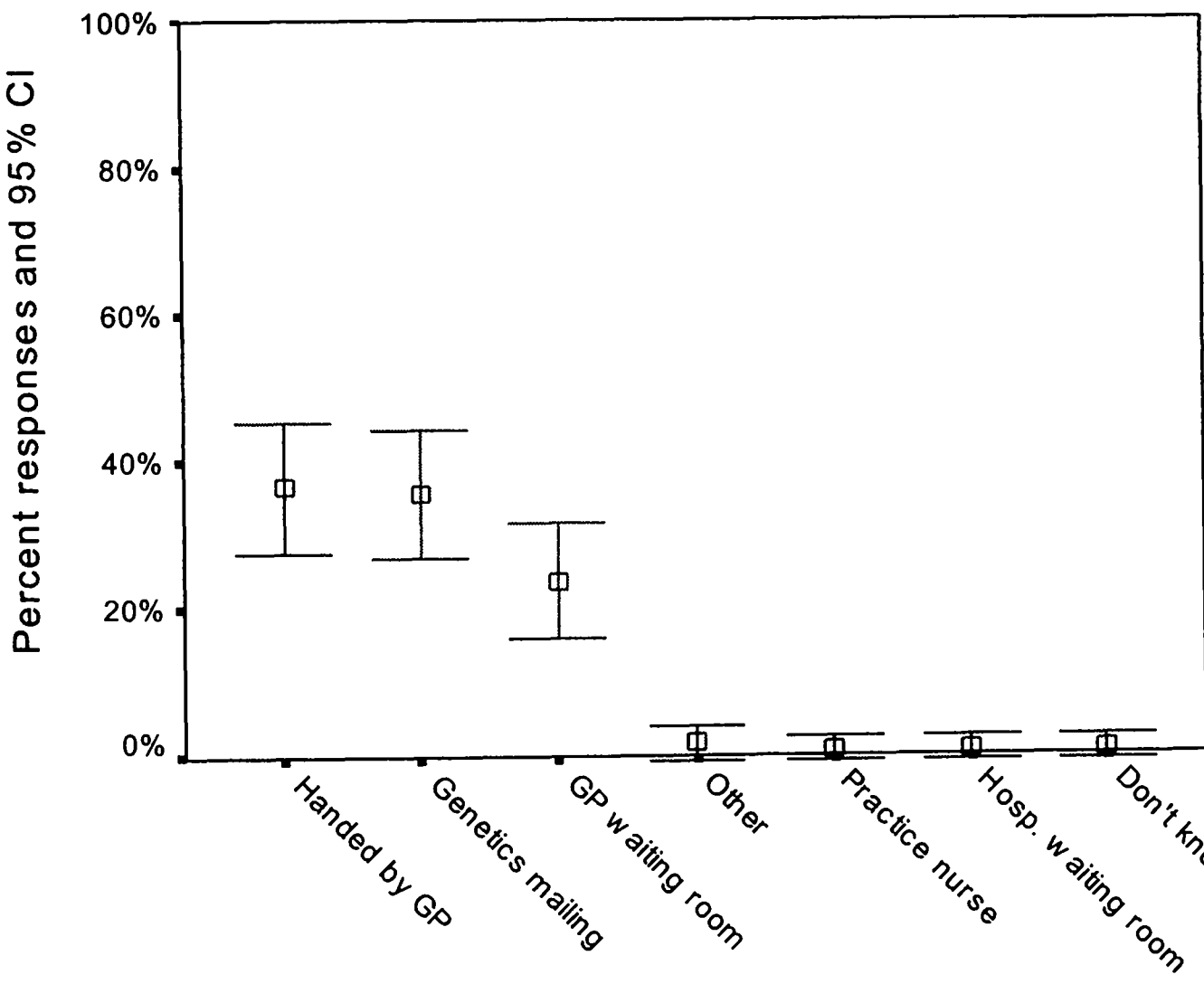
5.6.9. Perceived satisfaction at having received the leaflet

Regardless of the above comments for improvements, 91% of women (131/144, 95%CI 86-96) responded that they were pleased to have received this leaflet. One woman would have been glad to receive it "20 years ago!" (Respondent 1).

5.6.10. Preferred mode of leaflet delivery

As depicted in **Figure 5.6**, over a third of women most preferred to receive the leaflet directly from their GP (36% (n=43/118); 95%CI 28-45) or mailed from the genetics clinic (36% (n=42/118); 95%CI 27-44), and about a quarter preferred to pick it up in the GP's waiting room (24% (n=28/118); 95%CI 16-32).

Figure 5.6: Preferred mode of delivery of the leaflet



About a fifth of respondents (26/144, 18%) left the question blank (11/144, 8%) or ticked several choices (15/144, 10%), thus invalidating

their response. One woman wrote "I can see why you specify one box only, but it doesn't seem satisfactory to me – If someone understands it [the leaflet] that's fine, but to be handed it, or pick it up, could create anxiety and it needs to be talked through. If you feel GPs are able to advise women I'd be happy to agree" (Respondent 13). Corroborating this sentiment, three women felt that the point of delivery depended on the woman's risk level and needs. One woman wrote: "This is a difficult one – '1. Left in the GP's waiting room' is important for women seeking general reassurance. '2. Handed over by GP' is important for women who have gone with a more specific worry" (Respondent 75R). Another woman "didn't think enough people will read it if it is only displayed in a waiting room" (Respondent 87). Two women felt "all are very good ideas. The information I have learnt by reading this leaflet is outstanding" (Respondent 182) and "I don't mind [how the leaflet is distributed], just glad to have got it. Perhaps have it in all of them" (Respondent 96). One woman also suggested an alternate distribution source as being mobile breast units.

5.6.11. Perception of the best suited audience for the leaflet

When asked who would most likely find this leaflet useful, just over half responded "women with a relative diagnosed with breast cancer" (52%

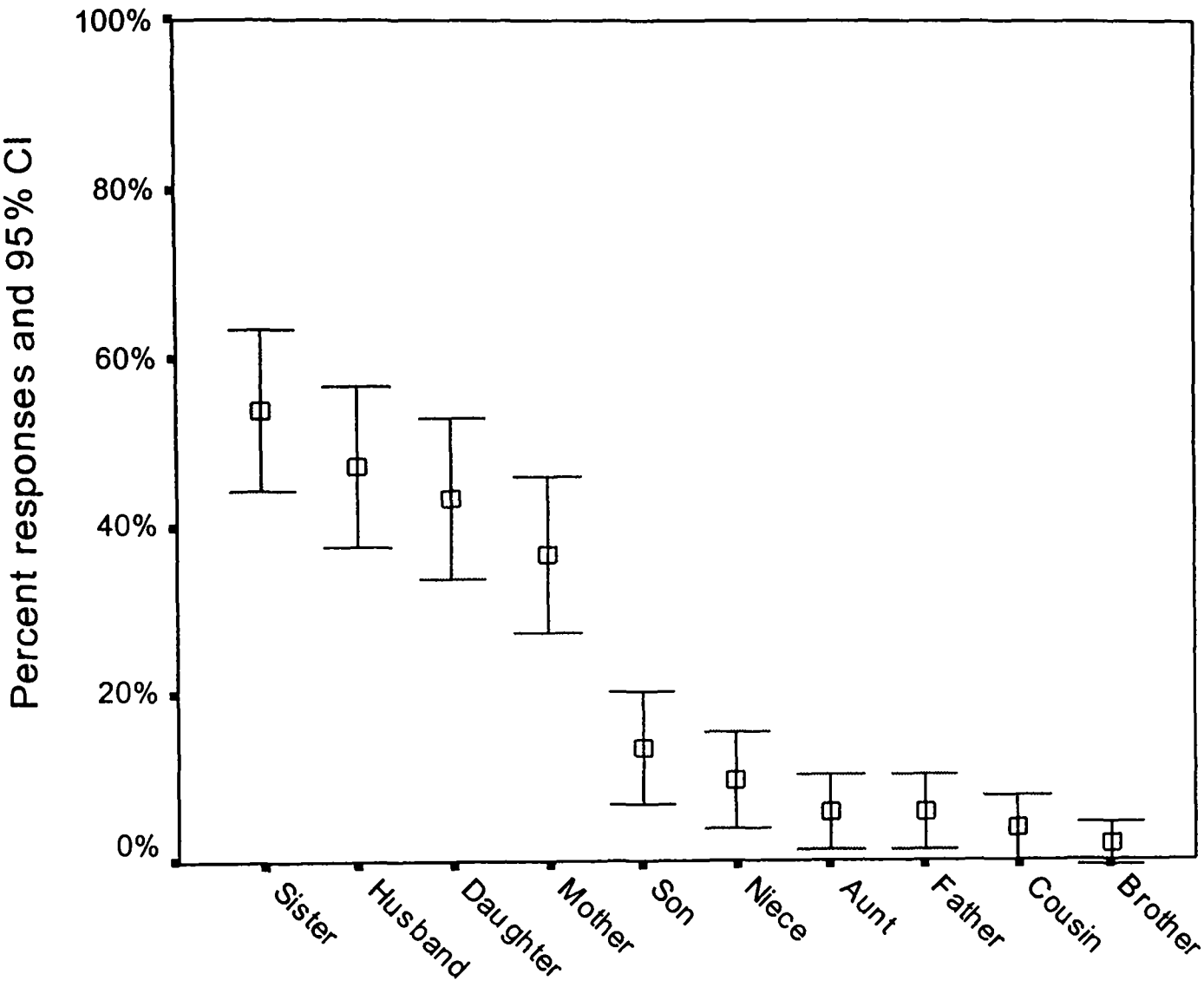
(n=71/137); 95%CI 43-60) and a little less than half responded "all women" (47% (n=64/137); 95%CI 38-55). Once again, 7 respondents (5%) ticked more than one response and one woman wrote "everybody" (Respondent 77).

5.6.12. Intention to show the leaflet to family members

Almost three-quarters of study respondents (73% (n=104/143); 95%CI 65-80) planned to show this leaflet to someone in their family. A little less than a quarter (24% (34/143); 95%CI 17-31) were not planning to do so, and five women (4%, 95%CI 0.4-6) were unsure. Of the respondents who were intending to show the leaflet to a family member (see **Figure 5.7**), the majority would show it to their sister (54% (n=56/104); 95%CI 44-64), husband (47% (n=49/104); 95%CI 37-57), daughter(s) (43% (n=45/104); 95%CI 34-53) and/or mother (37% (n=38/104); 95%CI 27-46).

Other family members intended to be shown the leaflet included (in descending order and with fewer than 15 responses each): sons, nieces, aunts, fathers, cousins and brothers. Three women also planned to show the leaflet to their boyfriend/partner, two to a friend or best friend, two to a sister-in-law, and two to a daughter-in-law.

Figure 5.7: To whom respondents intend to show leaflet



5.7. Results IIIb - Prospective descriptive study

Less than one tenth of women (9% (12/127); 95%CI 4-15) who were referred by their GP regarding a family history of breast cancer and subsequently participated in the prospective descriptive study reported having received the *Breast and/or ovarian cancer in the family* leaflet

from their GP. One woman said that she did not receive a leaflet because her GP had run out. Two women were not sure whether they had received the leaflet or not and one response was missing.

Of the 12 women who did receive the leaflet, 9 wanted the leaflet, 10 read the leaflet, 9 thought the leaflet was clear, 5 thought the leaflet covered what they wanted to know, 8 kept the leaflet and 3 showed the leaflet to others. One woman commented that she would have liked more information about symptoms and prevention (Respondent 76).

One of the women who had received the leaflet but did not receive an appointment at the genetics clinic because she was considered to be at low risk agreed to participate in a semi-structured interview about her recent experiences. When discussing the leaflet, it became clear that the woman focussed on the information about breast cancer genes, even though this information was not particularly relevant to her situation. She did not understand how having a mother who has had breast cancer (even though her mother was diagnosed after age 50) did not place her at greatly increased risk of developing breast cancer. Until further explanation of the leaflet was provided, she did not appreciate the importance to her situation of the paragraph that begins "most of the

time, these breast cancers occur in one family by unlucky chance." She felt that she would read past that part and continue straight to the section on genes. Only after some discussion was she reassured that the information regarding the 5% of cases with hereditary breast cancer was unlikely to pertain to her.

5.8. Discussion

5.8.1. Readability formulae

It is often difficult to obtain very high readability scores in medical writing [Ong et al, 1998]. With that in mind, the readability scores for the leaflet are quite acceptable and almost reach the target Flesch reading ease score of 70 or higher. Still, readability scores are only indicators and cannot assess the appeal or impact of a leaflet [Duman and Farrell, 2000]. It has even been argued that readability scores can be misleading [Meade and Smith, 1991; Pichert and Elam, 1985]. Therefore these formulae may be of limited value when used on their own and it would be important to supplement the use of readability formulae with other means of evaluating written materials.

5.8.2. Information assessment tools

Leaflet appraisal using the newly developed information assessment tools is an important first step in getting a feel for the quality and usefulness of patient information. The *Breast and/or Ovarian Cancer in the Family* leaflet meets the QUICK (and likewise the non-treatment related DISCERN) criteria. These tools are especially useful for helping individual patients to assess the quality of the information they encounter. However, the tools are limited to assessing the quality of the content of written materials, but not the clarity or presentation of the information. Moreover, as with readability formulae, information assessment tools are only indicators, and cannot determine whether the information is adequately understandable or truly useful to a patient population. Therefore, readability formulae and information assessment tools may complement formal evaluations with patients, but should not be used as replacements.

5.8.3. Formal evaluations with patients

The leaflet evaluation study provides the bulk of the evidence as to whether the leaflet is suitable for use in practice, and if so, what changes should be made to the leaflet prior to final printing and

distribution. These findings also provide useful information on preferred modes of leaflet distribution and predicted patterns of patient use.

5.8.3.1. Limitations of the leaflet evaluation study

With regards to the generalisability of the study, the sample was limited to women who were referred to a genetics clinic regarding their family history. Thus it is possible that these women may not be representative of all women presenting to primary care who might benefit from receiving the leaflet, or to women being referred to a breast care unit rather than to a genetics clinic. However, the personal and demographic characteristics of the study participants included the likely range of women who might be present to primary care and be referred regarding a family history of breast cancer. Moreover, results from the prospective descriptive study did not find many substantial differences between those women referred to a breast care unit and those referred to a genetics clinic (see **Chapter 3**). Thus it is likely that the results of this study are generalisable to all women being referred from primary care, if not all those presenting to primary care, regarding a family history of breast cancer.

5.8.3.2. Suitability of leaflet for use in clinical practice

Over 90% of women were glad to have received the leaflet. Women felt strongly that the leaflet was understandable, easy to read, written in a caring way, covered what they wanted to know, was relevant to their present needs and helped them to understand their situation. The great majority of women were also very satisfied with the design and layout of the leaflet. Overall, the evaluation indicated that the leaflet is acceptable to women and is suitable for use in clinical practice. A few women even felt that the leaflet legitimised their coming forward and raising breast cancer family history concerns with their GP. Although one woman thought the leaflet may raise more questions to bring up with GPs, and, this could potentially lead to increased workloads for GPs in the short term, the distribution of the leaflet may lead to increased patient satisfaction and fewer repeat consultations in the long term.

5.8.3.3. Implications for changes to the leaflet

Regarding what alterations needed to be made to the leaflet, over 30% of respondents considered each of the sections in the leaflet to be "most useful." Thus, none of the sections should be omitted.

Over a third of women, wanted additional information to be included in the leaflet. The topics of greatest interest related to 1) genetics and genetic testing, 2) ovarian cancer, 3) access to further information, 4) breast awareness, 5) cancer statistics, and 6) breast screening. The first request for more information was addressed by making the information about breast cancer genetics a section of its own, by elaborating on the information in the genetics clinic box and by adding another bullet point to the "Issues related to breast and/or ovarian cancer" section. The second request to extend the information about ovarian cancer would require more room than was available in this leaflet. Moreover, as this is a general leaflet for women at various levels of risk, ovarian cancer may only be relevant to a small minority of leaflet recipients. Therefore it was decided to omit reference to ovarian cancer in the leaflet and change the title to *Breast cancer in the family*. The text was adjusted accordingly, to more accurately reflect the contents and purpose of this leaflet. The development of a separate leaflet on ovarian cancer may be a logical next step given women's display of interest. The third request, to provide sources of further information was already addressed in the final section of the leaflet: "For more information". With regards to wanting more information about breast awareness in particular, high quality leaflets on this topic are widely available [Austoker, 1994a] and it was noted that

women could obtain such leaflets from their GP. Adding further cancer statistics such as the risks of the pill or HRT was considered too complex to be answered in this leaflet and therefore the subject remained flagged in the section on "Issues... that may be discussed with a doctor". Likewise regarding the pros and cons of breast screening and other such complex issues that could be discussed with health care professionals.

The many information requests voiced by only one or two respondents (i.e. risks to identical twins, risks associated with IVF, information about Cowden's disease, etc.) were beyond the scope of the leaflet, could be addressed in consultations and therefore did not warrant making changes to the leaflet.

Less that 5% of respondents found anything unclear or difficult to understand in the leaflet. Where possible, changes were made in accordance with these suggestions. For instance, in response to " 'In approximately 50% of families...' What is the bit in the brackets referring to?" the text was changed to "In approximately 5% of breast cancer cases (1 in 20)." However, some requests for clarification were beyond the scope of the leaflet (i.e. "should [oral contraceptives] be avoided or

is it a protection?" and "how can a blood test tell if you are at high risk or not?").

One fifth of women wanted to remove or change something about the leaflet. Of the leaflet layout and design characteristics, which were all well received, the least liked were the pictures, the cover, the colour scheme and the type size. Since so many women did not like the pictures very much or even at all, it was decided that they should be removed. The front cover would be made "livelier" and "more eye-catching" with a title that is larger and bolder as this was a common suggestion. Another common suggestion was to remove the background logo motif, and in any case, with the introduction of a new CRC logo, the motif would have had to be removed anyway.

The majority of respondents (>80%) were content with the colour scheme, although there were comments about changing the colours. The responses regarding how to alter the colours were inconsistent and it is unlikely that it will ever be possible to satisfy the diverse tastes of all people. The main reason for changing the colour scheme from blue and pink to purple and pink was to match the new CRC logo. Using the new colours also contributed to improving the design of the cover page.

With regards to the type size, there was some concern that it would be too small to be legible, especially for women with reading impairments. In October 1999, it became mandatory for the Health Services to provide accessible information under the Disability Discrimination Act (DDA) of 1996 [Wilson, 1999]. Thus in response to patient comments and in accordance with the DDA, steps were taken to ensure that the printed materials would be accessible to people with reading disabilities. Since the Royal National Institute for the Blind (RNIB) considers that 12 point font is appropriate for a general audience [Department of Trade and Industry, 1999], rather than altering the entire leaflet, a sentence was added to the back in 16 point font to alert people who may want a larger-print leaflet where to find it. The sentence reads: "A large-print version of this leaflet is available on request from the Cancer Research Campaign."

Although little valuable information regarding what changes to be made to the leaflet emerged from the leaflet evaluation part of the prospective descriptive study, the findings of the semi-structured interview did provide some rich data, albeit from a sample of one. Given that a main aim of the leaflet is to explain difficult concepts about risk and to provide

reassurance that most women with breast cancer in the family are not at increased genetic risk, minor alterations to clarify the section "Breast and/or ovarian cancer in families" were warranted. It was felt that placing the box on family history between the information about breast cancer in families and breast cancer genes would provide a pause between the information relevant to women at lower genetic risk and information for the women at greatly increased genetic risk. It was also considered important to acknowledge that women with a first-degree relative diagnosed before the age of 50 are in fact at increased epidemiological risk and therefore their perceptions of being at increased risk are not entirely untrue. Although most of these women are unlikely to be at increased genetic risk, their epidemiological risk is estimated to be approximately two times higher than the average population risk [Pharoah et al, 1997].

A list of all the wording and design changes made to the leaflet can be found in **Appendix 5.D**. The final version of the leaflet is in **Appendix 5.E**.

5.8.3.4. Leaflet audience and use

A little more than half of respondents of the leaflet evaluation study felt the leaflet was best suited for women with a family history of breast cancer, and a little less half felt it was best suited for all women. Over a third of women would have liked the leaflet handed to them by their GP, over a third would have liked it mailed from the genetics clinic and about quarter would have wanted to pick it up in the GP waiting room. Almost one fifth of respondents would have been happy with a number of the modes of delivery. Although this invalidated their answer for the purpose of this study, it illustrates that any of the three main ways of delivering the leaflet would be acceptable, and one woman suggested that the leaflet should be distributed by "all of them". Of note, several women felt that receiving a leaflet should not be a substitute for talking to someone about the issues contained therein. Almost three-quarters of respondents were planning to show the leaflet to one or more family members, especially to sisters, husbands, daughters and mothers. Thus the information contained in the leaflet goes beyond the individual case and is used to educate entire families.

5.8.3.5. Dissemination and delivery of the leaflet

Even if patients consider the leaflet to be very useful and user-friendly, unless they receive the leaflet, there is no point in having created it in the first place. Thus the distribution and delivery of the leaflet must be ensured as far as possible. Simply informing information providers that the material has been developed is an important step in promoting its implementation [Centre for Health Information Quality, 1999a]. Thus the existence of the leaflet and the fact that it had undergone extensive development and evaluation was made known to specialists in the field of familial breast/ovarian cancer through presentations at UK Cancer Genetics Group (formerly Cancer Family Study Group) meetings. The leaflet was also made known to other patient information producers and cancer charities through presentations at patient information conferences and registration of the leaflet in the Centre for Health Information Quality Patient Information Project Exchange Register (PIPER). An email announcement sent to a health information mailing list elicited dozens of requests for the leaflet from places as far away as India, Norway, USA and Canada, as well as from the UK.

Most importantly, the leaflet should be made known to GPs, who are likely to become the primary sources of distribution of the leaflet to

patients. Initially, this was done on a small scale by including copies of the leaflet in educational packs concerning familial breast/ovarian cancer distributed to GPs in the Oxfordshire region as part of a randomised controlled trial. There is evidence that the use of leaflets in general practice varies and is related to perceptions of the value and quality of the information [Dixon-Woods, 1998]. The results of the randomised controlled trial (RR 58%, n=264/457) show that 86% of the GPs had a positive opinion of the leaflet (n=177/206). Moreover, 90% of the GPs said they would give this leaflet to patients who present with concerns about their family history (n=195/216). Therefore there is a good indication from the GP study that the leaflet will be acceptable to GPs and distributed in primary care.

In practice, there has already been considerable demand for the leaflet from genetics departments and GPs throughout the UK and reports are that it has been very well received by women. The leaflet is now nationally available and has been sent to every GP in Scotland as part of the distribution there of the primary care educational pack on familial breast/ovarian cancer.

6. General Discussion

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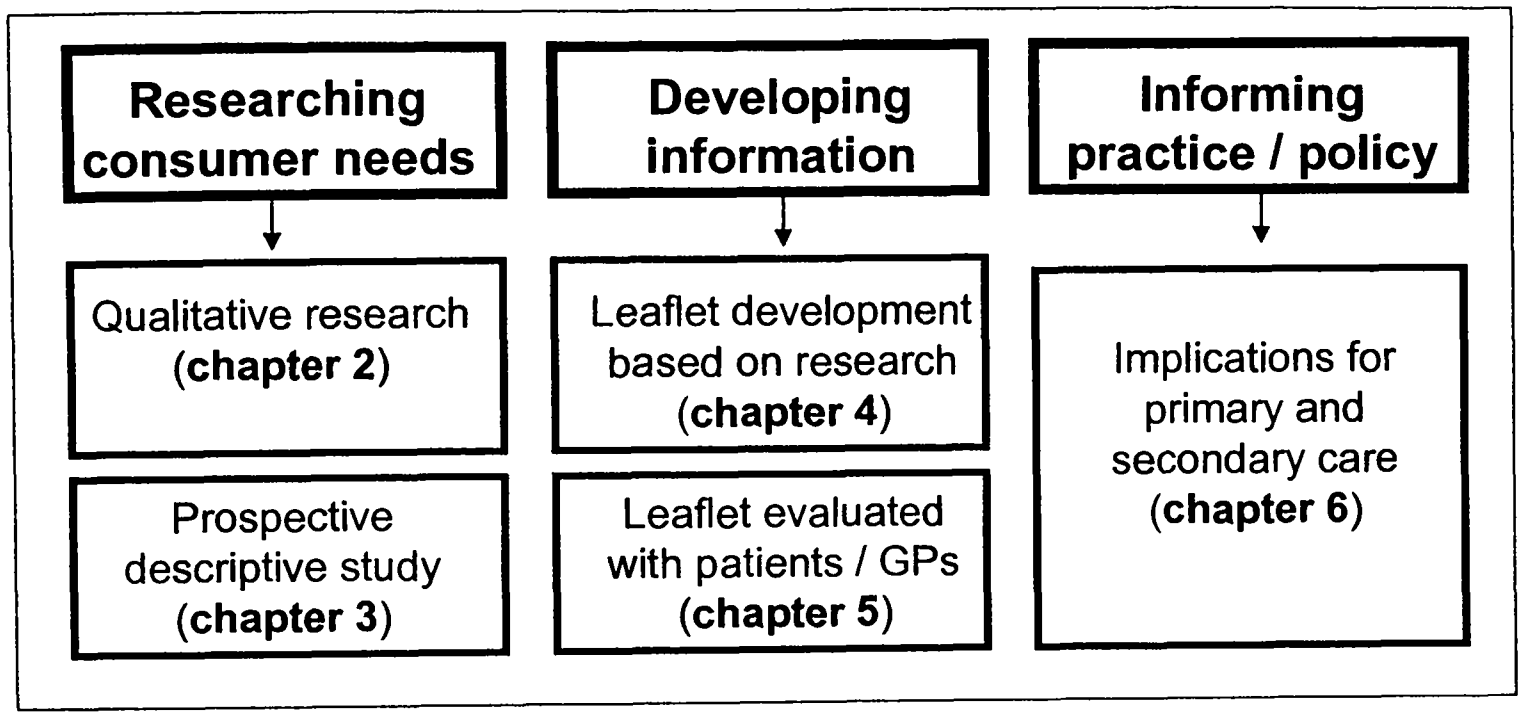
6.1. Overview

This thesis described the research involved in attempting to redress two gaps that existed in the literature at the time when this work began. First, there was no work published in the academic literature on the needs, expectations, and experiences of women with a family history of breast cancer that focused on the primary care setting. This is of particular importance, as the majority of these women will not be seen by a specialist, therefore the GP is their main source of information, advice and reassurance. Second, there were no consumer health information materials available that were appropriate for a general population of women with breast cancer in the family who consult primary care, although there was already evidence of a need for such materials [Hallowell et al, 1997b].

The research described in this thesis was carried out over the past three years and aimed to explore the needs, expectations and experiences of women with a family history of breast cancer who present to primary care using both qualitative and quantitative techniques. The findings of this research have helped to inform clinical practice and policy in this difficult area, as well as to inform the development of research-based

patient information materials for distribution in the primary care setting (see **Figure 6.1**).

Figure 6.1: Researching consumer needs, developing research-based information and informing clinical practice and policy



The following sections of the general discussion will present the highlights of the findings from the above work, explain the limitations of this research, suggest possible areas for further research, and describe the current implications of this work for clinical practice. As the dissemination of findings is an important part of the research process, lists of presentations and publications based on this work are included in **Appendices 6.A and 6.B**.

6.2. Summary of research findings

6.2.1. Qualitative research (Chapter 2)

As there was nothing published about the needs, expectations and experiences of women who present to primary care on account of a family history of breast cancer, the first step in the research process was to carry out exploratory work using qualitative methods. Qualitative research provided a deeper understanding of the patient experience from the individual's point of view, and also laid the groundwork for future research in this previously unexplored area (Pope and Mays, 2000).

The qualitative research of women's primary care consultation needs is reported in **Chapter 2**. It was found that women had often been thinking for some time about their family history of breast cancer and the implications of their relatives' illnesses for their own future well-being before presenting to primary care. Women found it difficult to raise the issue with their GP as they themselves were not acutely ill and they felt that they would be wasting their GP's limited time. Study participants tended to fall into four broad categories when presenting to primary care: those who wanted information, those who wanted reassurance,

those who wanted to be referred to secondary care and those who wanted any combination of the above.

The importance of information provision in primary care is supported by recent research [Hallowell et al, 1997b; Warner et al, 1999; Williams T et al, 1999]. The research that is reported in this thesis has shown that different women had different information needs, but there were certain topics of interest to a majority of women. The information topics that women wanted to know more about in primary care included: breast cancer in general, breast awareness, the risks of developing breast cancer, breast cancer genes and gene testing, prevention and early detection, the referral process and further sources of information. Women preferred verbal information supplemented by take-home materials such as leaflets. These findings are consistent with those published in the limited available literature on this subject [Warner et al, 1999; Williams T et al, 1999].

The qualitative study also found that although women thought that their feelings of reassurance might fade with time, they appreciated hearing advice that was tailored to their particular situation and that did not conflict with their preconceived notions of hereditary and breast cancer.

Having the opportunity to return to see their GP at a later time with further questions as needed was considered by women as an important step in providing and maintaining reassurance. This is also in keeping with recent work regarding patient experiences across the primary/secondary care interface [Preston et al, 1999].

Finally, the qualitative study revealed that women who sought referral to secondary care were mostly interested in mammographic screening or genetic counselling and testing. Women felt they had to push to be referred and often wanted access to early detection options despite knowledge of potential harmful effects. These findings are consistent with previous research regarding women's sense of duty to take preventive action in the face of a perceived risk of disease [Charles et al, 1998; Hallowell, 1999]. These issues were further investigated in the prospective descriptive study.

6.2.2. Prospective descriptive research (Chapter 3)

The prospective descriptive study constituted the largest part of the overall research programme because of the need to ascertain a broad range of views covering a wide array of topics. The topic areas covered in this research were informed by the findings of the qualitative study

and by the relevant literature in the field. Even though the latter mostly focussed on the secondary care setting, there were certain areas of overlap in terms of issues that were also relevant to primary care and the primary/secondary care interface (e.g. risk perceptions and cancer worries).

The findings of the prospective descriptive study are reported in **Chapter 3**. One hundred and ninety three women were invited to participate in the study. These women were identified on the basis of GP referrals regarding breast cancer family history that were made over a one year period to two breast clinics and two genetics clinics in Oxfordshire and Northamptonshire. The response rates for the initial and follow-up mailings were approximately 75%. Respondents had a mean age of 38 years (SD 10.0) and constituted a rather well educated group (30% had a college or university degree).

The prospective descriptive study showed that 87% of women who present to their GP about breast cancer in the family and are referred to secondary care had heightened risk perceptions of their own chances of developing the disease. These risk perceptions were correlated with women's cancer worries ($R=0.358$, $n=122$, $p<0.001$) and were also

associated with the desire for preventive options. Similar findings have been found elsewhere [Geller et al, 1999; Lerman et al, 1995a; Lloyd et al, 1996; Watson M et al, 1999]. Women's knowledge of mammography and gene testing was limited, and this too may in part explain women's eagerness for undertaking these options, as is supported by previous research [Domenighetti et al, 2000; Savalescu, 1997]. As well, being proactive and joining early detection programmes was considered by women as one of the ways in which they coped with their risk perceptions and cancer worries. In practice, however, only a small proportion of women referred to secondary care are eligible for mammographic screening, and even fewer have a strong enough family history to warrant gene testing [Langston et al, 1996].

Following the secondary care visit, overall women's risk perceptions and cancer worries decreased significantly (i.e. 36% believing themselves to be at greatly increased risk before the visit versus 17% after ($W=-2.977$, $n=45$, $p=0.003$), and correspondingly, the median Cancer Worries Scale score changed from 13/24 before the visit to 11/24 after ($W=-4.245$, $n=44$, $p<0.001$)). Overall, women's desire for mammography and gene testing also decreased. However, for over half of women, there was no change in any of the above areas, nor was there much improvement in

knowledge. This resistance to altering perceptions and beliefs following a secondary care visit is also supported by previous research [Evans et al, 1993; Lerman et al, 1995a; Watson M et al, 1998 and 1999].

Women's main reasons for presenting to primary care to begin with were related to a recent breast cancer diagnosis or death in the family, or the awareness that they themselves were reaching the age when a relative was diagnosed or died of breast cancer. Similar findings have been reported elsewhere [Brain et al, 2000; Kash, 1996].

In 94% of cases, it was the woman who raised the issue of family history with her GP. Women primarily wanted their GP to provide information (90%) and to discuss their risks of developing breast cancer (87%). However, importantly, only about half felt that these needs were met in primary care. Women had similar expectations of their secondary care visit, and in this case, women were more likely to feel that their needs were met.

An unexpected finding was that there may be an imbalance in the management of women with breast cancer in the family in that younger, more educated women tend to be referred to genetics clinics as

opposed to breast clinics. At the former, consultation times are generally longer and discussions of the risks and options tend to be covered in greater depth. Therefore, there is all the more reason why women should receive at least some of the information that they need in primary care.

6.2.3. Leaflet development (Chapter 4)

The findings of the qualitative and quantitative studies were intended to inform clinical practice and policy. The most important need identified by women with a family history of breast cancer presenting to primary care was for information. As there were no information materials suitable for a general population of women consulting primary care, a new leaflet was developed according to current best practice [Coulter et al, 1998; Duman, 1998; Duman and Farrell, 2000]. Thus the development of the information leaflet entitled *Breast Cancer in the Family: Learning more about your risks and options* was based on patient information needs and the best available research evidence. The process of producing such research-based information is found in **Table 6.1**.

Table 6.1: Producing research-based patient information

Systematic search of previously produced patient information
Research patient information needs
Systematic search of the literature Qualitative research Quantitative research
Systematic search of the evidence underlying patient information needs
Secondary sources (e.g. meta-analyses and systematic reviews) Primary sources (e.g. randomised-controlled trials) Key informants (e.g. service providers)
Develop draft leaflet following guidelines for clear communication
Pilot leaflet with key players (e.g. service providers, consumers)
Produce leaflet
Evaluate leaflet with the intended audience
Develop and pilot evaluation tool (i.e. questionnaire)
Revise leaflet according to evaluation findings
Produce revised leaflet
Promotion and distribution
Periodic reassessment and updating of materials

A key part of the leaflet development process was the evaluation of the leaflet with the intended audience, which constituted a separate study in its own right.

6.2.4. Leaflet evaluation (Chapter 5)

Evaluating the leaflet ensured that it would meet the needs of women with a family history of breast cancer presenting to primary care. Over

90% of respondents (response rate 76% (n=144/190)) were pleased to have received the leaflet and found that it was understandable, easy to read, written in a caring way and covered the information that they wanted to know. Over 85% of respondents were also pleased with all elements of the layout and design of the leaflet, with the exception of the pictures, which were therefore removed. Other minor changes to the leaflet content and style were also made when the same request was voiced by a substantial number of respondents.

Women were content to receive the leaflet in primary care or prior to being seen in secondary care. However, as was found in the qualitative study (**Chapter 2**) women felt the leaflet should complement but not replace discussions with health care professionals. This has also been supported by previous findings [Coutler, 1998].

Also important was the fact that 86% of GPs had a positive opinion of the leaflet (response rate 58% (n=264/457)), which is associated with increased likelihood of the materials being distributed in primary care [Dixon-Woods, 1998]. Ninety percent of GPs said they would give the leaflet to patients who present with concerns about a family history of breast cancer. As well, since almost three-quarters of the women in the

study planned to show the leaflet to family members, the leaflet has a potentially wider audience than those who present with concerns to primary care.

6.3. Limitations of the research

For all of the studies, although the focus of the research was on primary care, recruitment was limited to women who had been referred to secondary care. The reason for this was that although there may be an increasing number of women presenting to primary care overall about family history concerns, each GP only sees a small number of such cases each year [de Bock et al, 1997; Johnson N et al, 1995]. To recruit from primary care would have required a very large number of GPs being involved in the study, and this was not feasible within the time scale of this research.

A possible difficulty with recruiting from secondary care is that the population of women who are referred by their GP, represent only a proportion of those who consult primary care [Kahn, pers. comm.], and they may therefore have different characteristics. For example, those who are referred may be at greater risk of inherited breast cancer or have greater cancer-specific distress [Peshikin and Lerman, 1999].

In the qualitative study, it was possible that women's recall of the primary care consultation may have been altered over time and in relation to subsequent experiences. However, this is a limitation inherent to research of this kind and is not limited to this study. Nonetheless, women's views of the GP visit did not appear to differ amongst women who had and had not yet been seen in secondary care. Still, in the prospective descriptive study, recruitment was standardised in an attempt to minimise this effect such that questionnaires were mailed to all women one month after they were referred by their GP and one month after they were seen by the specialist. However, in doing so, there was not enough time to assess whether women were at increased risk or not, and therefore it was not then possible to mail out the low risk questionnaires to women who were inappropriately referred and would probably not be seen at the clinic. Thus to reach this audience of low risk women, a separate study may be warranted (see **Section 6.4.1**).

6.4. Areas for further research

There are several important areas for further research uncovered by the preliminary descriptive work described above (**Section 6.2**).

6.4.1. Women at low risk of inherited breast cancer

Firstly, there exists a large number of women who present to primary care, many of whom are at low risk, who are never referred to secondary care [Kahn, pers. comm.]. Although this is a difficult population to reach since each GP sees relatively few such cases a year, it would be important to know what these women's needs are, whether their needs are the same as those being referred and whether these needs are being met in primary care. Another very interesting and somewhat related group is women at low risk who <u>are</u> referred from primary to secondary care. Very often, because of the limited resources for clinical hereditary cancer services, many of these women are sent a letter from the clinic saying that due to their low risk status there is no need for them to be seen in secondary care. It is possible that the reactions of such women who are referred to secondary care but not offered an appointment may differ in important ways from those who are not referred at all. This group of low risk women referred to secondary care was intended to be part of the study population in the prospective descriptive study (see **Section 6.3**). However, due to the study design of sending out questionnaires one month after the GP referral, it turned out that there was not sufficient time for the clinic to assess the patient's risk status, and therefore the specifically-tailored low risk questionnaires

were not sent out. Thus, there is still a need to specifically target low risk women being referred to but not seen in secondary care to determine their needs and to assess whether these needs are being met by being sent a letter from the clinic or whether they need more from their GPs. Such research outlined above could also incorporate the use of the patient information leaflet to see whether being offered the leaflet or not has any effect on patient outcomes.

6.4.2. Patient views of the GP's role in their ongoing care

Another key area of interest in the development of patient-informed services in primary care genetics is to explore what role women at moderate to high risk want their GP to play once they have been referred to secondary care. Results from the prospective descriptive study (**Chapter 3**) indicate that very few women returned to their GP to tell them anything about what had happened at the clinic. However, due to time restrictions of this study, we were only able to send a single follow-up questionnaire mailed one-month after the secondary care visit. This may not have left sufficient time for women to return to see their GP. Therefore, a longer follow-up or a study that specifically addresses this question would be of interest. Specifically, one could explore how women with a family history view their GP in dealing with this subject, as

simply a gatekeeper or as someone who can provide ongoing reassurance and information even after being seen in secondary care? Are there any barriers to women consulting their GP after being referred to secondary care? Associated with this work, it would also be possible to explore further any potential inequalities in the management of women with a family history of breast cancer from affluent versus deprived backgrounds. There is also the potential for further development of a series of research-based patient information materials tailored to women's changing information needs throughout the health care "journey" [Bell S et al, 1996].

6.4.3. Risk perceptions and informed choice

Perhaps at the heart of the topic of breast cancer in the family is the issue of increased risk perceptions and its association with cancer worries and the desire for prevention, early detection or any other available options. There remains a great deal of scope for exploring how women understand their risks, what they understand "high" and "low" risk of developing breast cancer to mean, and how to decrease heightened risk perceptions, especially for women at low risk. As well, there is the issue of women not knowing a great deal about the pros and cons of mammographic screening for women of their age and risk, and

wanting some kind of surveillance to help them cope with their cancer worries despite any potential negative consequences. Therefore, further research could explore how to offer women that feeling of "being in the system" without necessarily making them feel obliged to undergo screening or other options that may be inappropriate for them. Associated with this, it would be important to explore further how women understand options such as mammography and gene testing, how to educate women about the pros and cons of available options in ways that they understand. Thus by understanding how to decrease inappropriately high risk perceptions and how to increase women's knowledge of the risks and options in ways that are useful in their decision-making processes, informed patient choice can be further promoted in the area of hereditary breast cancer.

6.5. Implications of findings for policy and practice

The research findings reported in this thesis have implications for primary care practice as well as for health care policy more broadly.

6.5.1. Information-giving in primary care

The qualitative and prospective descriptive studies showed that the main way in which GPs can meet the needs of women who consult

primary care about breast cancer in the family is to discuss their risks and to provide them with verbal and take-home information. Patient information and shared decision-making are becoming increasingly important components of health care provision [National Health Service Executive, 2000]. In all areas of medicine, there is a need for better communication between doctors and their patients [Charles et al, 2000]. Information giving and sharing decision-making are not simple tasks, but ethically-significant acts that should not be taken lightly [Coulter et al, 1998; Doxiadis, 1990; Entwistle et al, 1996; Thornton, 1998]. Individuals' decisions are greatly affected by what information they receive and the way in which the information is framed [Sarfati et al, 1998]. Therefore it is important to include all relevant information including any uncertainties or complexities in an unbiased and non-paternalistic way, and most importantly, in a way that patients can best understand [Austoker, 1999; Entwistle, 2000; Raffle, 2000]. Because every individual has different needs, the best way to determine what information is desired by patients and whether or not patients want to participate in shared decision-making is to ask [Benbassat et al, 1998].

The studies reported in this thesis found that patients consider it important that verbal information provided during the consultation is

supported by take-home materials. These materials, such as the leaflet that was produced, should be based on research that explores patient information needs, should synthesise the current best evidence, and should be extensively piloted and evaluated with the intended audience.

6.5.2. Legitimisation, reassurance and support in primary care

Hereditary breast cancer is a relatively new area, and the research reported in this thesis has shown that as women with concerns about breast cancer in the family are not themselves acutely ill, they often feel uncomfortable raising the issue. These findings suggest that general practitioners could greatly assist their patients by simply acknowledging that their family history concerns are a legitimate reason to have consulted primary care [Broom and Woodward, 1996]. Moreover, it was also found that women felt the leaflet entitled *Breast Cancer in the Family: Learning more about your risks and options* legitimised their coming forward with concerns. Therefore displaying these leaflets in GP waiting rooms may make it easier for women who feel inhibited about coming forward with their concerns to do so.

General practitioners are also in a very good position to provide women who do come forward with concerns about breast cancer in the family the reassurance and ongoing support that they need, regardless of their level of risk or further management. Especially in areas of uncertainty where difficult decisions must be made, the importance of physician support should not be underestimated [Pauker and Kassirer, 1997].

6.5.3. Nationally-accepted referral policy and information

The fact that hereditary breast cancer is such a new area rife with uncertainties means that there is no strong evidence to support one set of referral criteria over another. At present, there are no nationally agreed referral guidelines, nor are there any very widely distributed information materials for patients and primary care physicians. As a result, there are major discrepancies in practice and information provision throughout the UK [Hopwood et al, unpublished]. The research reported in this thesis has shown that these inconsistencies are particularly distressing for patients who receive different advice and care as compared with their close relatives who live in different areas. Consistency in familial cancer information provision is already considered a priority in other countries [National Health and Medical Research Council, 1999]. Regardless of whether there is strong

evidence for one set of referral criteria over another, there is evidence of a need for a nationally agreed upon management protocol as well as accompanying educational materials.

6.5.4. An integrated genetics education policy

With the recent decoding of the entire human genome [Cardon and Watkins, 2000], genetics will soon be playing an increasing role in clinical practice, perhaps most notably in prescribing medicines (i.e. pharmocogenetics) and in the risk management of common diseases [Fears et al, 2000; Kaprio, 2000]. These advances may not come into practice for several years, or even decades, and a great deal of caution must be taken in introducing these new technologies [Hubbard and Wald, 1997; Kevles and Hood, 1992]. However, there are some areas, such as hereditary cancer, where the genetic revolution is already changing clinical practice. For this reason, there is much to learn from the arena of cancer genetics about how to integrate the new knowledge and skills required by this paradigm shift. Researchers have begun to look at ways of facilitating the integration of genetics into primary care clinical practice including using pro-formas to identify patients at increased genetic risk [Leggatt et al, 1999; Westman et al, 2000], family history-taking in primary care [Rose et al, 1999], risk assessment and

referral guidelines for GPs [de Bock et al, 1999] and computerised support [Emery, 1999; Emery et al, 2000b]. Independently of research in this area, there have also been recent advances in the area of consumer health informatics to provide easier access to information that is tailored to the needs of the individual and provides greater insight into the patient experience [Bental et al, 1999; Eysenbach, 2000; Gillies, 2000; Herxheimer et al, 2000]. An integrated genetics education policy that ensures the ongoing development of research-based information for the public, for patients and for health care practitioners is an important element that is likely a necessary one for the smooth transition of health care into the genetic age. The research described in this thesis has provided a first step in that direction.

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OXFORD REGIONAL GENETICS SERVICE
Department of Clinical Genetics,
The Churchill Hospital, Oxford, OX3 7LJ,
Tel: (0)1865 226029, Fax: (0)1865 226011

July 1, 1998.

Dear Madam,

I am writing to ask if you would be interested in participating in a study we are conducting to investigate the expectations, experiences and satisfaction of women who discussed their family history of breast disease with their GP and were referred to a specialist clinic. This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care of Oxford University. The purpose of this study is to improve the medical services and information available to women like yourself.

Participating in this study would involve agreeing to be interviewed informally by a researcher from the Primary Care Education Research Group. Should you choose to participate, they would contact you by phone and arrange a mutually convenient place and time to meet to chat informally for approximately one hour. Any travel expenses will be reimbursed.

THIS INTERVIEW DOES NOT FORM PART OF YOUR MEDICAL CARE AND THEREFORE NO HEALTH ADVICE CAN BE OFFERED. Should you want any such advice, please contact the Department of Clinical Genetics on the above number.

ALL INFORMATION GATHERED DURING THIS STUDY IS STRICTLYCONFIDENTIAL AND THEREFORE WILL NOT BE SEEN BY ANY OF YOUR DOCTORS, YOUR FAMILY, OR ANY OTHER INDIVIDUAL. You are free to decide not to take part in this study, you are under no pressure to do so and you can leave it at any time. PARTICIPATING IN THE STUDY OR LEAVING THE STUDY AT ANY TIME WILL HAVE NO AFFECT ON YOUR NORMAL MEDICAL CARE.

If you have any queries about the research, please contact Anne Andermann or Eila Watson (the researchers) at the Primary Care Education Research Group on 01865-226-922 or 01865-226-788, rather than the Department of Clinical Genetics.

If you do not want to be contacted for this research, please fill out and return the slip below in the reply paid envelope provided, to me at the Department of Clinical Genetics. If we do not receive notification that you do not wish to participate in this study within two weeks, Anne Andermann will contact you by telephone and give you further details of the study. If you decide you wish to participate, a mutually convenient appointment will be set up. Thank you for your help.

Yours sincerely,

[redacted]

Dr. Anneke Lucassen
Consultant in Clinical Genetics

I (please print name) _____ do not agree to being contacted for the Department of Clinical Genetics and the Primary Care Education Research Group study.

Signature _____ Date _____

Consultant in Clinical Genetics
for Northamptonshire
(Child Health Directorate)
Oxford Regional Genetic Service
Tel: (01604) 34700. Ext 4659
Direct Line: (01604) 544659
Fax: (01604) 545988

Our Ref: SP/MG

Dear Madam,

I am writing to ask if you would be interested in participating in a study we are conducting to investigate the expectations, experiences and information needs of women who discussed their family history of breast cancer with their GP and were referred to a hospital clinic.

This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care of Oxford University. The purpose of this study is to improve the medical services and information available to women like yourself.

I would like to clarify that this research does not form part of your medical care and therefore no health advice can be offered by the researchers. Should you want any such advice, please contact our department on the above number.

If you do not want to participate in this research, please return the form below in the freepost envelope provided. If you would like to participate in this research, please read the study information sheet and fill out the questionnaire attached. Thank you for your help.

Yours sincerely

[redacted]

Dr Susan Price
Consultant in Clinical Genetics

----------(cut here)----------

I **do not wish to participate** in the Department of Clinical Genetics and the CRC Primary Care Education Research Group study.

For Office Use Only
Questionnaire Number

University of Oxford

CRC Primary Care Education Research Group

Division of Public Health and Primary Health Care
University of Oxford
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Tel 01865 226788
Fax 01865 226784
DD 01865 2269

Director Dr J Austoker

Study Information Sheet

Title: Experiences of Having Breast and/or Ovarian Cancer in the Family

Participating in this study would involve agreeing to fill out the attached questionnaire and returning it in the reply paid envelope provided.

If you have ever mentioned to your GP that a relative has had breast and/or ovarian cancer, we would be keen to hear your views. Most of our questions ask about your recent experiences, and have no right or wrong answers. Filling out this questionnaire should take about 10 to 15 minutes.

All information gathered during this study is strictly confidential and therefore will not be seen by any of your doctors, your family, or any other individual. You are free to decide not to take part in this study, and you are under no pressure to do so. Participating in the study or choosing not to participate will have no effect on your normal medical care.

If you have any queries about the research, please contact Anne Andermann at the Primary Care Education Research Group on 01865-226-922 or 01865-226-788.

Consultant in Clinical Genetics
for Northamptonshire
(Child Health Directorate)
Oxford Regional Genetic Service
Tel: (01604) 34700. Ext 4659
Direct Line: (01604) 544659
Fax: (01604) 545988

Our Ref: SP/MG

Dear Madam

I am writing once again to ask if you would be interested in participating in a study we are conducting to investigate the expectations, experiences and information needs of women who discussed their family history of breast cancer with their GP and were referred to a hospital clinic.

This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care of Oxford University. The purpose of this study is to improve the medical services and information available to women like yourself.

I would like to clarify that this research does not form part of your medical care and therefore no health advice can be offered by the researchers. Should you want any such advice, please contact our department on the above number.

If you do not want to participate in this research, please return the form below in the freepost envelope provided. If you would like to participate in this research, please read the study information sheet and fill out the questionnaire attached. Thank you for your help.

Yours sincerely

[redacted]

Dr Susan Price
Consultant in Clinical Genetics

----------(cut here)----------

I **do not wish to participate** in the Department of Clinical Genetics and the CRC Primary Care Education Research Group study.

For Office Use Only
Questionnaire Number



Consultant in Clinical Genetics
for Northamptonshire
(Child Health Directorate)
Oxford Regional Genetic Service
Tel: (01604) 34700. Ext 4659
Direct Line: (01604) 544659
Fax: (01604) 545988

Our Ref: SP/MG

Date as postmarked.

Dear Madam,

I am sending you a follow-up questionnaire as part of our study investigating the needs of women referred to the genetics clinic about a family history of breast cancer.

This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care of Oxford University. The purpose of this study is to improve the medical services and information available to women like yourself.

I would like to clarify that this research does not form part of your medical care and therefore no health advice can be offered by the researchers. Should you want any such advice, please contact our department on the above number.

If you no longer want to participate in this research, please return the form below in the freepost envelope provided. If you would like to continue to participate in this research, please read the study information sheet and fill out the questionnaire attached. Thank you for your help.

Yours sincerely

[redacted]

Dr Susan Price
Consultant in Clinical Genetics

----------(cut here)----------

I **do not wish to participate** in the Department of Clinical Genetics and the CRC Primary Care Education Research Group study.

For Office Use Only
Questionnaire Number

Northampton
GENERAL HOSPITAL TRUST

Consultant in Clinical Genetics
for Northamptonshire
(Child Health Directorate)
Oxford Regional Genetic Service
Tel: (01604) 34700. Ext 4659
Direct Line: (01604) 544659
Fax: (01604) 545988

Our Ref: SP/MG

Date as postmarked.

Dear Madam,

I am once again sending you a follow-up questionnaire as part of our study investigating the needs of women referred to the genetics clinic about a family history of breast cancer.

This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care of Oxford University. The purpose of this study is to improve the medical services and information available to women like yourself.

I would like to clarify that this research does not form part of your medical care and therefore no health advice can be offered by the researchers. Should you want any such advice, please contact our department on the above number.

If you no longer want to participate in this research, please return the form below in the freepost envelope provided. If you would like to continue to participate in this research, please read the study information sheet and fill out the questionnaire attached. Thank you for your help.

Yours sincerely,

[redacted]

Dr Susan Price
Consultant in Clinical Genetics

----------(cut here)----------

I **do not wish to participate** in the Department of Clinical Genetics and the CRC Primary Care Education Research Group study.

For Office Use Only
Questionnaire Number

University of Oxford

CRC Primary Care Education Research Group

Division of Public Health and Primary Health Care
University of Oxford
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Tel 01865 226788
Fax 01865 226784
DD 01865 2269

Director Dr J Austoker

Study Information Sheet

Title: Experiences of Having Breast and/or Ovarian Cancer in the Family

Continuing to participate in this study would involve agreeing to fill out the attached questionnaire and returning it in the reply paid envelope provided (no stamp needed).

Most of our questions ask about your recent experiences, and have no right or wrong answers. Filling out this questionnaire should take about 10 minutes.

All information gathered during this study is strictly confidential and therefore will not be seen by any of your doctors, your family, or any other individual. You are free to leave the study at any time, without having to give a reason for leaving. Participating in the study or leaving the study at any time will have no effect on your normal medical care.

If you have any queries about the research, please contact Anne Andermann at the Primary Care Education Research Group on 01865-226-922 or 01865-226-788.

BREAST CANCER IN THE FAMILY

The Cancer Research Campaign and the NHS are committed to improving the services available to women with a family history of breast cancer. As part of this, we are asking for your help with this survey which tries to identify the needs of women who have one or more relatives in their family who have been diagnosed with breast cancer. Your input is important to us whether you are at increased risk of breast cancer or not.

All the information you give will be treated as STRICTLY CONFIDENTIAL.

To complete the questionnaire, please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

QUESTIONS ABOUT BREAST CANCER INFORMATION

1. Where have you found out information about breast cancer? *(please tick ALL THAT APPLY)*

- Family members ☐
- Friends/colleagues ☐
- Family doctor (GP) ☐
- Hospital doctor ☐
- Newspaper/magazines ☐
- Television/radio ☐
- Internet (world wide web) ☐
- Leaflet(s) ☐
- Other *(please specify)* _____ ☐

2. If you had to choose one source of information, which would you say... *(for each, please specify)*

a) Provided you with the greatest amount of information? _____

b) Provided you with the most reassuring information? _____

c) Provided you with the most worrying information? _____

3. At this time, do you feel that you would like to know more information about ... *(for each, please tick ONE BOX ONLY)*

	I want to know more	I know enough
a) How common is breast cancer?	☐	☐
b) The age when most women get breast cancer?	☐	☐
c) Your chances of getting breast cancer?	☐	☐
d) The chances of your family getting breast cancer?	☐	☐
e) The possible signs of breast cancer?	☐	☐
f) What to do if you notice a change in your breast?	☐	☐
g) How breast cancer is diagnosed?	☐	☐
h) How breast cancer is treated?	☐	☐
i) The chances of surviving breast cancer?	☐	☐
j) Who should have mammography (breast x-rays)?	☐	☐
k) Who should have breast cancer gene tests?	☐	☐
l) Who can join research on preventing cancer?	☐	☐
m) Other *(please specify)* _____		

4. If you had to choose one piece of information, what would you most want to know now?

_____

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5. Would you <u>most</u> prefer to get that information by...

(please tick ONE BOX ONLY)

- Talking to your GP ☐
- Talking to a hospital doctor ☐
- Reading a leaflet ☐
- Calling an information help line ☐
- Looking it up on the internet ☐
- Watching an educational video tape ☐
- Other *(please specify)* _____ ☐

QUESTIONS ABOUT TALKING TO YOUR GP ABOUT BREAST CANCER

6. Have you ever seen your GP about a breast problem that <u>you thought</u> may have been a possible sign of breast cancer?

- Yes ☐
- No ☐

7. Have you ever been diagnosed with breast cancer?

- Yes ☐
- No ☐

8. When did you <u>first</u> mention to your GP that a member of your family has had breast cancer? *(Please tick ONE BOX ONLY)*

- During your recent visit ☐
- Several weeks ago ☐
- Several months ago ☐
- One or two years ago ☐
- Many years ago ☐
- Don't know ☐

9. Approximately how many times have you mentioned to your GP that a member of your family has had breast cancer?

☐☐ times

10. When you <u>most recently</u> spoke to your GP, who brought up the subject of breast cancer in your family? *(please tick ONE BOX ONLY)*

- Me - *(If yes, go to **question 11**)* ☐
- My GP - *(If yes, go to **question 13**)* ☐
- Practice nurse - *(If yes, go to **question 12**)* ☐
- Other *(please specify & go to **question 12**)* _____

11. If you brought up the subject, what <u>recently prompted</u> you to mention to your GP that a relative had breast cancer?

(please tick ALL THAT APPLY)

- A problem with my breasts ☐
- A relative recently got breast cancer ☐
- A discussion with friends/colleagues ☐
- Want to know if my GP thinks it's important ☐
- Approaching the age that my relative developed breast cancer ☐
- Something in the media (eg. magazine, TV) ☐
- A question about the pill or HRT ☐
- Suggested by *(please say by whom)* _____
- Other *(please specify)* _____

PAGE 3

12. What were you <u>hoping for</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer? *(If nothing, please tick this box ☐ and go to **question 13**)*

(for each response, please tick ONE BOX ONLY)

a) To be offered reassurance	Yes ☐	No ☐	Don't know ☐
b) To be given information	Yes ☐	No ☐	Don't know ☐
c) To discuss my risks of getting breast cancer	Yes ☐	No ☐	Don't know ☐
d) To have my GP examine my breasts	Yes ☐	No ☐	Don't know ☐
e) To be told the signs of breast cancer to look for	Yes ☐	No ☐	Don't know ☐
f) To discuss using the pill or HRT	Yes ☐	No ☐	Don't know ☐
g) To discuss mammogram screening (breast x-rays)	Yes ☐	No ☐	Don't know ☐
h) To discuss breast cancer gene testing	Yes ☐	No ☐	Don't know ☐
i) To be referred to a specialist	Yes ☐	No ☐	Don't know ☐
j) Other *(please specify)* _____			

13. What <u>actually happened</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer? Did your GP...

(please tick ALL THAT APPLY)

<u>Offer</u> you reassurance? ..... ☐

Ask :

a) How many relatives had breast cancer? ☐
b) The age(s) when your relative(s) got it? ☐
c) If any relatives had any other cancers? ☐

<u>Talk about</u> :

a) Your risks of getting breast cancer? ..... ☐
b) The signs of breast cancer? ..... ☐
c) The pill or HRT? ..... ☐
d) Mammography (breast x-rays)? ..... ☐
e) Breast cancer gene testing? ..... ☐
f) Research for preventing cancer? ..... ☐

<u>Examine</u> your breasts? ..... ☐

<u>Refer</u> you to a specialist? ..... ☐

Other *(please specify)* _____ ☐

14. Approximately how much time did you spend discussing breast cancer in your family with your GP during your <u>recent visit</u>? *(Please tick ONE BOX ONLY)*

A few minutes ..... ☐
5 to 10 minutes ..... ☐
More than 10 minutes ..... ☐
Don't know ..... ☐

15. Did you receive a leaflet called *"Breast and/or Ovarian Cancer in the Family"*? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 16)*** ..... ☐
No - *(If **No**, go to **question 17)*** ..... ☐
Don't know - *(If **DK**, go to **question 17)*** ..... ☐

PAGE 4

16. When you received the leaflet: *(for each, tick ONE BOX ONLY, if **No**, explain when appropriate)*

a) Did you want it?	Yes ☐	No ☐
b) Did you read it?	Yes ☐	No ☐
c) Was it clear?	Yes ☐	No ☐
d) Did it cover what you wanted to know?	Yes ☐	No ☐
e) Did you keep it?	Yes ☐	No ☐
f) Did you show it to anyone else?	Yes ☐	No ☐

g) Other *(please specify)* _____

What changes or additions to the leaflet, if any, would you suggest? *(please specify)* _____

_____

17. What are you <u>hoping will happen</u> during your visit with the specialist at the <u>genetics clinic</u>? *(for each response, please tick ONE BOX ONLY)*

a) To be offered reassurance	Yes ☐	No ☐	Don't know ☐
b) To be given detailed information on breast cancer	Yes ☐	No ☐	Don't know ☐
c) To discuss your risks of breast cancer in detail	Yes ☐	No ☐	Don't know ☐
d) To have your breasts examined	Yes ☐	No ☐	Don't know ☐
e) To be told the signs of breast cancer to look for	Yes ☐	No ☐	Don't know ☐
f) To be offered a mammogram (breast x-ray)	Yes ☐	No ☐	Don't know ☐
g) To be offered a breast cancer gene test	Yes ☐	No ☐	Don't know ☐
h) To be offered to join a cancer prevention study	Yes ☐	No ☐	Don't know ☐
i) To be offered to help with scientific research	Yes ☐	No ☐	Don't know ☐

j) Other *(please specify)* _____

QUESTIONS ABOUT MAMMOGRAPHY (BREAST X-RAY) SCREENING

18. Have you ever had a mammogram (an x-ray of the breast)?
(please tick ONE BOX ONLY)

Yes - *(If **Yes**, go to **question 19)*** ..... ☐
No - *(If **No**, go to **question 20)*** ..... ☐
Don't know - *(If **DK**, go to **question 20)*** ..... ☐

19. Why have you had a mammogram? *(please tick ALL THAT APPLY)*

For reassurance that you don't have cancer ☐
Because of a breast problem ..... ☐
Because a relative had breast cancer ..... ☐
As part of a national screening programme ☐
(free service offered to women aged 50 and over)
As part of a private screening service ..... ☐
(e.g. private health-care plan, offered through work)
Other *(please specify)* _____ ☐
Don't know ..... ☐

PAGE 5

20. Do you feel you would like to start regular breast screening (mammography) <u>now</u>? *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐
- Don't know ☐
- Already getting regular screening ☐

21. Please tell us any views you may have on the <u>potential benefits</u> of regular breast screening (mammography) for <u>women of your age</u> with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

22. Please tell us any <u>concerns</u> you may have about regular breast screening (mammography) for <u>women of your age</u> with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

23. How often do you think that breast screening (mammography) misses breast cancers? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

24. Do you think mammography <u>misses</u> breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

25. Women <u>who turn out not to have</u> breast cancer may need further tests after having a mammogram to rule out the possibility of cancer. How often do you think this happens? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

26. Do you think the number of women <u>who turn out not to have</u> breast cancer but require extra tests after having a mammogram to rule out the possibility of cancer is... *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ☐
- Don't know ☐

QUESTIONS ABOUT BREAST CANCER AND GENE TESTING

27. Has your mother or sister ever had breast cancer diagnosed? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 28)*** ☐
No - *(If **No**, go to **question 29)*** ☐
Don't know - *(If **DK**, go to **question 29)*** ☐

28. If Yes, please tick if it was your mother or your sister (or both) who had breast cancer, and write how old they were when the cancer was first diagnosed *(please put the approximate age at diagnosis if unsure)*

Mother ☐ diagnosed at age ☐☐ years

Sister ☐ diagnosed at age ☐☐ years

29. In total, how many of your relatives have had breast cancer diagnosed? *(please include mother, sisters, aunts and grandmothers on both your mother's side and your father's side)*

☐ relatives

30. Approximately how many women do you think will develop breast cancer at some point in their lifetime? *(Please tick ONE BOX ONLY)*

1 in 3 women ☐
1 in 10 women ☐
1 in 50 women ☐
1 in 100 women ☐
1 in 1000 women ☐
Don't know ☐

31. Compared to most other women your age, do you think your own chances of getting breast cancer at some time during your lifetime are... *(Please tick ONE BOX ONLY)*

Much less ☐
A little less ☐
About the same ☐
A little more ☐
Much more ☐

32. Do you think breast cancer occurs... *(Please tick ONE BOX ONLY)*

More often in women aged 50 and over ☐
More often in women under 50 years of age ☐
About equally in both age groups ☐
Don't know ☐

33. How often do you think women who are diagnosed with breast cancer carry an altered breast cancer gene that can be passed down in the family? Would you say... *(please tick ONE BOX ONLY)*

Very rarely ☐
Rarely ☐
Sometimes ☐
Quite often ☐
Very often ☐
Don't know ☐

34. At this time, do you feel you would like to have a breast cancer gene test? *(please tick ONE BOX ONLY)*

Yes ☐
No ☐
Don't know ☐

Any comments: _____

QUESTIONS ABOUT THINKING ABOUT YOUR CHANCES OF GETTING BREAST CANCER

35. During the past month, how often have you thought about your own chances of developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

36. During the past month, have thoughts about your chances of getting breast cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

37. During the past month, have thoughts about your chances of getting breast cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

38. How concerned are you about the possibility that you might get breast cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

39. How often do you worry about developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

40. How much of a problem is worrying about breast cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

41. What, if anything, has helped you cope with worries about breast cancer in the family?

_____

_____

GENERAL QUESTIONS ABOUT YOU AND YOUR FAMILY

42. What is your date of birth?
(please put day / month / year)

☐☐ / ☐☐ / ☐☐

43. What is your current marital status?
(please tick ONE BOX ONLY)

- Married or living as married ☐
- Single and never been married ☐
- Divorced or separated ☐
- Widowed ☐

44. How many sons have you had?
(please put '0' if you have no sons)

☐ sons

45. How many daughters have you had?
(please put '0' if you have no daughters)

☐ daughters

46. How old were you when you finished full time education? *(please tick ONE BOX ONLY)*

15 years or younger ..... ☐
16 to 18 years old ..... ☐
19 years or older ..... ☐

47. What is the highest level qualification you have? *(please tick ONE BOX ONLY)*

"O" level (or equivalent) ..... ☐
"A" level (or equivalent) ..... ☐
Clerical or commercial qualification..... ☐
(e.g. secretarial, hairdressing, NVQ, etc.)
College or university degree ..... ☐
None of these ..... ☐

48. What ethnic group would you use to describe yourself? *(please tick ONE BOX ONLY)*

White ..... ☐
Black ..... ☐
Indian/Pakistani/Bangladeshi ..... ☐
Chinese ..... ☐
Mixed ..... ☐
Other ..... ☐

FINAL SECTION - OPTIONAL

49. If you have any other thoughts about breast cancer in your family, please tell us in the space below *(continue on the next page if necessary)*

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

BREAST CANCER IN THE FAMILY:

FOLLOW UP QUESTIONNAIRE

Thank you for having returned the previous questionnaire. We are grateful for your contribution to this survey which is part of an ongoing effort by the Cancer Research Campaign and the NHS to improve the services available to women with a family history of breast cancer. Now that you have been to the genetics clinic, we would be interested to hear your views. Once again, all the information you give will be treated as STRICTLY CONFIDENTIAL.

Please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

QUESTIONS ABOUT YOUR CONTACT WITH THE GENETICS CLINIC

1. How soon after your GP referred you did you first hear from the genetics clinic?
(please tick ONE BOX ONLY)

- Less than one month ☐
- One to three months ☐
- More than three months ☐
- Don't know ☐

2. Did the genetics clinic ever send you a form to fill out about your family history?
(please tick ONE BOX ONLY)

- Yes - *(If **Yes**, go to **question 3)*** ☐
- No - *(If **No**, go to **question 4)*** ☐
- Don't know - *(If **DK**, go to **question 4)*** ☐

3. When you got the family history form: *(for each, please explain when appropriate)*

a) Was it clear what the form was asking for? Yes ☐ No ☐
b) Was it difficult to find all the information? Yes ☐ No ☐
c) Did completing the form worry you at all? Yes ☐ No ☐
d) Did completing the form take a lot of time? Yes ☐ No ☐

4. At your recent visit to the genetics clinic, with whom did you talk to about your family history of breast cancer?
(please tick ALL THAT APPLY)

- The doctor ☐
- The nurse ☐
- Other _____ ☐
- Don't know ☐

5. What actually happened during your recent visit to the genetics clinic? Did the doctor, nurse, or other individual...

(please tick ALL THAT APPLY - please note that not all options may be appropriate in your situation)

Go over your family history? ☐

Talk about :

a) Your risks of getting breast cancer? ☐
b) Your family's risks of breast cancer? ☐
c) The signs of breast cancer? ☐
d) The pill or HRT? ☐
e) The pros and cons of mammography? ☐
f) The pros and cons of gene testing? ☐
g) The pros and cons of ovarian screening? ☐
h) The pros and cons of joining research for preventing cancer? ☐
i) Other *(please specify)* _____ ☐

Suggest that you consider :

a) Regular mammography (breast x-rays)? ☐
b) Breast cancer gene testing? ☐
c) Joining an ovarian screening study? ☐
d) Joining research for preventing cancer? ☐
e) Other *(please specify)* _____ ☐

Offer you reassurance? ☐

PAGE 2

6. **How reassured did you feel by your visit to the genetics clinic?** *(Please tick ONE BOX ONLY)*

Very reassured ☐
Quite reassured ☐
Not very reassured ☐
Not at all reassured ☐
Don't know ☐

7. **Approximately how much time did you spend discussing breast cancer in your family <u>with the doctor at the genetics clinic</u>?** *(Please tick ONE BOX ONLY)*

Less than 10 minutes ☐
10 minutes to half an hour ☐
More than half an hour ☐

8. **Did you <u>understand everything</u> you were told at the genetics clinic?** *(Please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 10)*** ☐
No - *(If **No**, go to **question 9)*** ☐
Don't know - *(If **DK**, go to **question 10)*** ☐

9. **If No, what did you not understand?** *(Please specify)*

_____

_____

10. **Did you find out all the information that <u>you</u> wanted to know from your visit to the clinic?** *(Please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 13)*** ☐
No - *(If **No**, go to **question 11)*** ☐
Don't know - *(If **DK**, go to **question 13)*** ☐

11. **If No, what else did you want to know?** *(Please specify)*

_____

_____

12. **Would you <u>most</u> prefer to get that information by...**

(please tick ONE BOX ONLY)

Talking to your GP ☐
Talking to a hospital doctor ☐
Reading a leaflet ☐
Calling an information help line ☐
Looking it up on the internet ☐
Watching an educational video tape ☐
Other *(please specify)* _____ ☐

13. **<u>Overall</u>, how useful was your visit to the genetics clinic?** *(Please tick ONE BOX ONLY)*

Very useful ☐
Quite useful ☐
Not very useful ☐
Not at all useful ☐
Don't know ☐

Any comments about your visit to the genetics clinic: _____

_____

QUESTIONS ABOUT WHAT HAS HAPPENED SINCE YOUR GENETICS CLINIC VISIT

14. Since your visit to the genetics clinic, have you been back in touch with anyone from the genetics clinic to discuss breast cancer in your family?

- Yes, with a nurse - *(If **Yes**, go to **question 15)*** ☐
- Yes, with a doctor - *(If **Yes**, go to **question 15)*** ☐
- Yes, unspecified person - *(go to **question 15)*** ☐
- No - *(If **No**, go to **question 16)*** ..... ☐

15. If yes, what did you discuss with this person from the genetics clinic? *(please specify)* _____

_____

16. Since your visit to the genetics clinic, have you been back in touch with your GP to discuss breast cancer in your family?

- Yes - *(If **Yes**, go to **question 17)*** ..... ☐
- No - *(If **No**, go to **question 18)*** ..... ☐

17. If yes, what did you discuss with your GP? *(please specify)* _____

_____

18. Do you feel you would like to start regular breast screening (mammography) now? *(please tick ONE BOX ONLY)*

- Yes ..... ☐
- No ..... ☐
- Don't know ..... ☐
- Already getting regular screening ..... ☐

19. Overall, how much of a choice do you feel you have in making decisions about your management with respect to having breast cancer in your family? *(Please tick ONE BOX ONLY)*

- A lot of choice ..... ☐
- Some choice ..... ☐
- Very little choice ..... ☐
- No choice ..... ☐
- Unsure ..... ☐

20. Do you feel this much choice is? *(Please tick ONE BOX ONLY)*

- Too much ..... ☐
- About right ..... ☐
- Not enough ..... ☐
- Don't know ..... ☐

Any comments: _____

QUESTIONS ABOUT BREAST AWARENESS

21. Do you know the signs/symptoms of breast cancer to look and feel for? *(please tick ONE BOX ONLY)*

- Yes - *(If **Yes**, go to **question 22)*** ..... ☐
- No - *(If **No**, go to **question 23)*** ..... ☐
- Don't know - *(If **DK**, go to **question 23)*** ..... ☐

22. If yes, how confident do you feel about recognising these signs/symptoms? *(Please tick ONE BOX ONLY)*

- Very confident ..... ☐
- Quite confident ..... ☐
- Not very confident ..... ☐
- Not at all confident ..... ☐
- Don't know ..... ☐

QUESTIONS ABOUT MAMMOGRAPHY (BREAST X-RAY) SCREENING

23. Please tell us any views you may have on the potential benefits of regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

24. Please tell us any concerns you may have about regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

25. How often do you think that breast screening (mammography) misses breast cancers? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

26. Do you think mammography misses breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

27. Women who turn out not to have breast cancer may need further tests after having a mammogram to rule out the possibility of cancer. How often do you think this happens? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

28. Do you think the number of women who turn out not to have breast cancer but require extra tests after having a mammogram to rule out the possibility of cancer is... *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ☐
- Don't know ☐

QUESTIONS ABOUT THE CHANCES OF GETTING BREAST CANCER

29. Approximately how many women do you think will develop breast cancer <u>at some point</u> in their lifetime? *(Please tick ONE BOX ONLY)*

- 1 in 3 women ☐
- 1 in 10 women ☐
- 1 in 50 women ☐
- 1 in 100 women ☐
- 1 in 1000 women ☐
- Don't know ☐

30. Compared to most other women your age, do you think <u>your own chances</u> of getting breast cancer at some time during <u>your</u> lifetime are... *(Please tick ONE BOX ONLY)*

- Much less ☐
- A little less ☐
- About the same ☐
- A little more ☐
- Much more ☐

31. <u>Since your visit to the genetics clinic</u>, do you think <u>your own chances</u> of getting breast cancer at some time during your lifetime are... *(Please tick ONE BOX ONLY)*

- Lower than you had thought ☐
- About the same as you had thought ☐
- Higher than you had thought ☐
- Don't know ☐

Any comments: _____

32. Do you think breast cancer occurs... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

33. How often do you think women who are diagnosed with breast cancer carry an altered breast cancer gene that can be passed down in the family? Would you say... *(please tick ONE BOX ONLY)*

- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

34. Do you think <u>your own chances</u> of carrying an altered breast cancer gene are... *(Please tick ONE BOX ONLY)*

- Very low ☐
- Low ☐
- About average ☐
- High ☐
- Very high ☐
- Don't know ☐

35. <u>Since your visit to the genetics clinic</u>, do you think <u>your own chances</u> of carrying an altered breast cancer gene are... *(Please tick ONE BOX ONLY)*

- Lower than you had thought ☐
- About the same as you had thought ☐
- Higher than you had thought ☐
- Don't know ☐

Any comments: _____

QUESTIONS ABOUT THINKING ABOUT YOUR CHANCES OF GETTING BREAST CANCER

36. During the past month, how often have you thought about your own chances of developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

37. During the past month, have thoughts about your chances of getting breast cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

38. During the past month, have thoughts about your chances of getting breast cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

39. How concerned are you about the possibility that you might get breast cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

40. How often do you worry about developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

41. How much of a problem is worrying about breast cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

42. If you have any other thoughts about breast cancer in your family, please tell us in the space below ***(please continue on the back of this page if necessary)***

_____

_____

_____

_____

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

BREAST CANCER IN THE FAMILY

The Cancer Research Campaign and the NHS are committed to improving the services available to women with a family history of breast cancer. As part of this, we are asking for your help with this survey which tries to identify the needs of women who have one or more relatives in their family who have been diagnosed with breast cancer. Your input is important to us whether you are at increased risk of breast cancer or not.

All the information you give will be treated as STRICTLY CONFIDENTIAL.

To complete the questionnaire, please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
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cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

QUESTIONS ABOUT BREAST CANCER INFORMATION

1. Where have you found out information about breast cancer? *(please tick ALL THAT APPLY)*

- Family members ☐
- Friends/colleagues ☐
- Family doctor (GP) ☐
- Hospital doctor ☐
- Newspaper/magazines ☐
- Television/radio ☐
- Internet (world wide web) ☐
- Leaflet(s) ☐
- Other *(please specify)* _____ ☐

2. If you had to choose <u>one source</u> of information, which would you say... *(for each, please specify)*

a) Provided you with the <u>greatest amount</u> of information? _____

b) Provided you with the <u>most reassuring</u> information? _____

c) Provided you with the <u>most worrying</u> information? _____

3. <u>At this time</u>, do you feel that you would like to know more information about ... *(for each, please tick ONE BOX ONLY)*

	I want to know more	I know enough
a) How common is breast cancer?	☐	☐
b) The age when most women get breast cancer?	☐	☐
c) Your chances of getting breast cancer?	☐	☐
d) The chances of your family getting breast cancer?	☐	☐
e) The possible signs of breast cancer?	☐	☐
f) What to do if you notice a change in your breast?	☐	☐
g) How breast cancer is diagnosed?	☐	☐
h) How breast cancer is treated?	☐	☐
i) The chances of surviving breast cancer?	☐	☐
j) Who should have mammography (breast x-rays)?	☐	☐
k) Who should have breast cancer gene tests?	☐	☐
l) Who can join research on preventing cancer?	☐	☐
m) Other *(please specify)* _____		

4. If you had to choose one piece of information, what would you <u>most</u> want to know <u>now</u>?

_____

5. **Would you <u>most</u> prefer to get that information by...**

(please tick ONE BOX ONLY)

- Talking to your GP ☐
- Talking to a hospital doctor ☐
- Reading a leaflet ☐
- Calling an information help line ☐
- Looking it up on the internet ☐
- Watching an educational video tape ☐
- Other *(please specify)* _____ ☐

QUESTIONS ABOUT TALKING TO YOUR GP ABOUT BREAST CANCER

6. **Have you ever seen your GP about a breast problem that <u>you thought</u> may have been a possible sign of breast cancer?**

- Yes ☐
- No ☐

7. **Have you ever been diagnosed with breast cancer?**

- Yes ☐
- No ☐

8. **When did you <u>first</u> mention to your GP that a member of your family has had breast cancer?** *(Please tick ONE BOX ONLY)*

- During your recent visit ☐
- Several weeks ago ☐
- Several months ago ☐
- One or two years ago ☐
- Many years ago ☐
- Don't know ☐

9. **Approximately how many times have you mentioned to your GP that a member of your family has had breast cancer?**

☐☐ times

10. **When you <u>most recently</u> spoke to your GP, who brought up the subject of breast cancer in your family?** *(please tick ONE BOX ONLY)*

- Me - *(If yes, go to **question 11**)* ☐
- My GP - *(If yes, go to **question 13**)* ☐
- Practice nurse - *(If yes, go to **question 12**)* ☐
- Other *(please specify & go to **question 12**)* _____

11. **If you brought up the subject, what <u>recently prompted</u> you to mention to your GP that a relative had breast cancer?**

(please tick ALL THAT APPLY)

- A problem with my breasts ☐
- A relative recently got breast cancer ☐
- A discussion with friends/colleagues ☐
- Want to know if my GP thinks it's important ☐
- Approaching the age that my relative developed breast cancer ☐
- Something in the media (eg. magazine, TV) ☐
- A question about the pill or HRT ☐
- Suggested by *(please say by whom)* _____
- Other *(please specify)* _____

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12. What were you <u>hoping for</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer? *(If nothing, please tick this box ☐ and go to **question 13**)*

(for each response, please tick ONE BOX ONLY)

a) To be offered reassurance	Yes ☐	No ☐	Don't know ☐
b) To be given information	Yes ☐	No ☐	Don't know ☐
c) To discuss my risks of getting breast cancer	Yes ☐	No ☐	Don't know ☐
d) To have my GP examine my breasts	Yes ☐	No ☐	Don't know ☐
e) To be told the signs of breast cancer to look for	Yes ☐	No ☐	Don't know ☐
f) To discuss using the pill or HRT	Yes ☐	No ☐	Don't know ☐
g) To discuss mammogram screening (breast x-rays)	Yes ☐	No ☐	Don't know ☐
h) To discuss breast cancer gene testing	Yes ☐	No ☐	Don't know ☐
i) To be referred to a specialist	Yes ☐	No ☐	Don't know ☐
j) Other *(please specify)* _____			

13. What <u>actually happened</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer?

Did your GP...

(please tick ALL THAT APPLY)

<u>Offer</u> you reassurance? ..... ☐

<u>Ask</u> :
- a) How many relatives had breast cancer? ☐
- b) The age(s) when your relative(s) got it? ☐
- c) If any relatives had any other cancers? ☐

<u>Talk about</u> :
- a) Your risks of getting breast cancer? ..... ☐
- b) The signs of breast cancer? ..... ☐
- c) The pill or HRT? ..... ☐
- d) Mammography (breast x-rays)? ..... ☐
- e) Breast cancer gene testing? ..... ☐
- f) Research for preventing cancer? ..... ☐

<u>Examine</u> your breasts? ..... ☐

<u>Refer</u> you to a specialist? ..... ☐

Other *(please specify)* _____ ☐

14. Approximately how much time did you spend discussing breast cancer in your family with your GP during your <u>recent visit</u>? *(Please tick ONE BOX ONLY)*

- A few minutes ..... ☐
- 5 to 10 minutes ..... ☐
- More than 10 minutes ..... ☐
- Don't know ..... ☐

15. Did you receive a leaflet called *"Breast and/or Ovarian Cancer in the Family"*? *(please tick ONE BOX ONLY)*

- Yes - *(If **Yes**, go to **question 16**)* ..... ☐
- No - *(If **No**, go to **question 17**)* ..... ☐
- Don't know - *(If **DK**, go to **question 17**)* ..... ☐

16. When you received the leaflet: *(for each, tick ONE BOX ONLY, if **No**, explain when appropriate)*

a) Did you want it?	Yes ☐	No ☐
b) Did you read it?	Yes ☐	No ☐
c) Was it clear?	Yes ☐	No ☐
d) Did it cover what you wanted to know?	Yes ☐	No ☐
e) Did you keep it?	Yes ☐	No ☐
f) Did you show it to anyone else?	Yes ☐	No ☐

g) Other *(please specify)* _____

What changes or additions to the leaflet, if any, would you suggest? *(please specify)* _____

_____

17. What are you <u>hoping will happen</u> during your visit with the specialist at the <u>breast clinic</u>? *(for each response, please tick ONE BOX ONLY)*

a) To be offered reassurance	Yes ☐	No ☐	Don't know ☐
b) To be given detailed information on breast cancer	Yes ☐	No ☐	Don't know ☐
c) To discuss your risks of breast cancer in detail	Yes ☐	No ☐	Don't know ☐
d) To have your breasts examined	Yes ☐	No ☐	Don't know ☐
e) To be told the signs of breast cancer to look for	Yes ☐	No ☐	Don't know ☐
f) To be offered a mammogram (breast x-ray)	Yes ☐	No ☐	Don't know ☐
g) To be offered a breast cancer gene test	Yes ☐	No ☐	Don't know ☐
h) To be offered to join a cancer prevention study	Yes ☐	No ☐	Don't know ☐
i) To be offered to help with scientific research	Yes ☐	No ☐	Don't know ☐

j) Other *(please specify)* _____

QUESTIONS ABOUT MAMMOGRAPHY (BREAST X-RAY) SCREENING

18. Have you ever had a mammogram (an x-ray of the breast)?
(please tick ONE BOX ONLY)

Yes - *(If **Yes**, go to **question 19)*** ..... ☐
No - *(If **No**, go to **question 20)*** ..... ☐
Don't know - *(If **DK**, go to **question 20)*** ..... ☐

19. Why have you had a mammogram?

(please tick ALL THAT APPLY)

For reassurance that you don't have cancer ☐
Because of a breast problem ..... ☐
Because a relative had breast cancer ..... ☐
As part of a national screening programme ☐
(free service offered to women aged 50 and over)
As part of a private screening service ..... ☐
(e.g. private health-care plan, offered through work)
Other *(please specify)* _____ ☐
Don't know ..... ☐

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20. Do you feel you would like to start regular breast screening (mammography) now? *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐
- Don't know ☐
- Already getting regular screening ☐

21. Please tell us any views you may have on the potential benefits of regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

22. Please tell us any concerns you may have about regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

23. How often do you think that breast screening (mammography) misses breast cancers? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

24. Do you think mammography misses breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

25. Women who turn out not to have breast cancer may need further tests after having a mammogram to rule out the possibility of cancer. How often do you think this happens? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

26. Do you think the number of women who turn out not to have breast cancer but require extra tests after having a mammogram to rule out the possibility of cancer is... *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ☐
- Don't know ☐

QUESTIONS ABOUT BREAST CANCER AND GENE TESTING

27. Has your mother or sister ever had breast cancer diagnosed? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 28**)* ☐
No - *(If **No**, go to **question 29**)* ☐
Don't know - *(If **DK**, go to **question 29**)* ☐

28. If Yes, please tick if it was your mother or your sister (or both) who had breast cancer, and write how old they were when the cancer was first diagnosed *(please put the approximate age at diagnosis if unsure)*

Mother ☐ diagnosed at age ☐☐ years

Sister ☐ diagnosed at age ☐☐ years

29. In total, how many of your relatives have had breast cancer diagnosed? *(please include mother, sisters, aunts and grandmothers on both your mother's side and your father's side)*

☐ relatives

30. Approximately how many women do you think will develop breast cancer at some point in their lifetime? *(Please tick ONE BOX ONLY)*

1 in 3 women ☐
1 in 10 women ☐
1 in 50 women ☐
1 in 100 women ☐
1 in 1000 women ☐
Don't know ☐

31. Compared to most other women your age, do you think your own chances of getting breast cancer at some time during your lifetime are... *(Please tick ONE BOX ONLY)*

Much less ☐
A little less ☐
About the same ☐
A little more ☐
Much more ☐

32. Do you think breast cancer occurs... *(Please tick ONE BOX ONLY)*

More often in women aged 50 and over ☐
More often in women under 50 years of age ☐
About equally in both age groups ☐
Don't know ☐

33. How often do you think women who are diagnosed with breast cancer carry an altered breast cancer gene that can be passed down in the family? Would you say... *(please tick ONE BOX ONLY)*

Very rarely ☐
Rarely ☐
Sometimes ☐
Quite often ☐
Very often ☐
Don't know ☐

34. At this time, do you feel you would like to have a breast cancer gene test? *(please tick ONE BOX ONLY)*

Yes ☐
No ☐
Don't know ☐

Any comments: _____

QUESTIONS ABOUT THINKING ABOUT YOUR CHANCES OF GETTING BREAST CANCER

35. During the past month, how often have you thought about your own chances of developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

36. During the past month, have thoughts about your chances of getting breast cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

37. During the past month, have thoughts about your chances of getting breast cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

38. How concerned are you about the possibility that you might get breast cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

39. How often do you worry about developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

40. How much of a problem is worrying about breast cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

41. What, if anything, has helped you cope with worries about breast cancer in the family?

_____

_____

GENERAL QUESTIONS ABOUT YOU AND YOUR FAMILY

42. What is your date of birth? *(please put day / month / year)*

☐☐ / ☐☐ / ☐☐

43. What is your current marital status? *(please tick ONE BOX ONLY)*

- Married or living as married ☐
- Single and never been married ☐
- Divorced or separated ☐
- Widowed ☐

44. How many sons have you had?
(please put '0' if you have no sons)

☐ sons

45. How many daughters have you had?
(please put '0' if you have no daughters)

☐ daughters

46. How old were you when you finished full time education? *(please tick ONE BOX ONLY)*

15 years or younger ..... ☐
16 to 18 years old ..... ☐
19 years or older ..... ☐

47. What is the highest level qualification you have? *(please tick ONE BOX ONLY)*

"O" level (or equivalent) ..... ☐
"A" level (or equivalent) ..... ☐
Clerical or commercial qualification..... ☐
(e.g. secretarial, hairdressing, NVQ, etc.)
College or university degree ..... ☐
None of these ..... ☐

48. What ethnic group would you use to describe yourself? *(please tick ONE BOX ONLY)*

White ..... ☐
Black ..... ☐
Indian/Pakistani/Bangladeshi ..... ☐
Chinese ..... ☐
Mixed ..... ☐
Other ..... ☐

FINAL SECTION - OPTIONAL

49. If you have any other thoughts about breast cancer in your family, please tell us in the space below *(continue on the next page if necessary)*

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

BREAST CANCER IN THE FAMILY:

FOLLOW UP QUESTIONNAIRE

Thank you for having returned the previous questionnaire. We are grateful for your contribution to this survey which is part of an ongoing effort by the Cancer Research Campaign and the NHS to improve the services available to women with a family history of breast cancer. Now that you have been to the breast clinic, we would be interested to hear your views. Once again, all the information you give will be treated as STRICTLY CONFIDENTIAL.

Please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

QUESTIONS ABOUT YOUR CONTACT WITH THE BREAST CLINIC

1. How soon after your GP referred you did you <u>first</u> hear from the breast clinic?
(please tick ONE BOX ONLY)

- Less than one month ☐
- One to three months ☐
- More than three months ☐
- Don't know ☐

2. <u>At your recent visit to the breast clinic</u>, with whom did you talk to about your family history of breast cancer?
(please tick ALL THAT APPLY)

- The breast surgeon ☐
- The nurse ☐
- Other _____ ☐
- Don't know ☐

3. What <u>actually happened</u> during your recent visit to the <u>breast clinic</u>? Did the doctor, nurse, or other individual...

(please tick ALL THAT APPLY - please note that not all options may be appropriate in your situation)

<u>Examine</u> your breasts? ☐
<u>Send</u> you for a mammogram (breast x-ray)? ☐
<u>Go over</u> your family history? ☐
<u>Talk about</u> :
a) Your risks of getting breast cancer? ☐
b) Your family's risks of breast cancer? ☐
c) The signs of breast cancer? ☐
d) The pill or HRT? ☐
e) The pros and cons of mammography? ☐
f) The pros and cons of gene testing? ☐
g) The pros and cons of ovarian screening? ☐
h) The pros and cons of joining research for preventing cancer? ☐
i) Other *(please specify)* _____ ☐
<u>Suggest that you consider</u> :
a) Regular mammography (breast x-rays)? ☐
b) Joining an ovarian screening study? ☐
c) Joining research for preventing cancer? ☐
d) Learning more about breast awareness? ☐
e) Other *(please specify)* _____ ☐
<u>Offer</u> you reassurance? ☐
<u>Refer you to</u> : ☐
a) A genetics clinic? ☐
b) A gynaecologist? ☐

4. How reassured did you feel by your visit to the breast clinic? *(Please tick ONE BOX ONLY)*

- Very reassured ☐
- Quite reassured ☐
- Not very reassured ☐
- Not at all reassured ☐
- Don't know ☐

PAGE 2

5. **Approximately how much time did you spend discussing breast cancer in your family <u>with the doctor at the breast clinic</u>?** *(Please tick ONE BOX ONLY)*

Less than 10 minutes ☐
10 minutes to half an hour ☐
More than half an hour ☐

6. **Did you <u>understand everything</u> you were told at the breast clinic?** *(Please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 8**)* ☐
No - *(If **No**, go to **question 7**)* ☐
Don't know - *(If **DK**, go to **question 8**)* ☐

7. **If No, what did you not understand?** *(Please specify)*

_____

_____

8. **Did you find out all the information that <u>you</u> wanted to know from your visit to the clinic?** *(Please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 11**)* ☐
No - *(If **No**, go to **question 9**)* ☐
Don't know - *(If **DK**, go to **question 11**)* ☐

9. **If No, what else did you want to know?** *(Please specify)*

_____

_____

10. **Would you <u>most</u> prefer to get that information by...**

(please tick ONE BOX ONLY)

Talking to your GP ☐
Talking to a hospital doctor ☐
Reading a leaflet ☐
Calling an information help line ☐
Looking it up on the internet ☐
Watching an educational video tape ☐
Other *(please specify)* _____ ☐

11. **<u>Overall</u>, how useful was your visit to the breast clinic?** *(Please tick ONE BOX ONLY)*

Very useful ☐
Quite useful ☐
Not very useful ☐
Not at all useful ☐
Don't know ☐

Any comments about your visit to the breast clinic: _____

_____

_____

QUESTIONS ABOUT WHAT HAS HAPPENED SINCE YOUR BREAST CLINIC VISIT

12. Since your visit to the breast clinic, have you been back in touch with anyone from the breast clinic to discuss breast cancer in your family?

- Yes, with a nurse - *(If **Yes**, go to **question 13)*** ☐
- Yes, with a doctor - *(If **Yes**, go to **question 13)*** ☐
- Yes, unspecified person - *(go to **question 13)*** ☐
- No - *(If **No**, go to **question 14)*** ..... ☐

13. If yes, what did you discuss with this person from the breast clinic? *(please specify)* _____

_____

14. Since your visit to the breast clinic, have you been back in touch with your GP to discuss breast cancer in your family?

- Yes - *(If **Yes**, go to **question 15)*** ..... ☐
- No - *(If **No**, go to **question 16)*** ..... ☐

15. If yes, what did you discuss with your GP? *(please specify)* _____

_____

16. Do you feel you would like to start regular breast screening (mammography) now? *(please tick ONE BOX ONLY)*

- Yes ..... ☐
- No ..... ☐
- Don't know ..... ☐
- Already getting regular screening ..... ☐

17. Overall, how much of a choice do you feel you have in making decisions about your management with respect to having breast cancer in your family? *(Please tick ONE BOX ONLY)*

- A lot of choice ..... ☐
- Some choice ..... ☐
- Very little choice ..... ☐
- No choice ..... ☐
- Unsure ..... ☐

18. Do you feel this much choice is? *(Please tick ONE BOX ONLY)*

- Too much ..... ☐
- About right ..... ☐
- Not enough ..... ☐
- Don't know ..... ☐

Any comments: _____

QUESTIONS ABOUT BREAST AWARENESS

19. Do you know the signs/symptoms of breast cancer to look and feel for? *(please tick ONE BOX ONLY)*

- Yes - *(If **Yes**, go to **question 20)*** ..... ☐
- No - *(If **No**, go to **question 21)*** ..... ☐
- Don't know - *(If **DK**, go to **question 21)*** ..... ☐

20. If yes, how confident do you feel about recognising these signs/symptoms? *(Please tick ONE BOX ONLY)*

- Very confident ..... ☐
- Quite confident ..... ☐
- Not very confident ..... ☐
- Not at all confident ..... ☐
- Don't know ..... ☐

QUESTIONS ABOUT MAMMOGRAPHY (BREAST X-RAY) SCREENING

21. Please tell us any views you may have on the potential benefits of regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

22. Please tell us any concerns you may have about regular breast screening (mammography) for women of your age with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

23. How often do you think that breast screening (mammography) misses breast cancers? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

24. Do you think mammography misses breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

25. Women who turn out not to have breast cancer may need further tests after having a mammogram to rule out the possibility of cancer. How often do you think this happens? *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

26. Do you think the number of women who turn out not to have breast cancer but require extra tests after having a mammogram to rule out the possibility of cancer is... *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ☐
- Don't know ☐

QUESTIONS ABOUT THE CHANCES OF GETTING BREAST CANCER

27. Approximately how many women do you think will develop breast cancer <u>at some point</u> in their lifetime? *(Please tick ONE BOX ONLY)*

- 1 in 3 women ☐
- 1 in 10 women ☐
- 1 in 50 women ☐
- 1 in 100 women ☐
- 1 in 1000 women ☐
- Don't know ☐

28. Compared to most other women your age, do you think <u>your own chances</u> of getting breast cancer at some time during <u>your</u> lifetime are... *(Please tick ONE BOX ONLY)*

- Much less ☐
- A little less ☐
- About the same ☐
- A little more ☐
- Much more ☐

29. <u>Since your visit to the breast clinic</u>, do you think <u>your own chances</u> of getting breast cancer at some time during your lifetime are... *(Please tick ONE BOX ONLY)*

- Lower than you had thought ☐
- About the same as you had thought ☐
- Higher than you had thought ☐
- Don't know ☐

Any comments: _____

30. Do you think breast cancer occurs... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

31. How often do you think women who are diagnosed with breast cancer carry an altered breast cancer gene that can be passed down in the family? Would you say... *(please tick ONE BOX ONLY)*

- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

32. Do you think <u>your own chances</u> of carrying an altered breast cancer gene are... *(Please tick ONE BOX ONLY)*

- Very low ☐
- Low ☐
- About average ☐
- High ☐
- Very high ☐
- Don't know ☐

33. <u>Since your visit to the breast clinic</u>, do you think <u>your own chances</u> of carrying an altered breast cancer gene are... *(Please tick ONE BOX ONLY)*

- Lower than you had thought ☐
- About the same as you had thought ☐
- Higher than you had thought ☐
- Don't know ☐
- Not applicable ☐

Any comments: _____

QUESTIONS ABOUT THINKING ABOUT YOUR CHANCES OF GETTING BREAST CANCER

34. During the past month, how often have you thought about your own chances of developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

35. During the past month, have thoughts about your chances of getting breast cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

36. During the past month, have thoughts about your chances of getting breast cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

37. How concerned are you about the possibility that you might get breast cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

38. How often do you worry about developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

39. How much of a problem is worrying about breast cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

40. If you have any other thoughts about breast cancer in your family, please tell us in the space below ***(please continue on the back of this page if necessary)***

_____

_____

_____

_____

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

BREAST CANCER IN THE FAMILY

The Cancer Research Campaign and the NHS are committed to improving the services available to women with a family history of breast cancer. As part of this, we are asking for your help with this survey which tries to identify the needs of women who have one or more relatives in their family who have been diagnosed with breast cancer. Your input is important to us whether you are at increased risk of breast cancer or not.

All the information you give will be treated as STRICTLY CONFIDENTIAL.

To complete the questionnaire, please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

QUESTIONS ABOUT TALKING TO YOUR GP ABOUT BREAST CANCER

1. When did you <u>first</u> mention to your GP that a member of your family has had breast cancer? *(Please tick ONE BOX ONLY)*

- During your recent visit ☐
- Several weeks ago ☐
- Several months ago ☐
- One or two years ago ☐
- Many years ago ☐
- Don't know ☐

2. Approximately how many times have you mentioned to your GP that a member of your family has had breast cancer?

☐☐ times

3. When you <u>most recently</u> spoke to your GP, who brought up the subject of breast cancer in your family? *(please tick ONE BOX ONLY)*

- Me - *(If yes, go to **question 4**)* ☐
- My GP - *(If yes, go to **question 6**)* ☐
- Practice nurse - *(If yes, go to **question 5**)* ☐
- Other *(please specify & go to **question 5**)* _____

4. If you brought up the subject, what <u>recently prompted</u> you to mention to your GP that a relative had breast cancer?

(please tick ALL THAT APPLY)

- A problem with my breasts ☐
- A relative recently got breast cancer ☐
- A discussion with friends/colleagues ☐
- Want to know if my GP thinks it's important ☐
- Approaching the age that my relative developed breast cancer ☐
- Something in the media (eg. magazine, TV) ☐
- A question about the pill or HRT ☐
- Suggested by *(please say by whom)* _____
- Other *(please specify)* _____

5. What were you <u>hoping for</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer? *(If nothing, please tick this box ☐ and go to **question 6**)*

(for each response, please tick ONE BOX ONLY)

a) To be offered reassurance	Yes ☐	No ☐	Don't know ☐
b) To be given information	Yes ☐	No ☐	Don't know ☐
c) To discuss my risks of getting breast cancer	Yes ☐	No ☐	Don't know ☐
d) To have my GP examine my breasts	Yes ☐	No ☐	Don't know ☐
e) To be told the signs of breast cancer to look for	Yes ☐	No ☐	Don't know ☐
f) To discuss using the pill or HRT	Yes ☐	No ☐	Don't know ☐
g) To discuss mammogram screening (breast x-rays)	Yes ☐	No ☐	Don't know ☐
h) To discuss breast cancer gene testing	Yes ☐	No ☐	Don't know ☐
i) To be referred to a specialist	Yes ☐	No ☐	Don't know ☐
j) Other *(please specify)*			

6. What <u>actually happened</u> during your most <u>recent visit</u> when you mentioned to your GP that a relative had breast cancer? Did your GP...

(please tick ALL THAT APPLY)

<u>Offer</u> you reassurance? ..... ☐

<u>Ask</u> :

a) How many relatives had breast cancer? ☐
b) The age(s) when your relative(s) got it? ☐
c) If any relatives had any other cancers? ☐

<u>Talk about</u> :

a) Your risks of getting breast cancer? ..... ☐
b) The signs of breast cancer? ..... ☐
c) The pill or HRT? ..... ☐
d) Mammography (breast x-rays)? ..... ☐
e) Breast cancer gene testing? ..... ☐
f) Research for preventing cancer? ..... ☐

<u>Examine</u> your breasts? ..... ☐

<u>Refer</u> you to a specialist? ..... ☐

Other *(please specify)* _____ ☐

7. Approximately how much time did you spend discussing breast cancer in your family with your GP during your <u>recent visit</u>? *(Please tick ONE BOX ONLY)*

A few minutes ..... ☐
5 to 10 minutes ..... ☐
More than 10 minutes ..... ☐
Don't know ..... ☐

8. Did you receive a leaflet called *"Breast and/or Ovarian Cancer in the Family"*? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 9)*** ..... ☐
No - *(If **No**, go to **question 10)*** ..... ☐
Don't know - *(If **DK**, go to **question 10)*** ..... ☐

9. When you received the leaflet: *(for each, tick ONE BOX ONLY, if **No**, explain when appropriate)*

a) Did you want it?	Yes ☐	No ☐
b) Did you read it?	Yes ☐	No ☐
c) Was it clear?	Yes ☐	No ☐
d) Did it cover what you wanted to know?	Yes ☐	No ☐
e) Did you keep it?	Yes ☐	No ☐
f) Did you show it to anyone else?	Yes ☐	No ☐

g) Other *(please specify)* _____

What changes or additions to the leaflet, if any, would you suggest? *(please specify)*

_____

_____

_____

QUESTIONS ABOUT YOUR CONTACT WITH THE GENETICS CLINIC

10. How soon after your GP referred you did you first hear from the genetics clinic? *(please tick ONE BOX ONLY)*

- Less than one month ☐
- One to three months ☐
- More than three months ☐
- Don't know ☐
- Have not heard anything *(go to question 21)* ☐

11. Have you received a letter from the clinic saying you do not need an appointment? *(please tick ONE BOX ONLY)*

- Yes - *(If **Yes**, go to **question 12)*** ☐
- No - *(If **No**, go to **question 13)*** ☐
- Don't know - *(If **DK**, go to **question 13)*** ☐

12. If yes, how reassured do you feel by this letter? *(Please tick ONE BOX ONLY)*

- Very reassured ☐
- Quite reassured ☐
- Not very reassured ☐
- Not at all reassured ☐
- Don't know ☐

13. Since you heard from the genetics clinic, have you been back in touch with your GP to discuss breast cancer in your family?

- Yes - *(If **Yes**, go to **question 14)*** ☐
- No - *(If **No**, go to **question 15)*** ☐

14. If yes, what were your main reasons for going back to discuss this with your GP?

_____

_____

15. Since you heard from the genetics clinic, have you tried to find out any more information about breast cancer?

- Yes - *(If **Yes**, go to **question 16)*** ☐
- No - *(If **No**, go to **question 18)*** ☐

16. If yes, from where did you try to find the information? *(please tick ALL THAT APPLY)*

- Family members ☐
- Friends/colleagues ☐
- Family doctor (GP) ☐
- Hospital doctor ☐
- Newspaper/magazines ☐
- Television/radio ☐
- Internet (world wide web) ☐
- Leaflet(s) ☐
- Other *(please specify)* _____ ☐

17. If you had to choose one source of information, which would you say... *(for each, please specify)*

a) Provided you with the greatest amount of information? _____

b) Provided you with the most reassuring information? _____

c) Provided you with the most worrying information? _____

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18. At this time, do you have any questions about breast cancer in the family that you would still like to have answered? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 19)*** ☐
No - *(If **No**, go to **question 21)*** ☐
Don't know - *(If **DK**, go to **question 21)*** ☐

19. If Yes, what would you like to know? *(please write any questions you have below)* _____

_____

_____

_____

_____

_____

20. Would you most prefer to get the answers to your questions by...

(please tick ONE BOX ONLY)

Talking to your GP ☐
Talking to a hospital doctor ☐
Reading a leaflet ☐
Calling an information help line ☐
Looking it up on the internet ☐
Watching an educational video tape ☐
Other *(please specify)* _____ ☐

QUESTIONS ABOUT BREAST AWARENESS

21. Do you know the signs/symptoms of breast cancer to look and feel for? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 22)*** ☐
No - *(If **No**, go to **question 23)*** ☐
Don't know - *(If **DK**, go to **question 23)*** ☐

22. If yes, how confident do you feel about recognising these signs/symptoms? *(Please tick ONE BOX ONLY)*

Very confident ☐
Quite confident ☐
Not very confident ☐
Not at all confident ☐
Don't know ☐

QUESTIONS ABOUT MAMMOGRAPHY (BREAST X-RAY) SCREENING

23. Have you ever had a mammogram (an x-ray of the breast)? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 24)*** ☐
No - *(If **No**, go to **question 25)*** ☐
Don't know - *(If **DK**, go to **question 25)*** ☐

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24. Why have you had a mammogram? *(please tick ALL THAT APPLY)*

- For reassurance that you don't have cancer ☐
- Because of a breast problem ..... ☐
- Because a relative had breast cancer ..... ☐
- As part of a national screening programme ☐
  (free service offered to women aged 50 and over)
- As part of a private screening service ..... ☐
  (e.g. private health-care plan, offered through work)
- Other *(please specify)* _____ ☐
- Don't know ..... ☐

25. Do you feel you would like to start regular breast screening (mammography) <u>now</u>? *(please tick ONE BOX ONLY)*

- Yes ..... ☐
- No ..... ☐
- Don't know ..... ☐
- Already getting regular screening ..... ☐

26. Please tell us any views you may have on the <u>potential benefits</u> of regular breast screening (mammography) for <u>women of your age</u> with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

_____

27. Please tell us any <u>concerns</u> you may have about regular breast screening (mammography) for <u>women of your age</u> with no breast symptoms. *(Please tick the box if you have no particular views about this ☐)*

_____

_____

28. How often do you think that breast screening (mammography) misses breast cancers? *(Please tick ONE BOX ONLY)*

- Never ..... ☐
- Very rarely ..... ☐
- Rarely ..... ☐
- Sometimes ..... ☐
- Quite often ..... ☐
- Very often ..... ☐
- Don't know ..... ☐

29. Do you think mammography <u>misses</u> breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over .... ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ..... ☐
- Don't know ..... ☐

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30. **Women <u>who turn out not to have</u> breast cancer may need further tests after having a mammogram to rule out the possibility of cancer. How often do you think this happens?** *(Please tick ONE BOX ONLY)*

- Never ☐
- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

31. **Do you think the number of women <u>who turn out not to have</u> breast cancer but require extra tests after having a mammogram to rule out the possibility of cancer is...** *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ☐
- Don't know ☐

QUESTIONS ABOUT BREAST CANCER

32. **Approximately how many women do you think will develop breast cancer <u>at some point</u> in their lifetime?** *(Please tick ONE BOX ONLY)*

- 1 in 3 women ☐
- 1 in 10 women ☐
- 1 in 50 women ☐
- 1 in 100 women ☐
- 1 in 1000 women ☐
- Don't know ☐

33. **Compared to most other women your age, do you think <u>your own chances</u> of getting breast cancer at some time during your lifetime are...** *(Please tick ONE BOX ONLY)*

- Much less ☐
- A little less ☐
- About the same ☐
- A little more ☐
- Much more ☐

34. **<u>Since you heard from the genetics clinic</u>, do you think <u>your own chances</u> of getting breast cancer at some time during your lifetime are...** *(Please tick ONE BOX ONLY)*

- Lower than you had thought ☐
- About the same as you had thought ☐
- Higher than you had thought ☐
- Don't know ☐

Any comments: _____

35. **Do you think breast cancer occurs...** *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

36. **How often do you think women who are diagnosed with breast cancer carry an altered breast cancer gene that can be passed down in the family? Would you say...** *(please tick ONE BOX ONLY)*

- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

QUESTIONS ABOUT THINKING ABOUT YOUR CHANCES OF GETTING BREAST CANCER

37. During the past month, how often have you thought about your own chances of developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

38. During the past month, have thoughts about your chances of getting breast cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

39. During the past month, have thoughts about your chances of getting breast cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

40. How concerned are you about the possibility that you might get breast cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

41. How often do you worry about developing breast cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

42. How much of a problem is worrying about breast cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

43. What, if anything, has helped you cope with worries about breast cancer in the family?

_____

_____

GENERAL QUESTIONS ABOUT YOU AND YOUR FAMILY

44. What is your date of birth? *(please put day / month / year)*

☐☐ / ☐☐ / ☐☐

45. What is your current marital status? *(please tick ONE BOX ONLY)*

- Married or living as married ☐
- Single and never been married ☐
- Divorced or separated ☐
- Widowed ☐

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46. How many sons have you had?
(please put '0' if you have no sons)

☐ sons

47. How many daughters have you had?
(please put '0' if you have no daughters)

☐ daughters

48. How old were you when you finished full time education? *(please tick ONE BOX ONLY)*

- 15 years or younger ☐
- 16 to 18 years old ☐
- 19 years or older ☐

49. What is the highest level qualification you have? *(please tick ONE BOX ONLY)*

- "O" level (or equivalent) ☐
- "A" level (or equivalent) ☐
- Clerical or commercial qualification ☐
  (e.g. secretarial, hairdressing, NVQ, etc.)
- College or university degree ☐
- None of these ☐

50. What ethnic group would you use to describe yourself? *(please tick ONE BOX ONLY)*

- White ☐
- Black ☐
- Indian/Pakistani/Bangladeshi ☐
- Chinese ☐
- Mixed ☐
- Other ☐

FINAL SECTION - OPTIONAL

51. If you have any other thoughts about breast cancer in your family, please tell us in the space below *(continue on the next page if necessary)*

_____

_____

_____

52. As part of my research, I would be interested to speak with some of the women who complete this questionnaire. If you would not mind being contacted by me to arrange to have an informal discussion about breast cancer in your family, please write your name and phone number below. I would like to assure you that writing your name and phone number below places you under no obligation to participate in any further research.

Name: _____ **Phone Number:** _____

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

EXPERIENCES OF HAVING BREAST CANCER IN THE FAMILY

The Cancer Research Campaign and the NHS are committed to improving the services available to women with a family history of breast cancer. As part of this, we are asking for your help with this survey which tries to identify the needs of women who have one or more relatives in their family who have been diagnosed with breast cancer.

All the information you give will be treated as STRICTLY CONFIDENTIAL.

Please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only

Clinic	Patient Number	Family Number	Questionnaire

GENERAL QUESTIONS ABOUT YOU AND YOUR FAMILY

1. **What is your date of birth?**
   (please put day / month / year)

   ☐☐ / ☐☐ / ☐☐

2. **How old were you when you finished full time education?** *(please tick ONE BOX ONLY)*

   13 years or younger ☐
   14 to 16 years old ☐
   17 years or older ☐

3. **What qualification(s) do you have from school, college or the equivalent?**
   (please tick ALL THAT APPLY)

   "O" level (or equivalent) ☐
   "A" level (or equivalent) ☐
   Clerical or commercial qualification ☐
   (e.g. secretarial, hairdressing, NVQ, etc.)
   Nursing or teaching qualification ☐
   College or university degree ☐
   None of these ☐

4. **What is your current marital status?**
   (please tick ONE BOX ONLY)

   Married or living as married ☐
   Single and never been married ☐
   Divorced or separated ☐
   Widowed ☐

5. **Is the accomodation in which you live?**
   (please tick ONE BOX ONLY)

   Owned or mortgaged by you or your family ☐
   Rented from a private landlord ☐
   Rented from the council ☐
   Other ☐

6. **What ethnic group would you use to describe yourself?** *(please tick ONE BOX ONLY)*

   White ☐
   Black ☐
   Indo-european ☐
   Asian ☐
   Other ☐

7. **Have you ever had any children?**
   (please tick ONE BOX ONLY)

   Yes ☐
   No - If **No**, please go to **question 10** ☐

8. **How many children have you had?**

   ☐ children

9. **How old is each child and is the child male or female?** *(for each child, please put the age in years and tick a box for female or male)*

   1st child ☐☐ years female ☐ male ☐
   2nd child ☐☐ years female ☐ male ☐
   3rd child ☐☐ years female ☐ male ☐
   4th child ☐☐ years female ☐ male ☐

10. How many sisters do you have?
(please put '0' if you have no sisters, please include any sisters who have died)

☐ sisters

11. Have any of your sisters ever had breast cancer diagnosed?
(please tick ONE BOX ONLY)

Yes ☐
No ☐
Don't know ☐

If **Yes**, how old were they when the cancer was first diagnosed?

1st sister ☐☐ years
2nd sister ☐☐ years

12. Has your mother ever had breast cancer diagnosed? *(please tick ONE BOX ONLY)*

Yes ☐
No ☐
Don't know ☐

If **Yes**, how old was she when the cancer was first diagnosed? ☐☐ years

13. In total, how many family members have had breast cancer diagnosed?
(please include your mother and sisters, as well as any aunts and grandmothers on <u>both your mother's side and your father's side</u> who have had breast cancer diagnosed)

☐ relatives

14. Of these family members, how many were diagnosed <u>before age 50</u>?

☐ relatives

15. What is the <u>youngest age</u> at which one of your relatives was diagnosed? ☐☐ years

QUESTIONS ABOUT RISKS AND BREAST CANCER

16. Approximately how likely do you think it is that the average woman will develop breast cancer <u>at some point</u> in her lifetime? *(Please tick ONE BOX ONLY)*

1 in 3 ☐
1 in 10 ☐
1 in 50 ☐
1 in 100 ☐
1 in 1000 ☐
Don't know ☐

17. Compared to most other women, do you think <u>your own chances</u> of getting breast cancer at some time during your lifetime are... *(Please tick ONE BOX ONLY)*

Less ☐
About the same ☐
More ☐

18. How likely do you think it is that <u>you</u> will develop breast cancer at some time in your lifetime? *(Please tick ONE BOX ONLY)*

1 in 3 ☐
1 in 10 ☐
1 in 50 ☐
1 in 100 ☐
1 in 1000 ☐
Don't know ☐

19. **Do you think <u>this chance</u> of developing breast cancer at some time in your lifetime is...** *(Please tick ONE BOX ONLY)*

- Very low ☐
- Low ☐
- About average ☐
- High ☐
- Very high ☐

20. **Do you think breast cancer occurs...** *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ☐
- Don't know ☐

21. **How often do you think women who are diagnosed with breast cancer carry a faulty breast cancer gene? Would you say...** *(please tick ONE BOX ONLY)*

- Never or rarely ☐
- Sometimes ☐
- Very often ☐
- Almost all of the time ☐

QUESTIONS ABOUT BREAST SCREENING AND BREAST CANCER

22. **Have you ever had a mammogram (an x-ray of the breast)?** *(please tick ONE BOX ONLY)*

- Yes ☐
- No - If **No**, please go to **question 26** ☐
- Don't know - If **DK**, go to **question 26** ☐

23. **When was your last mammogram?** *(please tick ONE BOX ONLY)*

- Less than one year ago ☐
- One to three years ago ☐
- More than three years ago ☐
- Don't know ☐

24. **Why did you have your last mammogram?** *(please tick ONE BOX ONLY)*

- Because of breast symptoms ☐
- Because of breast cancer family history ☐
- As part of national screening programme ☐
  (free service offered to women aged 50 and over)
- As part of a private screening service ☐
  (e.g. private health-care plan, offered through work)
- Other *(please specify)* _____ ☐
- Don't know ☐

25. **Have you ever been called back for more tests following a mammogram?** *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐
- Don't know ☐

26. **Please tell us any views you may have on the <u>potential benefits</u> of regular breast screening (mammography) for women of your age with no breast symptoms.** *(Please tick the box if you have no particular views about this ☐)*

_____

_____

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27. **Please tell us any <u>concerns</u> you may have regarding regular breast screening (mammography) for women of your age with no breast symptoms.** *(Please tick the box if you have no particular concerns about this ☐)*

_____

_____

28. **What do you think is the purpose of regularbreast screening (mammography) for women with no breast symptoms?** *(Please tick ALL THAT APPLY)*

- To prevent breast cancer from developing ☐
- To allow earlier detection of breast cancer ☐
- To enable simpler treatments to be used ☐
- To prevent deaths from breast cancer ☐
- To reassure women that they do not have breast cancer ☐
- Other *(please specify)* _____ ☐
- Don't know ☐

29. **How much do you agree or disagree with the following statement: "If a breast screening mammogram showed that everything is OK, I would feel reassured."** *(Please tick ONE BOX ONLY)*

- Strongly agree ☐
- Agree ☐
- Not sure ☐
- Disagree ☐
- Strongly disagree ☐

Any comments? _____

30. **If you had a mammogram which showed that everything was OK, and you found a breast lump within three months after having the mammogram, what do you think you would do?** *(Please tick ONE BOX ONLY)*

- Nothing ☐
- Wait for my next mammography appointment ☐
- Visit my GP if the problem persisted for more than one month ☐
- Visit my GP if the problem persisted for more than three months ☐
- Other *(please specify)* _____ ☐
- Don't know ☐

31. **Do you think that breast screening (mammography) ever misses any breast cancers?** *(please tick ONE BOX ONLY)*

- Yes ☐
- No - If **No,** go to **question 35** ☐
- Don't know - If **DK**, go to **question 35** ☐

32. **How often do you think that breast screening (mammography) misses breast cancers?** *(Please tick ONE BOX ONLY)*

- Very rarely ☐
- Rarely ☐
- Sometimes ☐
- Quite often ☐
- Very often ☐
- Don't know ☐

33. **In terms of numbers, do you think that breast screening (mammography) misses...** *(Please tick ONE BOX ONLY)*

- 1 breast cancer in a million (1 in 1,000,000) ☐
- 1 breast cancer in a thousand (1 in 1,000) ☐
- 1 breast cancer in one hundred (1 in 100) ☐
- 1 breast cancer in ten (1 in 10) ☐
- 1 breast cancer in three (1 in 3) ☐
- Don't know ☐

34. Do you think mammography misses breast cancers ... *(Please tick ONE BOX ONLY)*

- More often in women aged 50 and over .... ☐
- More often in women under 50 years of age ☐
- About equally in both age groups ..... ☐
- Don't know ..... ☐

35. Sometimes women who turn out not to have breast cancer are called back after having a mammogram for extra tests to rule out the possibility of having breast cancer. How often do you think this happens? *(Please tick ONE BOX ONLY)*

- Very rarely ..... ☐
- Rarely ..... ☐
- Sometimes ..... ☐
- Quite often ..... ☐
- Very often ..... ☐
- Don't know ..... ☐

36. Please say approximately how many women who turn out not to have breast cancer require extra tests after having a mammogram *(Please tick ONE BOX ONLY)*

- 1 woman in a million (1 in 1,000,000) ..... ☐
- 1 woman in a thousand (1 in 1,000) ..... ☐
- 1 woman in a hundred (1 in 100) ..... ☐
- 1 woman in ten (1 in 10) ..... ☐
- 1 woman in three (1 in 3) ..... ☐
- Don't know ..... ☐

37. Do you think the number of women who turn out not to have breast cancer but require extra tests after having a mammogram is... *(Please tick ONE BOX ONLY)*

- Greater in women aged 50 years and over ☐
- Greater in women under 50 years of age ☐
- About equal in both age groups ..... ☐
- Don't know ..... ☐

QUESTIONS ABOUT BREAST CANCER INFORMATION

38. Where have you found out information about breast cancer? *(If you have not found out any information about breast cancer, please tick the box ☐ and go to **question 40**)*

(please tick ALL THAT APPLY)

- Family members ..... ☐
- Friends/colleagues ..... ☐
- Family doctor ..... ☐
- Hospital doctor ..... ☐
- Newspaper/magazines ..... ☐
- Television/radio ..... ☐
- Internet (world wide web) ..... ☐
- Leaflet ..... ☐
- Other *(please specify)* _____ ☐

39. If you had to choose one source of information, which would you say... *(for each, please specify)*

1. Provided you with the greatest amount of information? _____
2. Provided you with the most reassuring information? _____
3. Provided you with the most worrying information? _____

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40. Do you feel that you would like to know the following information...

(for each question, please tick ONE BOX ONLY)

What is breast cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐
What are my risks of getting breast cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐
At what age do most women get breast cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐
What are the chances of surviving breast cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐
What are the possible signs of breast cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐
What can I do if I notice a change in my breast?	Yes ☐	No ☐	Unsure ☐	Already know ☐
Who should have a mammogram?	Yes ☐	No ☐	Unsure ☐	Already know ☐
Who should have a breast cancer gene test?	Yes ☐	No ☐	Unsure ☐	Already know ☐
What lifestyle choices may help prevent cancer?	Yes ☐	No ☐	Unsure ☐	Already know ☐

Other *(please specify)* _____

41. If you had to choose one piece of information, what would you <u>most</u> want to know?

_____

42. Have you discussed breast cancer with your family? *(please tick ONE BOX ONLY)*

Yes ..... ☐
No ..... ☐
Don't know ..... ☐

If **Yes**, with which members of your family? *(please tick ALL THAT APPLY)*

Mother ..... ☐
Father ..... ☐
Sister ..... ☐
Brother ..... ☐
Aunt ..... ☐
Daughter ..... ☐
Other _____ ☐

QUESTIONS ABOUT TALKING TO THE GP ABOUT BREAST CANCER IN THE FAMILY

43. Has anyone in your family ever seen their GP about breast cancer in the family? *(please tick ONE BOX ONLY)*

Yes ..... ☐
No ..... ☐
Don't know ..... ☐

If **Yes**, was it your... *(please tick ALL THAT APPLY)*

Mother ..... ☐
Father ..... ☐
Sister ..... ☐
Brother ..... ☐
Aunt ..... ☐
Daughter ..... ☐
Other _____ ☐

44. Have you ever seen your GP about a breast problem that <u>you thought</u> may have been a possible sign of breast cancer? *(please tick ONE BOX ONLY)*

Yes ..... ☐
No ..... ☐

If **Yes**, how many <u>months</u> ago? ☐☐

OR how many <u>years</u> ago? ☐☐

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45. Prior to your recent visit, have you ever discussed breast cancer in your family with your GP when you had no signs or symptoms of breast cancer? *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐

46. When did you first discuss breast cancer in your family with your GP? *(Please tick ONE BOX ONLY)*

- During your recent visit ☐
- Several weeks ago ☐
- Several months ago ☐
- One or two years ago ☐
- Many years ago ☐
- Don't know ☐

47. Approximately how many times have you discussed breast cancer in your family with your GP?

☐☐ times

48. What recently prompted you to discuss breast cancer in your family with your GP? *(please tick ALL THAT APPLY)*

- A problem with my breasts ☐
- Approaching a certain age ☐
- A discussion with friends/colleagues ☐
- A friend/relative got breast cancer ☐
- A friend/relative died of breast cancer ☐
- A newspaper/magazine article ☐
- A television/radio program ☐
- An internet (world wide web) page ☐
- A leaflet/poster ☐
- It was suggested by: _____ ☐
- Other *(please specify)* _____ ☐

49. When you most recently spoke to your your GP, who brought up the subject of breast cancer in your family? *(please tick ONE BOX ONLY)*

- Me ☐
- My GP ☐
- Practice nurse ☐
- Other *(please specify)* _____ ☐

50. Approximately how much time did you spend discussing breast cancer in your family with your GP? *(Please tick ONE BOX ONLY)*

- A few minutes ☐
- 5 to 10 minutes ☐
- More than 10 minutes ☐
- Don't know ☐

51. Was the discussion with your GP about breast cancer in your family... *(Please tick ONE BOX ONLY)*

- Too short ☐
- About right ☐
- Too long ☐
- Don't know ☐

52. Overall, how satisfied were you with your recent discussion about breast cancer in your family with your GP? *(Please tick ONE BOX ONLY)*

- Very satisfied ☐
- Satisfied ☐
- Unsure ☐
- Dissatisfied ☐
- Very dissatisfied ☐

53. What were you <u>hoping for</u> when you went to see your GP to talk about breast cancer in the family? *(If you were not expecting to talk to your GP about breast cancer in the family or if you did not have any hopes in particular, please tick this box ☐ and go to **question 54**)*

(for each response, please tick ONE BOX ONLY)

To be offered reassurance	Yes ☐	No ☐	Unsure ☐
To be given information	Yes ☐	No ☐	Unsure ☐
To discuss my risks of getting breast cancer	Yes ☐	No ☐	Unsure ☐
To have my GP examine my breasts	Yes ☐	No ☐	Unsure ☐
To be told the signs/symptoms of breast cancer	Yes ☐	No ☐	Unsure ☐
To discuss my options with my GP	Yes ☐	No ☐	Unsure ☐
To be referred to a specialist	Yes ☐	No ☐	Unsure ☐

Other *(please specify)* _____

54. What <u>actually happened</u> when you recently visited your GP to talk about breast cancer in the family? Did your GP...

(for each response, please tick ONE BOX ONLY)

Offer you reassurance?	Yes ☐	No ☐	Unsure ☐
Give you information?	Yes ☐	No ☐	Unsure ☐
Discuss your risks of getting breast cancer?	Yes ☐	No ☐	Unsure ☐
Examine your breasts?	Yes ☐	No ☐	Unsure ☐
Tell you the signs/symptoms of breast cancer?	Yes ☐	No ☐	Unsure ☐
Discuss your options?	Yes ☐	No ☐	Unsure ☐

Other *(please specify)* _____

55. Did you receieve a leaflet called *Breast Cancer in the Family* when you recently visited your GP to discuss breast cancer in your family? *(please tick ONE BOX ONLY)*

Yes ..... ☐
No ..... ☐
Don't know ..... ☐

If **Yes**, please answer the following questions:

(for each question, please tick ONE BOX ONLY)

Did you want it?	Yes ☐	No ☐	Unsure ☐
Did you read it?	Yes ☐	No ☐	Unsure ☐
Did you keep it?	Yes ☐	No ☐	Unsure ☐
Did you show it to anyone else?	Yes ☐	No ☐	Unsure ☐
Was it clear?	Yes ☐	No ☐	Unsure ☐
Did it cover what you wanted to know?	Yes ☐	No ☐	Unsure ☐

Other *(please specify)* _____

Is there anything else you would have liked in the leaflet? (please specify) _____

_____

_____

Is there anything you would recommend to improve the leaflet? (please specify) _____

_____

_____

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56. In addition to discussing breast cancer in your family with your GP, would you find it helpful to receive any of the following? *(please tick ALL THAT APPLY)*

- A help line telephone number ☐
- A leaflet ☐
- Internet addresses ☐
- An educational video tape ☐
- Other *(please specify)* _____ ☐

57. Please add anything else about your GP visit about breast cancer in the family?

_____

_____

QUESTIONS ABOUT BEING REFERRED BY YOUR GP

58. Did you want your GP to refer you to a specialist regarding breast cancer in your family? *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐
- Don't know ☐

If **Yes**, was your main reason for wanting to be referred? *(please tick ALL THAT APPLY)*

- To talk to a specialist ☐
- To be examined by a specialist ☐
- To have a mammogram (breast x-ray) ☐
- To have a breast cancer gene test ☐
- Other *(please specify)* _____ ☐

59. When I see the specialist what I hope is...

*(if you do not have any hopes in particular, please tick this box ☐ and go to **question 61**)*

(for each response, please tick ONE BOX ONLY)

To be offered reassurance	Yes ☐	No ☐	Unsure ☐
To be given detailed information on breast cancer	Yes ☐	No ☐	Unsure ☐
To discuss my risks of getting breast cancer in detaiil	Yes ☐	No ☐	Unsure ☐
To have my breasts examined by a specialist	Yes ☐	No ☐	Unsure ☐
To be told the signs/symptoms of breast cancer	Yes ☐	No ☐	Unsure ☐
To discuss my options in detail	Yes ☐	No ☐	Unsure ☐
To be offered a mammogram (breast x-ray)	Yes ☐	No ☐	Unsure ☐
To be offered a breast cancer gene test	Yes ☐	No ☐	Unsure ☐
To be offered the chance to join a breast cancer prevention study	Yes ☐	No ☐	Unsure ☐
To help with scientific research	Yes ☐	No ☐	Unsure ☐
Other *(please specify)* _____			

60. What else, if anything, are you hoping for when you go to see the specialist? *(If you are not hoping for anything else in particular, please tick this box ☐)*

_____

_____

QUESTIONS ABOUT YOUR FEELINGS

61. During the past month, how often have you thought about your own chances of developing cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

62. During the past month, have thoughts about your chances of getting cancer affected your mood? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

63. During the past month, have thoughts about your chances of getting cancer affected your ability to perform daily activities? Would you say... *(please tick ONE BOX ONLY)*

- Not at all or rarely ☐
- Sometimes ☐
- Often ☐
- Almost all of the time ☐

64. How concerned are you about the possibility that you might get cancer someday? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Moderately ☐
- Very concerned ☐

65. How often do you worry about developing cancer? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Occasionally ☐
- Frequently ☐
- Constantly ☐

66. How much of a problem is worrying about cancer to you? Would you say... *(please tick ONE BOX ONLY)*

- Not at all ☐
- Somewhat ☐
- Definitely ☐
- Severe problem ☐

67. What, if anything, has helped you cope with worries about breast cancer in the family?

_____

_____

68. Overall, how much of a <u>choice</u> do you feel you have in making decisions about your health with respect to having breast cancer in your family? *(Please tick ONE BOX ONLY)*

- A lot of choice ☐
- Some choice ☐
- Very little choice ☐
- No choice ☐
- Unsure ☐

69. Overall, how much <u>control</u> do you feel you have in making decisions about your health with respect to having breast cancer in your family? *(Please tick ONE BOX ONLY)*

- A lot of control ☐
- Some control ☐
- Very little control ☐
- No control ☐
- Unsure ☐

FINAL SECTION

We would like to be able to contact you again once you have been seen by a specialist. We would be grateful if you gave us permission to do so. Your response to this request will not effect the care you receive in any way. To ensure your complete anonymity and confidentiality, your name and address will be kept seperately from this questionnaire.

If you give permission, please sign here and print your name and address in the section below. Please print in BLOCK CAPITALS as clearly as possible.

Signature: ☐

Today's date (*please put day / month / year*): ☐☐ / ☐☐ / ☐☐

Surname: _____

First name: _____

House number and street: _____

Town: _____

County: _____

Postcode: _____

PLEASE BE ASSURED THAT YOUR CONFIDENTIALITY WILL BE RESPECTED AT ALL TIMES.

Thank you very much for filling in this questionnaire. Could you please check that you have answered all the questions. Please return the questionnaire to us in the pre-paid envelope provided (no stamp is needed).

For Office Use Only

Questionnaire Number

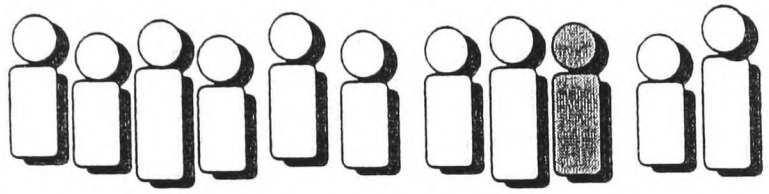
☐☐☐☐☐

Breast Cancer in the Family

Your Risks and Options Explained

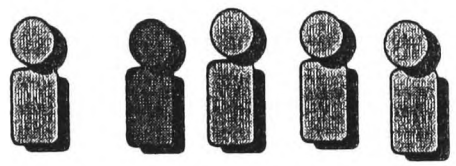
How common is breast cancer?

Breast cancer is a common disease. One in eleven (1 in 11) women in the UK will develop breast cancer during her lifetime.



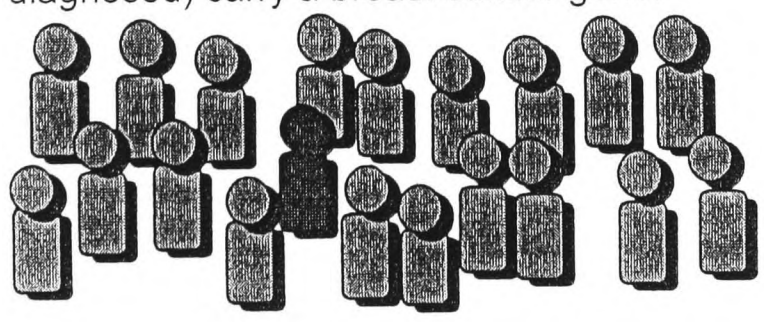
How old are most women who develop breast cancer?

Of the women who do get breast cancer, most (approximately 4 out of 5 women diagnosed) are over the age of 50.



How common is having a breast cancer gene?

Of the women who do get breast cancer, approximately 5% (1 out of 20 women diagnosed) carry a breast cancer gene.



How important is it for me that a member of my family has had breast cancer?

Because breast cancer is a common disease, many people have a relative with breast cancer just by chance.



So it is possible that your risk of developing breast cancer may be about the same as the risk for any woman your age, even if a member of your family has had breast cancer diagnosed.

Your family history of breast cancer becomes more important:

- The more relatives you have who have had breast cancer diagnosed
- The younger your relatives were when they were first diagnosed with breast cancer
- The more closely related these relatives are to you

What can I do if I think my family history of breast cancer may be important?

Your GP may refer you to a specialist, if appropriate, to discuss your family history of breast cancer in detail.

There are two kinds of specialists who deal with breast cancer in the family.

At the Regional Genetics Centre

- You will have the opportunity to talk to a geneticist or to a genetic counsellor about your breast cancer risks and options
- Your risk of developing breast cancer may be calculated by computer based on your family history of breast cancer
- Less commonly, you may also be offered a genetic test (a blood test which may be used to help predict the risk of developing breast cancer in people who have a strong family history)

At the Breast Care Unit

- You will have the opportunity to talk to a breast surgeon about your breast cancer risks and options
- Your breasts may be examined for possible signs of breast cancer by a doctor
- You may also be offered an x-ray examination of the breasts called a mammogram to look for possible early signs of breast cancer

What options might I consider?

Breast awareness
Breast screening
Genetic testing
Research trials for preventing the development of breast cancer
Preventive surgery
Lifestyle options

Where can I get more information about breast cancer in the family?

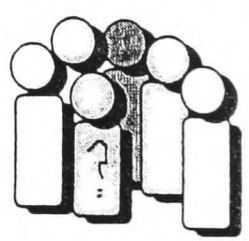
- **The Women's Nationwide Cancer Control Campaign (WNCCC)**
  Suna House, 128/130 Curtain Road,
  London, EC2A 3AR
  Helpline: 0171-729-2229
  Internet: http://dspace.dial.pipex.com/town/square/gm40/index.htm

- **Breast Cancer Care**
  Kiln House, 210 New King's Road,
  London, SW6 4NZ
  Helpline: 0500-245-345
  http://www.breastcancercare.org.uk

- **CancerBACUP**
  3 Bath Place, Rivington Street,
  London, EC2A 3JR
  Helpline: 0800-181-199
  Internet: http://www.bacup.org.uk

- **Macmillan Cancer Relief**
  Anchor House, 15/19
  Britten Street, London, SW3 3TZ
  Helpline: 0845-601-6161
  Internet: http://www.macmillan.org.uk

cancer research campaign



The (blue) leaflet entitled:

Breast and/or Ovarian Cancer in the Family:
Learning more about your risks and options

is located in the pocket on the inside back cover of this thesis.

James Mackay MA MD FRCP Edin
Consultant in Cancer Genetics



UNIVERSITY OF CAMBRIDGE
Department of Oncology

October 7, 1999

Dear

I am writing to ask if you would please consider participating in our project to evaluate an information leaflet called "*Breast and/or Ovarian Cancer in the Family.*"

This study is being run in collaboration with the Primary Care Education Research Group, in the Division of Public Health and Primary Heath Care at Oxford University. The purpose of this study is to improve the information available to women like yourself.

I would like to clarify that this research does not form part of your medical care and therefore no health advice can be offered by the researchers. Should you want any such advice, please contact our department on the above number.

If you would like to participate in this research, please read the study information sheet and the leaflet and fill out the questionnaire attached.

Yours sincerely

[redacted]

Dr James Mackay
Consultant in Cancer Genetics

For Office Use Only
Questionnaire Number

cancer research campaign

Box 193
Addenbrooke's Hospital
Hills Road
Cambridge CB2 2QQ

Telephone: 01223 274316
Fax: 01223 412213
E-mail: jm232@cam.ac.uk

University of Oxford

CRC Primary Care Education Research Group

Division of Public Health and Primary Health Care
University of Oxford
Institute of Health Sciences
Old Road
Headington
Oxford OX3 7LF

Tel 01865 226788
Fax 01865 226784
DD 01865 2269

Director Dr J Austoker

Study Information Sheet

Title: Evaluation of the leaflet called *Breast and/or Ovarian Cancer in the Family*

Participating in this study would involve agreeing to: 1) read the leaflet, 2) fill out the attached questionnaire and 3) return the questionnaire in the reply paid envelope provided (no stamp is needed). Altogether, this should only take about 10 to 15 minutes.

Please be assured that all information gathered during this study is strictly confidential, and therefore will not be seen by any of your doctors, your family, or any other individual.

You are free to decide not to take part in this study, without having to explain why. Whether you decide to participate in this study or not will have no effect on your normal medical care.

If you have any queries about the research, please contact Anne Andermann at the Primary Care Education Research Group on 01865-226-922 or 01865-226-788.

Thank you for your help. You are welcome to keep the leaflet.

BREAST AND/OR OVARIAN CANCER IN THE FAMILY

A QUESTIONNAIRE SURVEY OF AN INFORMATION LEAFLET

The Cancer Research Campaign and the NHS are committed to improving the information available to women with a family history of breast cancer. As part of this, we have prepared a leaflet called "*Breast and/or Ovarian Cancer in the Family*." We would be keen to hear what you think of it.

All the information you give will be treated as STRICTLY CONFIDENTIAL.

To complete the questionnaire, please tick ☑ the appropriate responses to the questions or write the answers in the spaces provided.

CRC Primary Care Education Research Group
Institute of Health Sciences
Old Road, Headington, OX3 7LF
Tel: (01865) 226-788

cancer research campaign

For Office Use Only
Questionnaire Number

SECTION 1: QUESTIONS ABOUT THE LEAFLET

1. Have you read the leaflet called "*Breast and/or Ovarian Cancer in the Family*"? *(please tick ONE BOX ONLY)*

Yes, all of it - *(If **Yes**, please go to **question 2**)* .. ☐
Yes, part of it - *(If **Yes**, please go to **question 2**)* ☐
No - *(If **No**, please go to **question 11**)* ..... ☐

2. Which section(s) of this leaflet do you consider <u>most useful</u>? *(please tick ALL THAT APPLY)*

Breast and ovarian cancer in the general population ..... ☐
Breast and ovarian cancer in families ..... ☐
Box 1: Your family history ..... ☐
What happens when I see my GP ..... ☐
Box 2: At the breast care unit ..... ☐
Box 3: At the genetics clinic ..... ☐
Issues related to breast and ovarian cancer ☐
For more information ..... ☐

3. <u>Overall</u>, is this leaflet...

	Very Much	Some-what	Not very Much	Not at all	Don't know
a) Relevant to your present needs?	☐	☐	☐	☐	☐
b) Providing information new to you?	☐	☐	☐	☐	☐
c) Providing what you want to know?	☐	☐	☐	☐	☐
d) Providing enough information?	☐	☐	☐	☐	☐
e) Easy to read?	☐	☐	☐	☐	☐
f) Written in a way you can understand?	☐	☐	☐	☐	☐
g) Written in a caring way?	☐	☐	☐	☐	☐
h) Useful to you in any way?	☐	☐	☐	☐	☐
i) Providing reassurance?	☐	☐	☐	☐	☐
j) Providing you with options?	☐	☐	☐	☐	☐
k) Helping you understand your situation?	☐	☐	☐	☐	☐
l) Helping you to talk with your doctors?	☐	☐	☐	☐	☐
m) Helping you to talk with your family?	☐	☐	☐	☐	☐
n) Other? *(please specify)* _____					

4. Would you like <u>any other information</u> that is not included in the leaflet? *(please tick ONE BOX ONLY)*

Yes - *(If **Yes**, go to **question 5**)* ..... ☐
No - *(If **No**, go to **question 6**)* ..... ☐
Don't know - *(If **DK**, go to **question 6**)* ..... ☐

5. If Yes, what other information would you like? *(please specify)* _____

_____

PAGE 3

6. **Is there anything in the leaflet that you find <u>unclear or difficult to understand</u>?**
(please tick ONE BOX ONLY)

Yes - *(If **Yes**, go to **question 7)*** ☐
No - *(If **No**, go to **question 8)*** ☐
Don't know - *(If **DK**, go to **question 8)*** ☐

7. **If Yes, what is unclear or difficult to understand?** *(please specify)* _____

_____

8. **Do you like the leaflet's...**

	Very Much	Some-what	Not very Much	Not at all	Don't know
a) Overall design?	☐	☐	☐	☐	☐
b) Title?	☐	☐	☐	☐	☐
c) Cover?	☐	☐	☐	☐	☐
d) Colour scheme?	☐	☐	☐	☐	☐
e) Layout?	☐	☐	☐	☐	☐
f) Ordering of the sections?	☐	☐	☐	☐	☐
g) Section headings?	☐	☐	☐	☐	☐
h) Information boxes?	☐	☐	☐	☐	☐
i) Pictures?	☐	☐	☐	☐	☐
j) Type size?	☐	☐	☐	☐	☐

k) Other? *(please specify)* _____

9. **Is there anything that you would <u>remove or change</u> in the leaflet?**
(please tick ONE BOX ONLY)

Yes - *(If **Yes**, go to **question 10)*** ☐
No - *(If **No**, go to **question 11)*** ☐
Don't know - *(If **DK**, go to **question 11)*** ☐

10. **If Yes, what would you remove or change?** *(please specify)* _____

_____

11. **Are you <u>glad</u> to have received this leaflet?**
(please tick ONE BOX ONLY)

Yes - *(If **Yes**, go to **question 12)*** ☐
No - *(If **No**, go to **question 13)*** ☐
Don't know - *(If **DK**, go to **question 13)*** ☐

12. **If Yes, what way would you have <u>most</u> preferred to have received this leaflet?**
(please tick <u>ONE BOX ONLY</u>)

Left for pick-up in the GP waiting room ☐
Handed to you by your GP ☐
Handed to you by the practice nurse ☐
Left for pick-up in hospital waiting rooms ☐
Mailed to you by the genetics clinic ☐
Other *(please specify)* _____ ☐
Don't know ☐

13. Who do you think is <u>most</u> likely to find this leaflet <u>useful</u>? *(please tick <u>ONE BOX ONLY</u>)*

- All women ☐
- Women under 50 years of age ☐
- Women with one or more relatives diagnosed with breast and/or ovarian cancer ☐
- Other *(please specify)* _____ ☐
- Don't know ☐

14. Do you plan to show this leaflet to anyone <u>in your family</u>? *(please tick ONE BOX ONLY)*

- Yes - *(If **Yes**, go to **question 15**)* ☐
- No - *(If **No**, go to **question 16**)* ☐
- Don't know - *(If **DK**, go to **question 16**)* ☐

15. If Yes, to <u>which members</u> of your family do you plan to show this leaflet?

(please tick ALL THAT APPLY)

Mother ☐	Father ☐
Sister ☐	Brother ☐
Daughter ☐	Son ☐
Aunt ☐	Niece ☐
Cousin ☐	Husband ☐

Other *(please specify)* _____

SECTION 2: QUESTIONS ABOUT YOU

16. What is your date of birth?
(please put day / month / year)

☐☐ / ☐☐ / ☐☐

17. What is the <u>highest</u> level qualification you have? *(please tick ONE BOX ONLY)*

- "O" level (or equivalent) ☐
- "A" level (or equivalent) ☐
- Clerical or commercial qualification ☐
  (e.g. secretarial, hairdressing, NVQ, etc.)
- College or university degree ☐
- None of these ☐

18. What ethnic group would you use to describe yourself? *(please tick ONE BOX ONLY)*

- White ☐
- Black ☐
- Indian/Pakistani/Bangladeshi ☐
- Chinese ☐
- Mixed ☐
- Other ☐

19. Has your mother or sister ever had breast cancer diagnosed? *(please tick ONE BOX ONLY)*

- Yes ☐
- No ☐
- Don't know ☐

20. In total, how many of your relatives have had breast cancer diagnosed? *(please include <u>only</u> mother, sisters, aunts and grandmothers on <u>both your mother's side and your father's side</u>)*

☐ relatives

Thank you very much for taking the time to complete this questionnaire.

Please return in the freepost envelope provided (no stamp is needed).

Complete list of changes made to the leaflet

The leaflet was very much liked by the women who participated in the evaluation. For this reason, all aspects of the leaflet wording, design and layout remained as much as possible the same as that of the previously produced leaflet. The minor changes that women recommended are listed below.

A. Changes to design and layout

1. **Front cover**
   - Front title made larger and more bold
   - The entire front cover made more "eye-catching"
   - New CRC logo added to the front cover

2. **Headings**
   - Headings made larger and more bold

3. **Overall**
   - Background old CRC logo design motif removed
   - Pictures removed

B. Changes to wording

1. **Front cover:**
   - "and/or Ovarian" omitted from title

2. **Section 1 (general population)**
   - "and ovarian" omitted from heading
   - "(1 in 11)" after "UK" omitted
   - "(9%)" added
   - "early" replaced with "detected early" after "breast cancer"
   - 3rd paragraph on ovarian cancer omitted

3. **Section 2 (in families)**
   - "and ovarian" omitted from heading
   - "Because breast cancer is a common disease," added to beginning
   - "there is" omitted from "whether there is an inherited factor"
   - **"Most of the time, however, breast cancer occurs by unlucky chance and is not caused by an altered gene"** added to the end of the 1st paragraph
   - Entire of 2nd paragraph changed to "Having a mother or a sister with breast cancer *does not mean* you are necessarily at risk of having inherited an altered breast cancer gene. Your risk of developing breast cancer may only be a little higher than that of the average woman in the community."

- Family history box moved to follow the 2nd paragraph
- "and/or ovarian" omitted from title of family history box
- "on the *same* side of the family (mother's *or* father's side)" added to the 1st point of family history box
- "and/or ovarian" omitted from 1st point of family history box
- "(especially under 50)" added to end of 2nd point of family history box
- 4th point added to family history box: "When there is a case of bilateral breast cancer (diagnosed in both breasts), male breast cancer, or breast and ovarian cancer in the family"

4. **After family history box, new section created called "Breast cancer genes"**
   - Paragraph added: "In approximately 5% of breast cancer cases (1 in 20), and especially when there is a very strong family history of breast cancer, it seems that an altered gene is largely responsible."
   - Paragraph added: "In these families, the altered gene can be passed down from one generation to the next by the mother or by the father. Family members who inherit this gene are at higher than normal risk of getting breast (and sometimes also ovarian) cancer and may be affected at an earlier age than usual. However, there is only a 50% (1 in 2) chance of inheriting the gene from a parent who is carrying the altered gene. Family members who do not inherit the gene are not at increased risk of breast or ovarian cancer, and cannot pass on the altered gene to their children."

5. **Section about GP**
   - Changed title to **"Seeing a GP about cancer in the family"**
   - Changed "and/or ovarian" to "(or ovarian)"
   - Added a comma after "In this case"
   - "Leaflets on breast awareness are available from your GP or from the organisations listed on the back of this leaflet" added to the end of the 1st point about breast awareness.

6. **After 3rd point "Notifying your GP" new section created called "Referral to a specialist"**
   - Paragraph added: "If appropriate, your GP may refer you to either a breast care unit or a genetics clinic to discuss your family history of breast (or breast/ovarian) cancer in detail."
   - "and/or ovarian" omitted from 1st point of 'At the breast care unit' box
   - Changed 1st point of 'At the genetics clinic' box "and/or ovarian" to "(or breast/ovarian)"
   - Changed 2nd point of 'At the genetics clinic' box "and/or ovarian" to "(or breast/ovarian)"
   - Changed entire 4th point of 'At the genetics clinic' box to read "Only a small minority of people with a very strong family history of breast (or breast/ovarian) cancer is likely to have an altered breast cancer gene. Very few women referred to the genetics clinic meet the criteria to be offered a genetic test (a blood test which may be used to help predict the risk of developing breast and ovarian cancer)"

- Added a 5th point to the 'At the genetics clinic' box "There may be a wait of several months before being seen at the clinic. Women considered by the clinic to be at low risk may not be invited for a specialist visit"

7. **Section on Issues related**
   - Changed heading to "**Issues related to breast cancer in the family that you may wish to discuss with a doctor**"
   - Added "therapy" to the end of the 3rd point
   - Changed 4th point to "Research trials for preventing the development of breast cancer or for detecting ovarian cancer"
   - Added a 5th point "The process, timing, pros and cons of gene testing that may be an option for a small minority of women who have a very strong family history of breast (or breast/ovarian) cancer"
   - Changed what is now 6th point on preventive surgery from "and/or ovarian" to "(or breast/ovarian)"
   - Added to what is now the 7th point on implications "the" in front of "family history"
8. **Final section on More information**
   - "and/or ovarian" omitted from heading
   - Added "The" to the beginning of the 1st point
   - Changed 2nd point postal code to "EC2A 3AQ", helpline number to "0171-729-4688" and internet address to "http://www.wnccc.org.uk"
   - Changed 3rd point helpline number to "0808-800-6000"
   - Changed 4th point helpline number to "0808-800-1234" and internet address to http://www.cancerbacup.org.uk"
   - Omitted the 5th point about Macmillan
   - Changed authors section (still in smaller print) to "This leaflet was prepared by Anne Andermann, Joan Austoker, Eila Watson (CRC Primary Care Education Research Group, Oxford University), Anneke Lucassen (Department of Clinical Genetics, Oxford Radcliffe NHS Trust) and James Mackay (Department of Oncology, Cambridge University)"
   - Added in very large print (minimum 16-point font) "A large-print version of this leaflet is available on request from the Cancer Research Campaign."
   - And finally at the end added: "The Cancer Research Campaign, 2000."

The (purple) leaflet entitled:

Breast Cancer in the Family:
Learning more about your risks and options

is located in the pocket on the inside back cover of this thesis.

Conference presentations, meetings and courses attended and society memberships held

Papers presented at scientific conferences:

Platform presentations

Andermann A, Watson E, Clements A, Lucassen A and Austoker J.Risk perceptions, cancer worries, expectations and experiences of women referred from primary care regarding a family history of breast cancer. 7th European Meeting on Psychosocial Aspects of Genetics. Manchester, England: September 21-23, 2000.

Andermann A, Watson E, Lucassen A and Austoker J. Risk knowldege, perception and behavioural preferences in women with a family history of breast cancer. Health and Risk: Second Biannual International Conference. Oxford, England: July 3-5, 2000.

Andermann A, Watson E, Austoker J, Lucassen A and Mackay J. Development and evaluation of an information leaflet for women with a family history of breast cancer. Cancer Genetics Group (formerly Cancer Family Study Group). Manchester, England: May 15-16, 2000.

Andermann A, Watson E, Lucassen A and Austoker J. Discussing breast cancer family history in primary care: the patient's perspective. Genetics in Primary Care Conference: "Opening Pandora's Box". The Oxford Primary Care Genetics Group, Oxford, England: October 6, 1999.

Andermann A, Watson E, Lucassen A and Austoker J. Experiences of presenting to primary care and being referred to secondary care regarding a family history of breast cancer: a qualitative study. The Genetics Revolution and the Future for Health and Social Care. The Welsh Society for Health and Social Care, Pontypridd, Wales: June 23-24, 1999.

Andermann A, Watson E, Austoker J, Lucassen A and Mackay J. Bringing up breast cancer family history: Identifying consumer needs. Cancer Genetics Group (formerly Cancer Family Study Group). Manchester, England: May 17-18, 1999.

Poster presentations

Andermann A, Watson E, Austoker J, Lucassen A and Mackay J. Developing and evaluating an information leaflet for women with a family history of breast cancer. Patient Information for All! Conference. Patient Information Forum (PiF), Birmingham, England: April 11, 2000.

Andermann A, Emery J, Rose P, Sidebottom E and Watson E. The Oxford Primary Care Genetics Group (OPCGG) Web Site. Genetics in Primary Care Conference: "Opening Pandora's Box". The Oxford Primary Care Genetics Group, Oxford, England: October 6, 1999.

Andermann A, Watson E, Lucassen A, Fordy C and Austoker J. Expectattions and experiences of women presenting to primary care with concerns about a family history of breast cancer: a qualitative analysis. 48th Annual Meeting of the American Society of Human Genetics. Denver, Colorado: October 27-31, 1998.

Meetings, symposia and workshops attended:

Cancer Screening Workshop. London School of Hygiene and Tropical Medicine. London, England: April 14, 2000.

Second National Conference on Genetics and Disease Prevention: Integrating Genetics into Public Health Policy, Research and Practice. Baltimore, Maryland: December 6-8, 1999.

Information Provision - How can we get it right? Marie Curie Cancer Care. London, England: October 1, 1999.

Ethics and the Transformation of Medicine. Hastings Centre, Harvard Medical School Division of Medical Ethics, Oxford Centre for Communication and Ethics in Health Care and University College. Oxford, England: September 17-18, 1999.

Genomics, Healthcare and Public Policy. Office of Health Economics. London, England: February 11, 1999.

The Influence of Genetics in Screening for Cancer. Women's Nationwide Cancer Research Campaign. London, England: November 11, 1998.

6th European Meeting on Psychosocial Aspects of Genetics. Paris, France: October 1-3, 1998.

Consensus Conference on the Management of Women with a Family History of Breast Cancer. R&D Office of the Anglia and Oxford NHS Executive and Unit for Public Health Genetics. London, England: January 12, 1998.

Courses attended:

Advanced Statistics Module, MSc in Evidence Based Health Care. Department for Continuing Education. Centre for Professional Development. Oxford, England: February 9 - April 12, 2000.

Consumer Health Care on the Internet. The British Library. London, England: November 10, 1999.

Genetics and Society Research Training Course. The Wellcome Trust. Hinxton Hall, Cambridgeshire, England: September 11-14, 1999.

Certificate Course in Evidence Based Health Care. Department for Continuing Education. Centre for Professional Development. Oxford, England: October 1998 - June 1999.

Society memberships held:

Cancer Genetics Group (formerly Cancer Family Study Group), member 1997-2000.

Society for Social Medicine, member 1997-2000.

American Society for Human Genetics, member 1998-2000.

Recent Publications and Publications in Preparation

Andermann A, Austoker J, Watson E, Clements A, Lucassen A. Expectations and experiences of women referred from primary care regarding a family history of breast cancer. In preparation.

Andermann A, Austoker J, Watson E, Lucassen A, Mackay J. Development and evaluation of a general information leaflet for women with a family history of breast cancer. Submitted to *J Cancer Educ*.

Andermann A, Austoker J, Watson E, Clements A, Lucassen A. Primary care consultation needs of women referred regarding a family history of breast cancer. Submitted to *Health Expectations*.

Emery J, Watson E, Rose P, Andermann A. A systematic review of the literature exploring the role of primary care in genetic services. *Fam Pract* 1999; **16**(4): 426-445.

Andermann, A. Watson, E., Lucassen, A., Fordy, C. and Austoker, J. Expectations and experiences of women presenting to primary care with concerns regarding a family history of breast cancer: a qualitative analysis [abstract]. *Am J Hum Genet* 1998; **63**(4): A198.